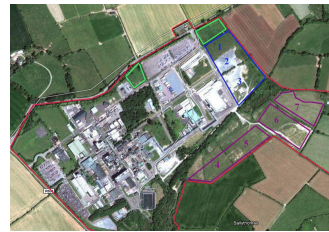
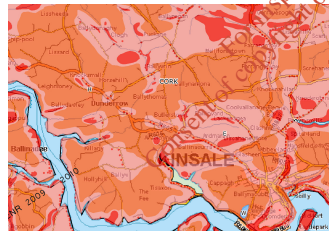
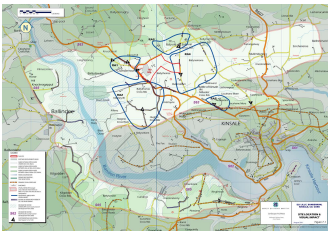




IE 43 Biotech Manufacturing Facility



Environmental Impact Statement

December 2011

ARUP

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

IE43 Biotech Manufacturing Facility

Environmental Impact Statement

C2613.40

Issue 1 | December 2011

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It is not intended for and should not be relied upon by any third party and no responsibility is undertaken to any third party.

Job number C2613.40

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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.
DAHG	Department of Arts, Heritage and the Gaeltacht
DMBR	Design Manual for Roads and Bridges
DOEHLG	The Department of the Environment, Heritage and Local Government
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
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.
LPG	Liquid Petroleum Gas
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 Sence 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
NRA	National Roads Authority
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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List of Contributors

This Environmental Impact Statement (EIS) is based on an assessment of the environmental effects of the proposed Lilly IE43 project 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 sub-consultant, 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

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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1 Introduction

1.1 Introduction

Eli Lilly S.A. - Irish Branch (Lilly) is a bulk pharmaceutical manufacturing plant, located at Dunderrow, Kinsale, Co. Cork. Refer to the site location **Figure 1.1** and site layout in **Figure 3.1**.

Lilly proposes to construct a new biotechnology manufacturing facility, to be known as IE43 within the existing site boundary. The project will include modifications to existing facilities and utilities. The new facility will expand the production capacity for biopharmaceutical products at the Kinsale plant.

The project will be referred to as the 'IE43 Biotech Manufacturing Facility' or 'IE43' in this Environmental Impact Statement.

1.2 Outline of IE43 Biotechnology Manufacturing Facility

The proposed IE43 biotechnology manufacturing facility will be a dedicated facility used to produce biotechnology products in bulk form for the treatment of cancers and other ailments.

The new facility will consist of a main manufacturing building located in the north eastern part of the site and ancillary facilities. The building footprint is presented in **Figure 3.2** whilst the building elevations are presented in **Figures 3.3** and **3.4**.

The building will comprise 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.

The main features of the IE43 project are as follows:

- Construction of IE43, a three storey biotech manufacturing facility with scope for expansion if needed in the future. IE43 will be located to the east of IE42 as shown on **Figures 3.2**.
- 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 and a warehouse also on the ground floor.
- A HVAC plant room on the first floor.
- Some utility plant will be located externally including cooling towers, steam pressure reduction station and a nitrogen storage tank.

- The facility will be provided with water and steam from the existing plant. Effluent treatment will be undertaken in the existing site effluent treatment plant.
- Two small supporting electrical utility buildings.
- Partial diversion of a section of the stream flowing through the site.

The generic process sequence for products that will be manufactured in IE43 is as follows: cell culture, broth clarification, detergent inactivation, capture column purification step (chromatography), low-pH inactivation, intermediate purification step (chromatography), final polishing step (chromatography). The chromatography steps are followed by filtration steps. The process is water based as opposed to solvent based used in traditional synthetic pharmaceutical manufacturing.

The project will take approximately 30 months to construct. The first biopharmaceutical products are expected to be shipped from the facility in 2015. Once operational, the plant will be run 24 hours a day, 7 days a week in line with existing facilities in Kinsale.

1.3 Company Profile

1.3.1 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 their 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 8 countries with approximately 20% of the workforce involved in research and development. In 2010, Lilly had net sales in excess of \$23 billion.

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 the 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 injectible 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	<p>In late 2000, Lilly submitted Forteo®, a novel treatment for osteoporosis, for regulatory review.</p> <p>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.</p> <p>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 nonstimulant, noncontrolled medication to treat attention-deficit hyperactivity disorder, is approved.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>

	<p>In 2008, Cialis® was approved by the FDA for once-daily use for the treatment of erectile dysfunction.</p> <p>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.</p> <p>In 2009, Efiel™ was approved by the FDA for the prevention of atherothrombotic events in patients with acute coronary syndrome undergoing percutaneous coronary intervention.</p> <p>Also in 2009, Adcirca™ was approved for pulmonary arterial hypertension.</p> <p>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.</p> <p>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.</p> <p>In 2011, Tradjenta™ was approved by the FDA. These are tablets for the treatment of type 2 diabetes.</p> <p>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.</p>
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1.3.2 Eli Lilly S.A. - Irish Branch

Eli Lilly S.A.- Irish Branch site is approximately 62.7 hectares (155 acres) in area. The developed site is 42.5 hectares (105 acres) with 80% of this currently occupied. The site is located in Dunderrow, approximately four kilometres from Kinsale, in Co. Cork. Dunderrow is approximately 32 kilometres to the southwest of Cork City. Refer to **Figure 1.1** which shows the site location.

Approximately four hundred and fifty permanent staff are employed at Lilly, 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,

The plant is one of 13 Lilly pharmaceutical manufacturing plants worldwide. Active pharmaceutical ingredients 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 four main chemical synthesis production buildings on site and then shipped to finishing plants for formulation, filling and finishing as tablets, vials or capsules.

Lilly is completing the commissioning of the new IE42 Biotech manufacturing facility, 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 new IE43 facility will also be a cell culture based process, with similar process steps to the IE42 facility.

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 months. Over the past 25 years, the facilities have expanded and now approximately 80% of the developed site is occupied by a mixture of production, production support and administration facilities.

In 2010, 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 €120 million.

The main milestones in the sites development were:

- 1978-81** Construction
- 1981** Production start-up of the dedicated facility IE3
- 1984** IE8, the second production facility added. IE2 small production facility added
- 1988** IE8 production facility expanded to three rigs for campaigned production
- 1995** Animal health products introduced
- 1999** IE16 small scale, high containment facility introduced. New product launches
- 2000** IE16 large scale facility constructed
- 2002** New laboratory and office (IE28) constructed
- 2004** New clean manufacturing facility (IE30) constructed
- 2006** Complete validation of IE30 facility
- 2011** Commissioning of new IE42 biotech manufacturing facility. This will be fully in production by 2012.

The Kinsale facility manufactures active ingredients for a number of Lilly's most important human health medicines for use in the areas of schizophrenia, depression, postmenopausal health and cancer. The products from Kinsale are shipped to finishing plants around the world where they are converted to final dosage forms such as tablets, capsules or injectibles. The products manufactured in Kinsale, are as follows: Evista®, Zyprexa®, Strattera®, and Alimta®.

1.4 EIS Methodology

1.4.1 Purpose and Screening

Schedule 5 of the Planning and Development Regulations, 2001, as amended, specifies the types and size of developments that require an EIS to be submitted as part of the planning application.

The extension of an existing pharmaceutical manufacturing plant is a development listed in Part 2 of Schedule 5 as follows:

- '11 Changes, extensions, development and testing*
- (a) Any change or extension of development which would:-*
- (i) result in a 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 percent of the appropriate threshold,*
- whichever is the greater.'*

The IE43 building will result in an increase in total floor area of 39% which is greater than the threshold in the Regulations. Therefore, an EIS must be submitted with the planning application.

1.4.2 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. Schedule 6 of the Planning and Development Regulations, 2001 specify the information to be contained in an EIS, including the following:

"A description of the proposed development comprising information on the site, design and size of the proposed development

A description of the measures envisaged in order to avoid, reduce and, if possible, remedy significant adverse effects

The data required to identify and assess the main effects which the proposed development is likely to have on the environment

An outline of the main alternatives studied by the developer and an indication of the main reasons for his or her choice, taking into account the effects on the environment."

Information is also required on the following matters:

"A description of the physical characteristics of the whole proposed development and the land-use requirements during the construction and operational phases

A description of the main characteristics of the production processes, for instance, nature and quantity of the materials used

An estimate, by type and quantity, of expected residues and emissions (including water, air and soil pollution, noise, vibration, light, heat and radiation) resulting from the operation of the proposed development."

Aspects of the environment likely to be significantly affected by the proposed IE43 development are also to be described, including in particular:

“Human beings, fauna and flora

Soil, water, air, climatic factors and the landscape

Material assets, including the architectural and archaeological heritage, and the cultural heritage

The inter-relationship between the above factors.”

A description is required of the likely significant effects (including direct, indirect, secondary, cumulative, short, medium and long-term, permanent and temporary, positive and negative) of the proposed IE43 development on the environment resulting from:

“The existence of the proposed development

The use of natural resources

The emission of pollutants, the creation of nuisances and the elimination of waste”

and a description of the forecasting methods used to assess the effects on the environment.

A summary in non-technical language of this information is also to be included.

Finally, any difficulties encountered by the developer in compiling the required information should be indicated.

Reference is made in this EIS to environmental impacts of various qualities, significance, duration and types. A glossary of impacts is provided in **Appendix A1.1**.

1.4.3 EPA Guidelines

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

1.5 Consultation Process

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

- Environmental Protection Agency.
- Cork County Council.
- National Monuments Service, Department of Arts, Heritage and the Gaeltacht.
- Inland Fisheries Ireland.
- National Parks and Wildlife Service.

1.6 Difficulties Encountered During the Study

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

1.7 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

Government of Ireland (2001) Planning and Development Regulations, 2001 (S.I. No 600 of 2001)

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2 Background to the Project

2.1 Introduction

In this chapter, the background to the proposed IE43 biotech manufacturing facility is presented. The reasons Lilly perceives the need for the project at this time are explained. The alternative designs considered are also described.

2.2 Need for the 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.

By virtue of the successful establishment of the IE42 facility, 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 not only meets Lilly's requirements for commercial scale capacity for its biopharmaceutical products but also positions 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 results directly from the site's development master plan, which identifies the eastern end of the site as the preferred location for the development of biotech manufacturing facilities and future associated support facilities. Refer to **Figure 3.2**.

Key services, staff facilities and utilities will be shared with the existing site, thereby providing an economical solution and avoiding costly duplication.

2.2.1 Alternative Sites considered

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

2.2.2 Alternative Design Options

The internal layouts and stack-up arrangement of the building are the combined influence of processing requirements and the sloping characteristic of the site. 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. These constraints offered little opportunity for further consideration of alternatives.

However, many iterations were performed on the building facades with the intention of offering a most aesthetically pleasing facility while mitigating visual impacts. The final design arises from reviews by the design team, Lilly management personnel, external consultants and consultations with Cork County Council.

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3 Site and Scheme Description

3.1 Introduction

This chapter presents a description of the proposed IE43 biotech manufacturing facility. Information is provided on the current site layout and facilities in addition to neighbouring land uses. The main features of the proposed development are described and health and safety aspects, regulatory control of the facility and site decommissioning are addressed.

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 Ballyvryn Road, and to the west by the R605 regional road as shown on **Figures 1.1** and **3.1**. 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 Inishannon. The N71 national secondary route passes through Inishannon and Bandon to the north of Dunderrow.

A stream flows in an approximate northeast-southwest direction through the Lilly site and discharges into the Bandon Estuary at Doon Creek, as shown on **Figure 14.2**. The Bandon Estuary is situated to the west of Dunderrow and extends southwards to the sea at Kinsale harbour. The proposed IE43 biotech manufacturing facility will be located at eastern end of the Lilly site as shown on **Figure 3.2**.

3.3 Current Site Layout and Facilities

3.3.1 General

Eli Lilly S.A. - Irish Branch manufactures bulk pharmaceutical active ingredients 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	Warehouses and drum stores
IE2	Laboratories & manufacturing facility
IE3	Multi-purpose manufacturing facility
IE4	Powerhouse (boiler house) and utilities building
IE5, IE10	Administration facilities and offices
IE6	Pump house
IE7	Waste treatment building

Building No.	Use
IE8, IE16	Multipurpose manufacturing facilities
IE9, IE21	Engineering offices, workshops and stores
IE11 IE20	Wastewater treatment plant Main Tank Farm
IE22	Nitrogen plant compressor house
IE28	Laboratories and offices
IE30	Dedicated clean manufacturing facility
IE31	MCC (motor control centre)compressor house
IE42	Biotechnology manufacturing facility (currently being made ready for commercial production)

The current site layout is shown in **Figure 3.1**, with the main features identified.

3.3.2 Existing Production Facilities

There are six main production buildings on the site, namely IE2, IE3, IE8, IE16, IE30 and IE42. 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 for commercialisation.
- IE3 production building has been in operation since 1981 and was dedicated to the manufacturing of antibiotics and animal health products. Human antibiotic production ceased on the site in June 2003 and the products were outsourced. The animal health products were outsourced from 2010. The building is now de-commissioned.
- 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. It is currently de-commissioned except for the utilities section which supplies IE42.
- Lilly have recently completed the construction and are currently commissioning the new IE42 biotech manufacturing facility. IE42 is 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.

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, 23 of which are in service for the storage of solvents required for the production processes. New solvent, recovered solvent and spent solvent for recovery are stored in this tank farm. As the usage of bulk solvents on site has reduced by an estimated 75% in recent years, 6 tanks are currently decommissioned but may be re-assigned in the future. 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 7 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,
- Hydrogen storage pad,
- IE15 drum store, and cylinder store, and
- IE15B water-reactive 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, and
- gases, which are directed to the hydrogen storage pad.

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 plant (WWTP). 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 11.4**). In 2005, an upgrade project of the 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 recently completed, 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. Offgases 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 chillers and four cooling towers. There is a site wide fire protection system and a retention pond to retain water used in fire fighting, which may need to be treated prior to discharge.

IE30 has its own standalone utilities which support production in that building and the IE42 building. The utilities in IE30 consists 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. Steam and water are supplied to IE30 & IE42 from the existing IE4 facility.

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.

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 building, IE42 will use biotechnology processes to manufacture pharmaceutical products. In the biotech process to be undertaken in IE42, final products will be manufactured through the cultivation of cells by a sequence of steps. Each production step will comprise 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 3.3** and are discussed below.

3.3.5.1 Cell Culture

Frozen cells in small vials will be transported from the cell bank to the inoculation laboratory and thawed. The cells will then be combined with appropriate media and put under appropriate physical conditions for cell growth. After the laboratory scale the cells will be passed through a seed bioreactor train. The final cell culture

stage will be performed in production bioreactors. The production bioreactor will be 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 byproducts.

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

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

3.3.5.2 Cell Culture Clarification

The "Raw cell culture broth" will be 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 will be 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 will be thermally inactivated with clean steam prior to changeout 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 will be discarded.

3.3.5.3 Detergent Inactivation Operations

In this operation, detergent will be added to the "clarified broth" to inactivate lipid-enveloped unwanted components. After an appropriate period of agitation, the media will be filtered, producing "detergent inactivated cell-free media." This solution will be passed on to the capture charge tank, where temperature adjustment will be carried out in sections so that partial lots can be processed through the purification area. Prior to each lot, the centrifuge and filter set will be cleaned/sanitized with cleaning solutions and rinsed with water.

3.3.5.4 Purification Operations

There will be a number of purification operations which will 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 will be prepared as needed. Between preparations of each batch of buffer, the buffer preparation tanks will be cleaned with CIP solutions and rinsed with water.

Chromatography

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

- Ancillary equipment rinsed with water. The column matrix will be regenerated/sanitized using appropriate buffers.
- The product stream will be charged to the column matrix to “load” product; product and other proteins bind to the matrix, while cell culture media components will flow through the column.
- The column will be equilibrated using appropriate buffers to remove DNA, non-product protein, endotoxins, and other impurities from the column – while the product will remain on the column matrix.
- Product will then be eluted using appropriate buffers (or a concentration gradient between two buffers) to produce purified, concentrated product.
- After elution, the chromatography column will be regenerated/sanitized and washed with appropriate buffers and the column will be filled with storage buffer. Storage buffer will be 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 will be re-adjusted to neutrality. The solution will be cooled (if needed) and filtered. The resulting product stream may be 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 will be flushed with water. After each batch, nano-filtration cartridges will be 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 will be 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 will be flushed with water, caustic, and diafiltration buffer. In this operation, product will be concentrated and diafiltered (i.e., the buffer is exchanged) via nano-filtration and a stabilizer will be added. The nano-filtration system will be 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 will be 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 Project Design Philosophy and Constraints

3.4.1 Principle Design Objectives

The key user requirements considered were:

- 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 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.
- Expandable to a larger scale if required.

3.4.2 Main Design Features

The main design features are:

- Dispensing area for solids/liquids dispensing.
- Buffer and media make up areas (for small volume make up and large).
- Bioreactor train.
- Purification area with sufficient bays to allow a number of chromatography steps, tangential flow filtration steps and a nanofiltration step.
- Separate area for final purification.
- Separate area for bottle filling of final product.
- Suitable refrigerated storage of raw materials and product.
- Safety and industrial hygiene, current Good Manufacturing Practice compliance and environmental controls to meet local and corporate standards.
- Building orientation parallel to the existing IE42 biotech manufacturing facility.
- Dedicated administration, locker rooms and break room.

3.4.3 Design Constraints

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

- Location at the eastern end of the site consistent with existing site master plan.
- Location of the proposed IE43 in relation to the stream on the southern side of the existing facility.
- 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 buildings.
- The building will use the topography of the site to create a step in the building to follow the ground profile and minimise visual impact. This will allow ground level access at two different levels.
- 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

3.5.1 Introduction

The main features of the project are as follows:

- Construction of IE43, a three storey biotech manufacturing facility, with scope for expansion if needed in the future. IE43 will be located to the east of IE42, as shown on **Figure 3.2**.
- 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 and a warehouse also 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.
- Laboratory functionality to support biotech manufacturing will be accommodated in the existing IE28 laboratory building.
- Two small electrical utility buildings.
- Partial diversion of the existing stream within the site.

The IE43 biotech manufacturing facility will be a dedicated facility which will produce bulk biotechnology products. The facility processes will be self-contained and will contain areas 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

When the proposed IE43 facility is operational, Lilly anticipates that the majority of the staff will be re-deployed from the existing plant and additional personnel will be employed as required. 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. The production processes to be carried out in IE43 will be the same as those which will be undertaken in IE42 and which are described in Section 3.3.5 above. The IE43 facility has been designed to be multipurpose and it will have the capability to process other mammalian cell culture based products.

3.5.2 Building Layout

The facility will comprise 3 main floor levels in a split level configuration: a lower ground utility floor, a ground floor level with a production floor and an administration area topped on the upper level by a building services area above the production floor. The facility will be approximately 110 m in length by 100 m in width. Due to the split level arrangement, the building is presented as 21m high to the front (northern elevation) and 30m high to the rear. The building footprint is presented in **Figures 3.2** whilst the building elevations are presented in **Figures 3.4** and **3.5**.

The top floor will house the air handling systems required to service the cleanroom areas associated with the production floor level and the administration area. 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 Section 3.4.2 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. Also on the ground floor is the administration area containing offices, break room, changing facilities and control room. Allied to the administration area is the material warehouse.

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.

3.5.3 Equipment Cleaning

The process vessels and equipment will be designed for 'clean-in place' (CIP). 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 Agent A	600
CIP Agent B	290

3.5.4 Process Control System

The plant will be capable of operating continuously in a safe, reliable and consistent manner. Production operations in the IE43 building will be controlled and monitored by a process control system. The process control system will assist 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 will be capable of implementing process safety controls and interlocks to ensure the plant adheres to current Irish safety and environmental legislation and IPPC Licence requirements.

To maximize computer control, the IE43 building 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,
- 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, environment and personnel at all times.

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

3.5.5 Utility Requirements

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

- Ethylene glycol (4°C) heat transfer medium
- Ethylene glycol (50°C) heat transfer medium
- Plant steam
- Carbon dioxide gas
- Oxygen gas
- Water for injection
- Clean steam
- Potable water
- Compressed air
- Cooling Water
- Water for Operations

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

- Plant steam
- Water for operations
- Potable water

3.5.6 Modification to various existing services and utilities

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

3.5.7 Environmental Controls and Waste Systems

The existing waste treatment facilities will have sufficient capacity to treat the solid and liquid wastes for the IE43 building.

The liquid wastes from the IE43 process will be segregated into two waste systems, aqueous waste and biowaste. The aqueous waste system will be the waste that does not contain activated cells and also the waste from the cleaning processes. The aqueous waste stream will be sent to the site waste water treatment plant. A biowaste system will handle any streams which potentially could contain activated cells. In this biowaste system, cell matter will be inactivated by means of a retention tube and a steam ejector which will allow the tank contents to be heat in-activated so that only inactivated cell matter will be sent to the site waste water treatment plant.

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

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.

In November 2001, the site environmental management system has been certified to be in compliance with the requirements for ISO 14001 Environmental Management Systems for many years. 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 biotech manufacturing facility.

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.
- Fire alarm system and detection systems.

These systems will be extended to the IE43 facility.

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 implements and maintains 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.

3.8 Lilly Environmental Policy

Lilly operates in accordance with its Environmental Policy. The Policy is reviewed annually and was last updated in 2010. A copy of the policy is included in the Annual Environmental Report (AER) which is available on the EPA website - www.epa.ie.

3.9 Environmental Management Programme

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

Lilly prepares an annual Environmental Management Programme, which is fully integrated into the site management system. This programme is included in the AER. The programme addresses the requirements of Lilly's IPPC 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 Annual Environmental Report (which includes the EMP) for 2010 is available on the EPA website - www.epa.ie.

3.10 Regulatory Control of the Facility

3.10.1 IPPC 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 Act, 1992, as amended by the Protection of the Environment Act 2003. The licence has been revised over the years. The current licence, number P0009-03, was granted by the Environmental Protection Agency (EPA) to Lilly in April 2005.

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 IPPC licence are listed in the first schedule of the Environmental Protection Agency Acts 1992 and 2003. The facility is licensed to carry out the following activities:

Class 5.16 The use of a chemical or biological process for the production of basic pharmaceutical products and

Class 11.1 The recovery or disposal of waste in a facility, within the meaning of the Waste Management Act 1996, which facility is connected or associated with another activity specified in this Schedule in respect of which a licence or revised licence under Part IV is in force or in respect of which a licence under the said Part is or will be required.

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

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

Condition 11. Notifications, Records and Reports

Condition 12. Financial Charges and Provisions

SCHEDULE A: Limitations

SCHEDULE B: Emission Limits

SCHEDULE C: Control & Monitoring

SCHEDULE D: Annual Environmental Report

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

Lilly has had preliminary discussions with the EPA in relation to the proposed IE43 biotech manufacturing facility and further detailed discussions are underway. The IE43 facility will be designed and operated in compliance with the site's IPPC licence conditions.

3.11 Site Status in Relation to the 'Seveso 2' Directive 96/82/EC as amended by Council Directive 2003/105/EC

3.11.1 Background to the 'Seveso' Directive

In Ireland, the requirements of the Council Directive 96/82/EC on the control of major accident hazards involving dangerous substances as amended by Council Directive 2003/105/EC of 16 December 2003 are implemented through SI 76 of 2006 European Communities (Control of Major Accident Hazards involving Dangerous Substances) Regulations 2006.

These Regulations require operators of establishments where dangerous substances are present, in quantities equal to or in excess of defined threshold, 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 quantity equal to or greater than those specified in Column 3 of Parts 1 and 2 of Schedule 1 of the Regulations.

3.11.2 Status of the Lilly Facility in Relation to the Seveso 2 Directive

Lilly currently is an establishment to which SI 74 of 2006 applies because the quantity of dangerous substances present at the site is above the upper qualifying thresholds specified in Column 3 of Parts 1 and 2 of Schedule 1 of SI 74 of 2006. It is envisaged that the status of the plant will remain unchanged following the construction and operation of the IE43 biotech manufacturing facility.

Lilly has satisfied all of the requirements of S.I. 74 of 2006. One of these is the requirement to prepare, submit to the central competent authority, Health and Safety Authority, and make available to the public a Safety Report. The purpose of the Safety Report is to effectively demonstrate that:

- A Major Accident Prevention Policy and a safety management system for implementing it have been put into effect in accordance with the Major Accident Prevention Policy requirements.
- Major Accident Hazards have been identified and that the necessary measures have been taken to prevent such accidents and to limit their consequences for man and the environment.
- Adequate safety and reliability have been incorporated into the design, construction, operation and maintenance of any installation, storage facility, equipment and infrastructure connected with its operation which is linked to accident hazards inside the establishment.

- Internal emergency plans have been drawn up and information supplied to enable the external plan to be drawn up in order that the necessary measures may be taken in the event of a major accident.

The Safety Report fulfils the requirements of Article 12 of the Seveso II Regulations.

Lilly has developed a site-specific Major Accident Prevention Policy a Safety Management System and a Major Accident Hazard Identification and Risk Assessment to fulfil the requirements of the regulations. The Major Accident Prevention Policy aims to prevent major accidents, limit their consequences and ensure a high level of protection in a consistent and effective manner through the implementation of the site safety management system. The site safety management system for major accident prevention is referred to on site as the globally integrated process safety management which incorporates the requirements of the Seveso II Directive 2003/105/EC. All elements of the globally integrated process safety management, including the major accident hazard identification and risk assessment processes will be applied to the design, construction & operation of the IE43 biotech manufacturing facility plant.

3.12 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 GHG023-1 in 2004.

The table of contents of the permit is as follows:

Reason for the decision

Activities Permitted

Glossary of Terms

Condition 1: The Permitted Installation

Condition 2: Notification

Condition 3: Monitoring and Reporting

Condition 4: Allowances

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.

3.13 Genetically Modified Microorganism Licensing

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. It is anticipated that the initial activities in IE43 will also involve Class 1 entities. The current permit (GMO Registry Entry No. 267(03)) will need to be modified with an addendum to designate IE43 as a further processing facility in due course.

3.14 Provisions for Site Decommissioning

The proposed IE43 facility 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 IPPC 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 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.

3.15 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.

4 Construction Activities

4.1 Introduction

This chapter describes the construction operations and phasing for the proposed IE43 biotech manufacturing facility and outlines the measures to be taken to ensure that the impact of the construction activities is minimised.

4.2 Duration and Phasing

Due to the size and nature of the project, the overall period for construction of the development is expected to be thirty months.

Construction activities for the proposed project will include the following:

- earthworks and site preparation,
- construction of manholes,
- installation of drainage and underground services,
- construction of retaining walls,
- construction of concrete foundations,
- erection of steelwork for the structural frame of the buildings piperacks, platforms, and walkways,
- 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,
- construction of two electrical service buildings,
- construction of concrete bases for external utility equipment (cooling towers and tanks),
- partial diversion of stream within the site,
- landscaping,
- installation of a new piperack linking IE42 with IE43,
- connections and modifications to existing site services, and miscellaneous works including of site lighting, site roads and road markings.

Figure 4.1 shows the proposed Construction Site Layout Plan and illustrates features such as construction compound, construction laydown areas, car parking, and temporary haul road within the site. The construction access is shown on **Figure 4.1**.

4.3 Site Preparation

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. Some surplus excavated material from the construction of IE42, which is still at the construction and commissioning stage, is stored on this land.

The site of the proposed IE43 development is located to the east of IE42, as shown on **Figures 3.2**. It is proposed to undertake bulk excavation which will create two platforms, one at circa 38.000mOD and a lower one at circa 29.000mOD, in a similar manner to the two platforms created as part of the IE42 construction project. Similar to the IE42 building and the IE30 building, IE43 will be a split level facility, hence the two platforms.

To achieve this, approximately 157,000m³ of material will be excavated. 50,000m³ of this material is expected to be stockpiled material, from previous projects on site, with the remainder being new excavation consisting of sandy, gravelly clay with cobbles and occasional boulders, and weathered and intact rock. The stockpiled material contains some inert construction and demolition waste. The bedrock, underlying the clay, consists of thinly laminated mudstones and siltstones, the top 0.6m of which is weathered. The bedrock to be excavated will contain approximately 16,000m³ of weathered rock and intact rock.

All excavated material will be retained on site. The excavated bedrock will be re-used as engineering fill where possible. Material not suitable for engineering fill will be used to provide improved landscaping to the open fields in the southern part of the site as shown in **Figure 3.2**. The inert construction and demolition waste will be disposed of, off-site, at a permitted or licensed facility, as appropriate.

Two existing concrete pads will be demolished and the arising concrete will be crushed and reused on site as suitable fill or removed off-site to a suitable waste facility.

The bridge crossing over the stream, constructed to facilitate the IE42 construction works, will be used to access the areas to be landscaped on the southern side of the stream.

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 will be carried out in consultation with, and the approval of the EPA and the Environmental Department of Cork County Council.

The impact on traffic from the construction phase is assessed in Chapter 8 of this EIS: *Roads and Traffic*.

4.4 Construction Methods

Construction specifications, procedures and methods will be similar to those employed during the construction of IE42. In fact the IE42 facility effectively provides the template for not only the physical aspects of IE43 but also the means and methods by which it will be constructed.

Excavation of superficial deposits and upper moderately/ highly weathered bedrock would be expected to be undertaken using conventional large back-actor excavators. 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 IE43 building will be constructed as follows:

- Foundations and retaining walls in reinforced concrete.
- Structural frame will be steel with reinforced concrete lift shaft.
- Floors will be reinforced concrete.
- Internal walls will mainly be stud partitions, the remainder being concrete block construction.
- 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 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.

Two small electrical service buildings will also be constructed.

The majority of the fit-out works will take place indoors, following construction of the building.

The project involves the diversion of a section of the existing stream which flows through land owned by Lilly. It is necessary to carry out this diversion to facilitate the development of IE43 at the site. The proposed stream diversion is a permanent wet diversion to replace the existing channel. The works will entail the excavation of a new river channel of approximately 250m, construction of rock armour bank protection, stone deflectors, and other in-stream structures. The project will require temporary damming of the new channel, diversion of the existing river into the new channel, planting & landscaping and other related construction activities. A preliminary construction method statement for the stream diversion works is provided in **Appendix A4.1**

4.5 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.

4.6 Employment and Accommodation

Typically the manpower on site will average 450, with a peak of 550, during construction of IE43. 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 IE42 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.

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 provides adequate site supervision to co-ordinate, monitor and implement site regulations.

Normal construction working hours will be observed. These are 07.00 – 19.00 Monday to Friday; 08.00 – 16.00 on Saturday. It may be necessary to work overtime, including at weekends and at night, at certain stages. Working outside normal hours may be necessitated through considerations 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. It should be noted that a significant portion of the work will take place indoors, once the IE43 building is constructed.

4.7 Services Requirements

4.7.1 Drainage

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

4.7.2 Electricity

A temporary power supply, for 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.

4.7.3 Water

The volume of water required during construction on an average daily basis is estimated at approximately 50m³.

4.7.4 Storm Water and Foul Water Disposal

Disposal of sanitary effluent during construction will be via a tie-in to the site sewage system. A small number of convenience self contained toilet units may be

employed to ensure that the most remote parts of the construction site are facilitated.

Stormwater collection and disposal is as described in Chapter 14 *Soils, Geology, Surface Water and Groundwater*.

4.8 Construction Safety

The requirements of the Safety, Health and Welfare at Work Act 2005, the associated Safety, Health and Welfare at Work (General Application) Regulations 2007, the Health, Safety and Welfare at Work (Construction) Regulations, 2006 and other relevant Irish and EU safety legislation will be complied with at all times.

As required by the Construction Regulations, 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 revised as necessary as the development progresses. The contents of the Health and Safety Plan will follow the recommendations 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.

4.9 Potential Construction Impacts

4.9.1 Construction Access and Traffic

Construction traffic issues are dealt with in Chapter 8, *Roads and Traffic*.

4.9.2 Noise and Vibration

The contract documents will specify that the Contractor, undertaking the construction of the works, will be obliged to take specific noise abatement measures and comply with the recommendations of BS5228: *Noise and vibration control on construction and open sites, Part 1: Code of Practice for basic information and procedures for noise and vibration control (1997)*. It is envisaged that the noise emanating from the project site will cause negligible impact on neighbouring residences.

Noise and vibration sources during construction and mitigation measures are dealt with in more detail in Chapter 9, *Noise and Vibration* of this EIS.

4.9.3 Soils, Geology, Surface Water and Groundwater Issues

Soils, Geology, Surface Water and Groundwater potential impacts and mitigation are addressed in Chapter 14, *Soils, Geology, Surface Water and Groundwater*.

4.9.4 Dust and Debris

Construction activities have the potential to generate some dust emissions. 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 and wind direction.

The potential for impact from dust depends on the distance to potentially sensitive locations and whether the wind can carry the dust to these locations. Most of the dust would be deposited close to the potential source and any impacts from dust deposition would typically be within several hundred metres or so of the construction area. In order to minimise dust nuisance, a series of measures will be implemented, as described in section 4.10.2 below.

4.9.5 Other Potential Construction Impacts

Other impacts arising from the construction phases of the project are dealt with in specific chapters. There is an evaluation of the impacts on flora and fauna in Chapter 13 *Flora and Fauna*. The protection of surface water, groundwater and soils during the construction phases is described in Chapter 14 *Soils, Geology, Surface Water and Groundwater*. The impact on the archaeological, architectural and cultural heritage is addressed in Chapter 15 *Archaeological, Architectural and Cultural Heritage*.

In general it is anticipated, that with the proper management, the construction phases of the development will have no significant or long-term negative impacts.

4.10 Mitigation Measures

4.10.1 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.

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.

The contractor will implement neighbour information and liaison programme 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*, and to address the removal and placement of organic fill material, control rain water run-off and prevent contamination of soils and groundwater are addressed in Chapter 14, *Soils, Geology, Surface Water and Groundwater*.

4.10.2 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.
- Exhausts emissions from vehicles operating within the site, including trucks, excavators, diesel generators or other plant equipment, will be minimised through regular servicing.
- 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 IPPC licence for the facility will continue to be implemented.

4.10.3 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.
- 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.

4.10.4 Construction Waste Management

4.10.5 General

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*.

It will include the following as a minimum:

- Name and contact details of the main contractor including the nominated project manager.
- Description of the Project.
- Specific waste management objectives for the project.
- Roles including training and responsibilities for construction and demolition waste.
- Wastes arising including proposals for minimisation/reuse/recovery/recycling.
- Estimated cost of waste management.
- Demolition Plan.
- Material handling procedures.
- Waste auditing protocols.
- Record keeping procedures.
- Proposals for education of workforce and plan dissemination programme.

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.
- 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.

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 arisings 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.
- Building rubble arising from the demolition of miscellaneous concrete structures will be disposed off site at suitably permitted waste facilities. Quantities will be relatively small. It is estimated that approximately 55 truck loads of this material will leave the site.

4.11 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 negative residual impacts arising from the construction of this development.

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5 Planning and Policy Context

5.1 Introduction

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

The proposed development has been examined in the context of the policies and objectives of the documents listed below:

National Policy Guidance

- National Development Plan 2007 – 2013
- Making Ireland's Development Sustainable, Review, Assessment and Future Action 2002
- National Spatial Strategy 2002 – 2020
- National Climate Change Strategy 2007

Regional Policy Guidance

- Regional Planning Guidelines 2010 – 2022

Local Policy Guidance

- Cork County Development Plan 2009
- Bandon Electoral Area Local Area Plan: Public Consultation Draft November 2010
- Integrated Strategy for Economic, Social & Cultural Development of County Cork 2002 – 2011
- Cork Area Strategic Plan (2001-2020)

5.2 National Policy Guidance

5.2.1 National Development Plan 2007 – 2013

The €184 billion National Development Plan 2007-2013 builds on the significant social and economic achievements of the 2000-2006 National Development Plan. Launched in January 2007, and entitled Transforming Ireland - A Better Quality of Life for All, this new seven year plan is presented as a major milestone in building a prosperous Ireland for all, characterised by sustainable economic growth, greater social inclusion and balanced regional development. The stated central aim of the National Development Plan 2007-2013 is 'to improve the quality of life for all.'

The main objectives of the Plan include:

- 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 support these objectives include:

- 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.
- The provision of value for tax payers' money.

Conformance of the Project to the Policy Objectives

The proposed IE43 project will conform to the policy objectives of the National Development Plan by helping to consolidate and build on the southwest region's recent 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 facility 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 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, been 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.

Conformance of the Project to the Policy Objectives

The proposed IE43 project 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 ISO 14001 Environmental Management System.

The plant operation is regulated under an Integrated Pollution Prevention Control licence from the EPA. This requires the company to undertake various actions to meet their environmental obligations, including ongoing efforts at waste minimisation and the implementation of clean technology. The plant is a member of Pharmaceutical Ireland and has embraced for over 15 years its responsible care code and objectives.

5.2.3 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.
- 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.

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.

5.2.4 The 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.

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.

5.3 Regional Policy Guidance

5.3.1 The Regional Planning Guidelines, May 2004

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. The purpose and role of the Guidelines are explained thus in 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 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 the 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 pharmaceutical, 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.”

Conformance of the Project to Policy Objectives

The project will lead to the appropriate sustainable growth of the pharma-chem 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 which is suitable land for the expansion and it continues to be regulated by the EPA, thereby ensuring continuous environmental protection.

5.4 Local Policy Guidance

5.4.1 Cork County Development Plan (2009)

The Cork County Development Plan came into effect in February 2009. 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 1.1.6 of the Plan states *“If the County is to continue to play its part as a prosperous counter weight to Dublin and other regions, it is critical that it maintains its cost competitiveness in terms of employment and quality of life benefits, which can only be maintained if sustainable land use planning and policy decisions are adopted and implemented.”* (CCDP 2009 p3).

Objective ECON 1-1 states *“It is an objective generally to encourage all forms of economic and employment development throughout the County in response to the policies and objectives contained within the National Spatial Strategy, the Regional Planning Guidelines, the North and West Cork Strategic Plan, the CASP Update 2008 and in accordance with the overall development strategy and objectives of this plan.”* (CCDP 2009 p135).

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.

5.4.2 Bandon Electoral Area Local Area Plan: Public Consultation Draft November 2010

Dunderrow is located within the Bandon Electoral Area. The November 2010 draft of the Bandon Electoral Area Local Area Plan (LAP) will be either ‘amended’ or ‘made’ in due course by Cork County Council. The Planning and Development Acts make provision for the draft 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 draft Plan 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". The draft Plan indicated Eli Lilly as one of the main employers in the electoral area.

The draft Plan states that *"Any extension to this existing development (Lilly) will be acceptable in principle subject to the terms of the Seveso II Directive and the policies and objectives of the County Development Plan"*.

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 project will create additional employment during the construction phase and sustain existing employment on the site in the long term.

The planning of the IE43 project has been undertaken in accordance with the Seveso II Directive and the County Development Plan.

5.4.3 Integrated Strategy for Economic, Social and Cultural Development of County Cork 2002 – 2011

In 1998, the Government established an Inter-Departmental Task Force to address the issue of the integration of Local Government and Local Development Systems. The Task Force recommended the establishment of County and City Development Boards, with the principal objective of each County and City Development Board being to prepare and implement a 10-year strategy.

The Cork County Development Board was established in March 2000 and produced the Integrated Strategy document in March 2002.

The Strategy states that among the major goals to be achieved is the following:

- to achieve a widespread distribution of employment opportunities and economic growth with adherence to sustainable development principles.

The Strategy seeks to achieve this goal by increasing rural sustainability, creating access to employment opportunities throughout the County and by stimulating balanced sectoral economic growth through renewal and diversification of the economic base. It aims to reduce outward migration particularly of highly educated young people, attract a skilled workforce to the County, and to maintain and increase populations in rural areas.

Conformance of the Project to the Policy Objectives

The proposed Lilly IE43 project conforms to the policy objectives in that it will sustain existing employment and create further employment in a rural area. It will require a highly skilled workforce and thus maintain the population in the county.

5.4.4 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 the 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 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 and smaller facilities at Bandon, Macroom and Kinsale.

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 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.

5.5 Planning and Development Evaluation

5.5.1 Site Zoning

The Lilly Site at Dunderrow is in the Bandon Electoral Area. A Local Area Plan (LAP) was prepared for the Bandon Electoral Area in 2005 however specific zoning relating to Lilly is not included in the LAP.

LAP 2-4 of the 2009 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 Bandon Electoral Area Local Area Plan: Public Consultation Draft November 2010 does not give specific zoning for the Eli Lilly site.

The Lilly site has been operating as a pharmaceutical facility since early 1981 in compliance with its planning permissions. The proposed IE43 biotech manufacturing facility 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.

5.6 References

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

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

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

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

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

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

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

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

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

6 Human Beings

6.1 Introduction

This chapter assesses the impact of the proposed development on human beings. Recent local trends in population, employment and economic performance are reviewed, and the potential impact of the development is assessed in this context. Amenity issues are also addressed.

6.2 Assessment 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 2002, 2006 and 2011 Censuses (where available). The data included information on population and number of persons at work and unemployment profile. Information was also sourced from the following documents/websites:

- Cork County Development Plan 2009
- Bandon Electoral Area Local Area Plan Consultation Draft 2010
- Central Statistics Office (CSO) website www.CSO.ie

6.2.2 Strategic Context

For 2009, Central Statistics Office (CSO) figures show that the pharmaceutical sector exported products to the value of over €47 billion, 56% of the national total exports. The pharmaceutical industry is an important employer in Ireland. In 2006, 25,100 people in Ireland were employed in the sector “*Manufacture of chemicals and chemical products*” which includes manufacture of pharmaceutical products (CSO 2007). The pharmaceutical sector is a very important employer of third level graduates. It is estimated that over 50% of the total workforce is drawn from third level institutions. A recent survey of 20 pharmaceutical companies in Ireland indicated expenditure of about €350 million during 2009 on capital projects, consistent with continuous investment and facilities upgrades in the sector over the past decade (PharmaChemical Ireland Strategic Plan, IBEC, 2010).

Approximately four hundred and fifty permanent staff are employed at Lilly, 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.

Most of the staff are from the Cork area. In 2010, 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 €120 million.

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 1 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 Population

The population of Cork (City and County) rose from 481,295 in 2006 to 518,128 in 2011. This represents a total increase in population of 7.7% during this period. The population of Cork City actually fell during this time by 0.4%, however the population of the County area rose by 10.3% since 2002 (Central Statistics Office, 2011).

The Central Statistics Office online population data for Kinsale is provided in the following **Table 6.1**. The table outlines the population change and growth rate of Kinsale Town between 2002 and 2011. The population of the area has decreased by 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.

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.

Table 6.1 Population of Kinsale Town, Bandon and Cork County 2002, 2006 and 2011

District	2002	2006	2011	Change from 2006-2011 (%)
Kinsale town	2,257	2,298	2,197	-4.4
Bandon town	1,578	1,721	1,913	+11.1
Bandon rural area	17,963	20,323	22,726	+11.8
Cork County	324,767	361,877	399,216	+10.3

(Data source: CSO website)

6.3.1 Trends in Employment

6.3.1.1 Quarterly National Household Survey

The CSO Quarterly National Household Survey, Quarter 1 of 2011 states that 1,804,200 persons were in employment in the State in the first quarter of 2011, an annual decrease for that quarter of 53,400 or 2.9%. This compares with an annual decrease in employment of 3.4% in the previous quarter and a decline of 5.5% in the year to the first quarter of 2010. The annual decrease of 2.9% in the number of persons in employment is the lowest fall since the third quarter of 2008 when the rate of decrease was 32.0%. On a seasonally adjusted basis, employment fell by 9,300 (-0.5%) in the quarter. This follows on from a seasonally adjusted fall in employment of 12,600 (-0.7%) in Q4 2010.

The survey states that in the first quarter of 2011, there were 295,700 persons unemployed, an increase of 20,700 (+7.5%) in the year. This represents an increase of 6,900 (+3.5%) to 201,800 for male unemployment and female unemployment increasing by 13,600 (+17.0%) to 93,800.

6.3.1.2 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 is 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.

Table 6.6 Kinsale employment 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

6.4 Land Use and Local Amenity

The land-uses of the proposed site and of the surrounding area are described in Chapter 3 of this EIS: *Site and Scheme Description* whilst the landscape and visual character of the site are described in Chapter 7: *Landscape and Visual Impact*.

The Lilly site is surrounded by agricultural land and Dunderrow village is 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 IE30 and IE42. No economic activity will be displaced by the construction of IE43.

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.

6.5 Characteristics of the Proposed Development

6.5.1 Construction Phase

During the construction phase, employment will be provided on site for an average of 450 workers for thirty months and the workforce is expected to peak at 550. 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 capital investment estimated at €300 million.

6.5.2 Operational Phase

When the proposed IE43 facility is operational, Lilly anticipate that the majority of the staff for IE43 will be deployed from the existing plant. It is expected that a significant number of jobs will be generated in the wider economy as a result of these permanent Lilly jobs.

6.6 Identification of Potential Impacts

The proposed development will have a significant positive impact, initially by providing employment for an average of 450 workers during the construction phase, and also by sustaining employment within the Lilly facility during the operational phase. 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; traffic impacts are assessed in Chapter 8 whilst noise and air quality impacts during construction are evaluated in Chapters 9 and 10 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.

6.7 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: *Traffic*, Chapter 9: *Noise and Vibration* and Chapter 10: *Air Quality and Climate*.

6.8 Residual Impacts

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

6.9 References

- 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*
- The Irish Pharmaceutical & Chemical Manufacturers Federation IPPCMF, (1999) *Survey on Expenditure & Human Resources*
- Indecon International Consultants RPS and Savills HOK (2008) *Cork Area Strategic Plan – Strategy for Additional Economic and Population Growth - An Update*
- Pharmaceutical Ireland (2010) *Innovation and Excellence Strategic document*

7 Landscape and Visual Assessment

7.1 Introduction

Brady Shipman Martin carried out a landscape and visual assessment of the likely landscape and visual impacts arising from the development of the IE43 Biotech Manufacturing Facility to expand the existing operations at Lilly, Dunderrow, Co. Cork.

The objective of the assessment is to appraise the existing landscape of the site and its wider setting, to assess the likely landscape and visual impacts arising from the proposed development and describe the proposed landscape mitigation measures and the resulting residual landscape and visual impacts.

7.2 Methodology

The visual assessment of the site was carried out between July and August 2011.

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 regard to, and the methodology is based on, the EPA Guidelines on the information to be contained in Environmental Impact Statements, 2002 and EPA Advice Notes on Current Practice (in the preparation of Environmental Impact Statements), 2003, 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, verifiable photomontages were prepared of the proposed development to assist in the landscape and visual assessment process. The baseline photography was taken with a wide angle lens (24°) and with a 'standard' lens (50°). The existing views are contained in **Figures 7.2.1a to 7.2.8a**. The wide angle views which are taken to show the proposed development within the wider context of the landscape are contained in **Figures 7.2.1b to 7.2.8b**. The 'standard' lens views are contained in **Figures 7.2.3c, 7.2.4c, 7.2.5c, 7.2.6c, 7.2.7c and 7.2.8c**.

7.2.1 Significance Assessment Criteria

The significance criteria used for the landscape and visual impact assessment is based on those given in the EPA Guidelines on the information to be contained in Environmental Impact Statements, 2002 and as set out in **Table 7.1**.

Table 7.1 Significance Criteria

Impact Level	Definition
Imperceptible	An impact capable of measurement 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.
Profound	An impact, which obliterates sensitive characteristics.

Impacts, which may be rated as positive, neutral or negative, are also considered in terms of duration as set out in the EPA Guidelines ranging from:

- temporary (lasting for 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).

7.2.2 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 Existing Environment

7.3.1 Existing Environment (see Figure 7.0)

Lilly has an existing pharmaceutical plant located at Dunderrow, Co. Cork.

Dunderrow is a small village on the R605 road between Inishannon and Kinsale approximately 4.5km to the northwest of Kinsale. The surrounding landscape is rolling, agricultural landscape with elevated land to the north and south. The Bandon River lies 1.5km to the southwest.

The Lilly plant directly adjoins Dunderrow to the north. Over the past 25 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 circa 30m OD Malin. The main access point to the plant is via the R605 along the southwestern boundary of the site. There is a large employee/visitor car park at the entrance. The plant covers a wide area and comprises a wide variety of building types and tanks. The colour of the built structures is predominantly dark green/juniper green.

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 surprisingly slight. This has been achieved through the utilisation of dark building colours which, when seen against the backdrop of the surrounding elevated landscape, help to incorporate the buildings into the landscape.

The northern boundary of the site adjoins a small country road and is heavily planted with an evergreen hedge approximately 8m in height along much of its length. The western boundary adjoins the R605 road and the main entrance to the site is close to Dunderrow Cross Roads. This boundary is planted with a mixture of ornamental evergreen hedges (*Leylandii* and *Griselinia*) and deciduous Ash (*Fraxinus excelsior*) trees. The southern boundary of the operating site adjoins a small stream and has a mixture of indigenous hedgerow species, including Hawthorn (*Crataegus*), Ash (*Fraxinus excelsior*) and Alder (*Alnus*), growing along the stream. The eastern boundary is planted with evergreen trees (*Leylandii*) and adjoins agricultural lands.

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. The main entrance to the site is via the R605 road, which runs along the western boundary of the site. There is also a secondary entrance off the R605. Additionally there is a temporary site entrance off the Ballyvrrin road. From much of the surrounding landscape, the Lilly plant is relatively well screened by existing vegetation and topography.

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 valley at the circa 30m OD contour. There are undulations in the valley. 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 approximately 1km. The southern horizon is defined by the east-west ridgeline at Tisaxon, 1.5km to the south, and the elevated ridgeline, approximately 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 northwesterly 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 runs along the northern boundary of the Lilly site linking Dunderrow to the townland of Ballyvtrin. There is a disused schoolhouse along this road. Opposite the school, there is a site entrance for construction traffic into the Lilly plant. Some 500m to the east, there is another third class road linking the townland of Ballyvtrin to Millwater Cross Roads.

The recorded site of the Battle of Kinsale lies 1.8km to the southeast of the site in the townland of Ardmartin.

7.3.2 Site Significance

The site is situated within the landscape character area 7: Rolling Patchwork Farmland in the 2009 Cork County Development Plan. Kinsale Harbour/Bandon River, with its incised patchwork and wooded estuary landscape character lies close (1.5km) to the west. There are a number of scenic and landscape designations either covering or in close proximity to the site.

7.3.2.1 Designated Scenic Landscape

The Bandon River Valley 1.5km to the south and west is located within a designated scenic landscape area. The policies relating to these areas (Volume 1, Chapter 7 of the Cork County Development Plan 2009) read:

‘ENV 2-7 Scenic Landscape

It is a particular objective to preserve the visual and scenic amenities of those areas of natural beauty identified as ‘scenic landscape’ and shown in the scenic amenity maps in Volume 3 of this plan

‘ENV 2-9 General Views and Prospects

It is a general objective to 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 recognised in the Landscape Strategy.’

Where a particular area of zoned land has a scenic landscape designation or adjoins a scenic landscape designation, this does not mean that development is automatically prohibited. Volume 1, Chapter 7 of the Cork County Development Plan 2009 reads:

‘7.2.32 The protection of these scenic routes and scenic landscapes is important in maintaining the uniqueness of Cork County and its distinctive landscape as a sustainable economic and tourist resource into the future. Whilst advocating the protection of such scenic resources the plan also recognises the fact that all landscapes are living and changing, and therefore an objection in principle to development situated on or adjoining scenic routes is not proposed. This principle will encourage appropriate landscaping and screen planting of developments along scenic routes. All proposals should be assessed on their merits taking into account the overall character of the scenic route including the elements listed in the Scenic Route Profile (Volume 2) and Appendix B (Volume 2) of the plan and

(where relevant) the character of any of the Scenic Landscapes through which the route passes. Maps of the scenic routes are shown in Volume 3 of this plan’.

7.3.2.2 Designated Scenic Routes

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

‘ENV 2-11 Scenic Routes

It is a particular objective to preserve the character of those views and prospects obtainable from scenic routes identified in this plan. These routes are shown on the scenic amenity maps in Volume 3 and listed in Volume 2 of this plan. A profile of each route and the views to be protected are listed in Volume 2 of this plan’.

‘ENV 2-12

It is an objective to protect the character and quality of those particular stretches of scenic routes that have very special views and prospects’.

‘ENV 2-13 Development on Scenic Routes

(a) It is also an objective of the Planning Authority to 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) It is an objective to encourage appropriate landscaping and screen planting of developments along scenic routes. Where scenic routes run through settlements street trees and ornamental landscaping may also be required. Refer to Objective ENV 4-13, which provides guidance in relation to landscaping.’

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

The S63 “R605 Regional Road and Local Road between Inishannon and Kinsale via Ship-pool” runs from Kinsale to Inishannon. 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 Barrel Cross Roads to Kilnacloon” runs along the top of the Bandon River Valley on its southwestern side 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 the dark green colour of the existing buildings at the Lilly plant when seen against the backdrop of the elevated hills to the north, the visual impact of the existing plant is slight.

7.3.3 Visual Envelope

The visual envelope of the site is indicated on **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 north 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.

7.3.3.1 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. The dark green/juniper colour of the buildings when viewed against the surrounding agricultural landscape and the ridgelines at Ardmartin help to absorb the buildings into the surrounding landscape. **Figures 7.1, 7.2, 7.2.1a, 7.2.2a and 7.2.3a.**

Residential Area RA02 (Kilny/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/The Fee forms the visual boundary. **Figures 7.1, 7.2 and 7.2.5a.**

Residential Area RA03 (Ballyvrin)

The residential properties in this area to the northeast of the site are at a higher elevation affording views of the existing plant. 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 5.1, 5.2 and 5.2.4a.**

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 intermittent nature of the views through the intervening hedgerows and the existing building colours. **Figures 7.1, 7.2 and 7.2.6a.**

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 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, as such, the plant has only a slight impact on views from this area.

On the Kinsale to Inishannon 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 7.1, 7.2, 7.2.7a and 7.2.8a.**

7.3.3.2 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 Inishannon via Ship-pool

When approaching Dunderrow from Kinsale to the southeast, there are a number of vantage points with 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 7.2.8a.**

When approaching Dunderrow from Inishannon to the northwest, there are views of the plant. 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 7.2.2a.**

The entrance to the plant is on the R605 close to Dunderrow Cross Roads. There are views into the site with views of some of the larger buildings. **Figure 7.2.1a.**

This road is a designated scenic route (S63) in the 2009 Cork County Development Plan.

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, affording views of the taller elements of the buildings in the Lilly plant. The majority of the lower level buildings are screened by a small, intervening hill.

This road is a designated scenic route (S62) in the 2009 Cork County Development Plan.

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 glimpsed views of some of the buildings through the construction entrance, which is opposite the disused school.

Roads to the East of the Site

There are 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 existing buildings are seen against the backdrop of the ridgelines on the western side of the Bandon River at Ballinadee. The buildings' dark green colour helps to visually recede the buildings into the landscape.

Figure 7.2.4a.

There is a small country road running approximately north/south some 750m to the east 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 vantage points of the site through gaps in the hedgerows. **Figure 7.2.6a.**

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. The extent of the roads in which the site is visible is indicated on **Figure 7.0.**

Roads to the South and West of the Bandon River

The road from Kinsale to Inishannon 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 7.0.** 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, 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 Inishannon to Ballinadee to Kinsale Western Bridge") is a designated scenic route (S65) in the 2009 Cork County Development Plan.

7.3.4 Landscape Character

The character of the landscape is agricultural in nature with rolling, east-west oriented, valley/ridge topography, with a patchwork of various field sizes typical of the south Cork coastline. In Chapter 7 of the 2009 Cork County Development Plan, the landscape is characterised as 7, Rolling Patchwork Farmland. The

character of the Bandon River Estuary to the south is defined by the steep side slopes of an incised valley with agriculture and woodland being the predominant land use.

Historically, this broad valley was the landscape in which the Battle of Kinsale was fought in 1601. The battle site is located some c. 1.8km to the southeast of the site at Millwater Cross Roads on the R605. Due to undulations in the topography of the valley, there are no views of the existing plant from the battle site.

The existing Lilly plant is generally well screened and is well absorbed within the landscape. Its overall impact on the rural character of the area is generally neutral.

7.4 Identification of Potential Impacts

The proposed development is for the construction of a new IE43 building to the east of the existing buildings on site.

The IE43 biotech manufacturing facility will involve:

- Construction of a split level facility with two levels visible from the front (north) and three levels visible from the rear (south). The building is approximately 110m in length and 100m wide. The height ranges from approximately 9m at the front to 30m at the rear. The design allows scope for expansion if needed in the future.
- Some utility plant will be located externally including cooling towers, steam reduction station and oxygen, carbon dioxide and nitrogen storage tanks.
- Entrance and car parking.
- Two small electrical buildings associated with the IE43 facility.
- Partial diversion of an existing stream within the site.

In addition to the primary building works, there will be the following elements of development:

- Site services including road lighting, over ground pipe racks leading to/from the building, underground fire water, foul and surface water pipes.
- Localised regrading and earthworks. There will be significant earthworks on the site in creating two level platforms for the proposed building. The excavated material (155,000cu.m.) will be retained and used in the landscaping of fields to the south of the building. During the excavation and earth moving process there will be visual impact from the machinery. Due to the nature of the topography, this will appear between 2 to 3m above existing ground levels from outside the site boundary, and as such will not result in significant impact. It is intended that the landscaped areas will be seeded and planted with indigenous tree planting to assist in the integration of the facility within the landscape.
- Construction activity, contractor's compounds and car parking, and construction storage areas. Construction access will be via the existing construction entrance the Ballyvryn Road. It is intended that this construction access point will become a staff access point for the proposed scheme.

Dunderrow from Inishannon, there will be glimpse 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 7.2.1b, 7.2.2b, 7.2.3b/c.**

7.4.3 Impact 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 IE43 building 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 7.2.1b, 7.2.2b and 7.2.3b/c.**

Residential Area RA02 (Kilany/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. The upper elements of the IE43 building will be partly visible behind the existing buildings on site from some locations in this area leading to slight, negative visual impact. **Figure 7.2.5b/c.**

Residential Area RA03 (Ballyvrin)

The residential properties in this area to the northeast of the site are at a higher elevation affording views of the existing plant. The IE43 building will be seen against the backdrop of the surrounding landscape, leading to moderate, negative visual impact. **Figure 7.2.4b/c.**

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 will be views of the upper parts of the IE43 building behind the existing tree boundaries, resulting in a moderate, negative visual impact. **Figure 7.2.6b/c.**

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 glimpsed views of the upper parts of the IE43 building, but these will be seen 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, negative. **Figure 7.2.7b/c and 7.2.8b/c.**

There will be long-range glimpse views of the upper elements of the IE43 building 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.

hedgerows, but always against a backdrop of existing vegetation and existing buildings on site, leading to slight, negative visual impact. **Figure 7.2.4b/c.**

A local road runs south from the Ballyvrin 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 IE43 buildings, with the lower portions being screened behind existing vegetation. **Figure 7.2.6b/c.**

Roads to the South of the Site

South of the R605 road that runs along the western 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 glimpse views of the upper parts of the IE43 building leading to slight, negative visual impact. **Figure 7.2.5b/c.**

Roads to the South and West of the Bandon River

There will be long range glimpse views of the top of the IE43 building 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 Ballinadee, the IE43 building 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 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.

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. Additional planting will not further reduce the visual impact. Soil from the construction site will be used for landscaping & provision of berms on completion of the project. This will also contribute to reduction in 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. 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.

7.6 Residual Impacts

The proposal is a substantial 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 impacts will range from none to slight when viewed from all but the eastern and north eastern locations. From these latter directions, the proximity of some vantage points will result in an increased degree of impact, but the building will be set into the landscape, will display colours/textures that assist its blending into the landscape, and only the upper parts will be visible and always against a backdrop of existing vegetation or buildings.

7.7 References

The following are the main texts reviewed in the course of the study:

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

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

EPA (2003). *Advice Notes On Current Practice (in the preparation of Environmental Impact Statements)*

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8 Roads and Traffic

8.1 Introduction

This chapter describes the existing environment, estimates the future traffic generated by the IE 43 biotech manufacturing facility and assesses the impact of this generated traffic on the surrounding network.

8.2 Existing Situation

8.2.1 Site Location

Dunderrow is located approximately 32 kilometres south west of Cork City and 4 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**.

8.2.2 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 and the third route is via L3025 (Ballydonagh Road) onto the R607 serving Cork City. In addition, the Lilly site is served by Ballyvryn Road, which is very tightly trafficked. The Ballyvryn Road was widened over a short section east of Dunderrow to support the provision of a dedicated construction entrance to serve the Lilly complex.

8.2.3 Access to Lilly

The Lilly site is currently served by three accesses, as shown in **Figure 8.2**. The Lilly Main Access (Entrance 1) is located off the R605 at the north western end of the site and serves staff and deliveries to the site. The Lilly Secondary Access (Entrance 2) is located off the R605 at the western end of the site and serves staff and contractor traffic. The Lilly Construction Access (Entrance 3) which is located off the Ballyvryn Road at the north eastern end of the site and acts as a construction entrance and also serves some staff.

8.2.4 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 Wednesday 11th of May 2011 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 08:00 – 09:00 and 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 with the development evening peak period aligning with the network peak period.

Traffic counts were carried out at the following junctions:

1. R605/ Ballydonaghy Road (L3025) Junction
2. R605/ Ballyvrin Road Junction
3. R605/ Lilly Main Access (Entrance 1)
4. R605/ Lilly Secondary Access (Entrance 2)
5. Ballyvrin Road/ Temporary Construction Access (Entrance 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)	AM Peak (08:00 – 09:00)	PM Peak (16:00 – 17:00)
R605 (North of Ballydonaghy Road)	115 vph	116 vph	142 vph
Ballydonaghy Road (L3025)	176 vph	125 vph	107 vph
R605 (South of Ballydonaghy Road)	283 vph	225 vph	235 vph
R605 (North of Ballyvrin Road)	319 vph	384 vph	312 vph
Ballyvrin Road (West of Entrance)	73 vph	53 vph	36 vph
Ballyvrin Road (East of Entrance)	39 vph	41 vph	33 vph
R605 (North of Entrance 1)	294 vph	375 vph	310 vph
R605 (North of Entrance 2)	204 vph	314 vph	259 vph
R605 (South of Entrance 2)	176 vph	320 vph	230 vph
Entrance 1	134 vph	106 vph	71 vph
Entrance 2	194 vph	102 vph	125 vph
Entrance 3	84 vph	48 vph	35 vph

From **Table 8.1**, it can be seen that the Lilly entrances are busiest between 07:00 and 08:00 while the R605 is busiest between 08:00 – 09:00 with traffic flows on the R605 between 300 and 400 vehicles per hour (vph). The staggering of the peak demands during the morning peak period ensures that traffic generated by the Lilly facility does not impact on commuter and school trips in the area.

8.3 Characteristics of Proposed Development

8.3.1 Nature of IE43 Development

The proposed development will involve the construction of a new biotech manufacturing facility, IE43, within the existing site boundary along with modifications to existing facilities and utilities. The existing site employs approximately 450 permanent employees and 200 - 300 contract staff (250 staff averaged over the year). It is envisaged that the IE43 facility will employ 150 staff which will come from within the existing workforce. The existing plant production operations are carried out under a shift basis and the IE43 facility will be operated in a similar manner. Staff of IE43 will use the entrance to the site from the Ballyvrin Road (Entrance 3).

8.3.2 Projected Traffic Generation

The projected traffic generation at the new entrance (Entrance 3) has been calculated from comparing the volume of traffic generated by the existing facility with the existing number of staff. **Table 8.2** outlines the volume of traffic generation associated with the existing 700 staff based on the recent traffic count data.

Table 8.2 Traffic Generation - Existing Lilly complex

	In	Out	Total
AM Peak (07:15 – 08:15)	387 vph	25 vph	412 vph
AM Peak (08:00 – 09:00)	237 vph	19 vph	256 vph
PM Peak (16:00 – 17:00)	8 vph	223 vph	231 vph

Based on the projected increase in staff associated with the IE 43 project (150 personnel) the following increase in traffic is expected at Entrance 3. As stated earlier, the IE43 staff will come from the existing Lilly workforce. Currently, this staff use Entrance 1 and Entrance 2, however they will change to using Entrance 3 once IE43 becomes operational. Therefore, there will be an increase in traffic using the Ballyvrin Road between the R605 and Entrances 3 and a corresponding reduction in traffic on the R605 accessing Entrance 1 and Entrance 2.

Table 8.3 Traffic Generation – IE43 Operational Traffic

	In	Out	Total
AM Peak (07:15 – 08:15)	83 vph	5 vph	88 vph
AM Peak (08:00 – 09:00)	51 vph	4 vph	55 vph
PM Peak (16:00 – 17:00)	2 vph	48 vph	50 vph

In addition to staff traffic, the development of the IE43 facility will generate some additional movements associated with the production process. However, it is envisaged that the increase in production traffic will be offset by the reduction in production traffic from the existing Lilly facility. Therefore, the operation of the proposed development will not generate any additional traffic loadings onto the public roadway. The operational traffic will continue to use the existing entrances on the R605.

8.4 Trip Distribution

As stated previously, employee traffic associated with the IE43 will use the entrance to the site from Ballyvrin Road, which will result in a corresponding decrease in the use of the existing two entrances accessing the R605. Staff traffic will be discouraged from accessing the site from the east of Ballyvrin Road through the erection of signage, entrance bollards and geometric upgrades to the Ballyvrin Road entrance.

8.5 Traffic Assignment

Using the traffic distribution profile outlined in **Table 8.3**, traffic from the proposed development was assigned to the surrounding road network links. The results of this exercise can be viewed in **Table 8.4**.

Table 8.4 Projected Two Way Traffic Flows

Link	AM Peak (07:15 – 08:15)	AM Peak (08:00 – 09:00)	PM Peak (16:00 – 17:00)
R605 (North of Ballydonaghy Road)	0 vph	0 vph	0 vph
Ballydonaghy Road (L3025)	0 vph	0 vph	0 vph
R605 (South of Ballydonaghy Road)	0 vph	0 vph	0 vph
R605 (North of Ballyvrin Road)	0 vph	0 vph	0 vph
Ballyvrin Road (West of Entrance)	88 vph	55 vph	50 vph
Ballyvrin Road (East of Entrance)	0 vph	0 vph	0 vph
R605 (North of Entrance 1)	-35 vph	-22 vph	-20 vph
R605 (North of Entrance 2)	-4 vph	-3 vph	-3 vph
R605 (South of Entrance 2)	0 vph	0 vph	0 vph
Entrance 1	-31 vph	-19 vph	-18 vph
Entrance 2	-57 vph	-36 vph	-33 vph
Entrance 3	88 vph	55 vph	50 vph

8.5.1 Construction Generated Traffic

8.5.1.1 Construction Staff

The IE43 project is expected to take approximately 30 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 estimated number of cars/vans entering/leaving the site on a daily basis is shown in **Table 8.5**, based on the following assumptions:

- 100% of construction workers will arrive on site by car/van.
- On average there will be 1.1 construction workers per car/van.
- 80% of construction staff will arrive/depart during the peak hour periods.
- On average each construction staff vehicle will carry out 3 trips per day.

Table 8.5 Estimated Construction Staff Traffic

	Construction Staff	Daily Traffic	Peak Hour Traffic
Average	450	1,227 trips	327 trips
Peak	550	1,500 trips	400 trips

8.5.1.2 Construction Deliveries

The estimated number of trucks/vans entering/leaving the site on a daily basis is shown below in **Table 8.6** and is based on an average 12 hour working day (07:00 -19:00).

Table 8.6 Estimated Construction Deliveries Traffic

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

From **Table 8.6**, 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.

8.5.1.3 Total Construction Related Traffic

Table 8.7 presents the total expected volume of traffic associated with the peak construction activities.

Table 8.7 Total Construction Deliveries Traffic

	Daily Traffic	Peak Hour Traffic
Peak	1,500 trips	400 trips
General Construction Deliveries	120 trips	10 trips
TOTAL	1,620 trips	410 trips

8.5.2 Trip Distribution (Construction Phase)

Construction related traffic associated with the development proposals will be instructed not to access the site via Ballvrin Road from the east. The existing construction entrance will be upgraded to make it difficult to turn left into the site and turn right out of the site and additional signage will be erected which will instruct traffic not to turn left in or right out of the site.

In addition, to the restrictions to traffic associated with the IE 43 project, HGV traffic associated with the IE43 project will be contractually instructed to access the site via the R605 and HGV traffic will be instructed not to use the Ballydonaghy Road (L3025). **Table 8.8** demonstrates the projected distribution of trips associated with the development proposals.

Table 8.8 Traffic Distribution Construction Phase

Link	Trip Distribution
R605 (North of Ballydonaghy)	40%
Ballydonaghy Road (L3025)	30%
R605 (South of Entrance 2)	30%

8.5.3 Traffic Assignment (Construction Phase)

Using the traffic distribution profile outlined in **Table 8.8** 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 8.9**.

Table 8.9 Projected Two Way Traffic Flows

Link	AM Peak (07:15 – 08:15)	AM Peak (08:00 – 09:00)	PM Peak (16:00 – 17:00)
R605 (North of Ballydonaghy Road)	164 vph	41 vph	164 vph
Ballydonaghy Road (L3025)	123 vph	31 vph	123 vph
R605 (South of Ballydonaghy Road)	287 vph	71 vph	287 vph
R605 (North of Ballyvrin Road)	287 vph	71 vph	287 vph
Ballyvrin Road (West of Entrance)	410 vph	102 vph	410 vph
Ballyvrin Road (East of Entrance)	0 vph	0 vph	0 vph
R605 (North of Entrance 1)	123 vph	31 vph	123 vph
R605 (North of Entrance 2)	123 vph	31 vph	123 vph
R605 (South of Entrance 2)	123 vph	31 vph	123 vph
Entrance 1	0 vph	0 vph	0 vph
Entrance 2	0 vph	0 vph	0 vph
Entrance 3	410 vph	102 vph	410 vph

8.6 Predicted Impact of the Proposed Development

8.6.1 General

The 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 IE43 project.

The three peak periods, AM Development peak (07:15 – 08:15), AM Network peak (08:00 – 09:00) and peak PM period (16:00 – 17:00) have been examined in order to assess the busiest case in terms of local traffic on the road network and traffic generated by the proposed development.

It is assumed that the proposed development will be operational by 2015. Traffic on the existing road network has been increased by 1.3% per annum. 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.

8.6.2 Link Flows

The traffic flows for both the 'with' and 'without' development scenario in 2015 are quoted in **Table 8.10** below.

Table 8.10 2015 Link Flows before and after Proposed Development

Link	Year 2015 Before Development Completed			Year 2015 After Development Completed		
	07:15 - 08:15	08:00 - 09:00	16:00 - 17:00	07:15 - 08:15	08:00 - 09:00	16:00 - 17:00
R605 (North of Ballydonaghy)	121 vph	122 vph	150 vph	121 vph	122 vph	150 vph
Ballydonaghy Road (L3025)	185 vph	132 vph	113 vph	185 vph	132 vph	113 vph
R605 (South of Ballydonaghy)	298 vph	237 vph	247 vph	298 vph	237 vph	247 vph
R605 (North of Ballyvrrin Road)	336 vph	404 vph	329 vph	336 vph	404 vph	329 vph
Ballyvrrin Road (West of Entrance)	77 vph	56 vph	38 vph	165 vph	111 vph	88 vph
Ballyvrrin Road (East of Entrance)	41 vph	43 vph	35 vph	41 vph	43 vph	35 vph
R605 (North of Entrance 1)	310 vph	395 vph	326 vph	274 vph	373 vph	306 vph
R605 (North of Entrance 2)	215 vph	331 vph	273 vph	210 vph	328 vph	270 vph
R605 (South of Entrance 2)	185 vph	337 vph	242 vph	185 vph	337 vph	242 vph

It can be seen from **Table 8.10** above, that following the completion of the proposed development it is envisaged that most of the roadways (i.e. R605, Ballydonaghy Road) will not experience any increase in traffic as all IE43 staff are already employed within the existing Lilly facility. The only section of road

that is expected to see an increase in traffic is the section of Ballyvrin Road between its junction with the R605 and Entrance 3.

8.6.3 Junction Analysis

As stated above the primary change in traffic associated with the development proposals is the transfer of traffic from the existing entrances on the R605 to Entrance 3 on the Ballyvrin Road. The operation of the existing traffic signal controlled junction is examined as part of this assessment to understand the potential impact the transfer of traffic to Entrance 3 will have on the operation of the signals.

8.6.4 R605/ Ballyvrin Road Junction

The junction of 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 8.11** below.

Table 8.11 2015 ‘With’ Development – R605/ Ballyvrin Road

Roadway	AM Development Peak 07:15 -08:15		AM Network Peak 07:15 -08:15		PM Network Peak 07:15 -08:15	
	Capacity	Queue	Capacity	Queue	Capacity	Queue
R605 North	18%	1 veh	18%	1 veh	6%	0 vehs
Ballyvrin Road	13%	1 veh	12%	1 veh	17%	2 vehs
R605 South	5%	0 vehs	10%	1 veh	17%	2 vehs

It can be seen from **Table 8.11** above that the junction is expected to have sufficient capacity to accommodate the traffic associated with the proposed development during its operational phase.

8.6.5 Impact of Construction Traffic

Construction traffic will enter the site via the existing construction entrance on Ballyvrin Road. Ballyvrin Road was widened previously to accommodate the construction of IE30 and IE 42 and is now of sufficient width to allow two vehicles to pass safely.

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 IE43 project is of a similar level as the IE42 project, which was completed within the Lilly facility in recent years. During the construction phase of the IE42 project, construction traffic was well managed and there was limited impact on traffic conditions on the surrounding road network.

As with the operational traffic; three peak periods, AM Development peak (07:15 – 08:15), AM Network peak (08:00 – 09:00) and peak PM period (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 2014. Traffic on the existing road network has been increased by 1.3% per annum. 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.

8.6.5.1 Link Flows

The traffic flows for the construction phase of the works are quoted below in the **Table 8.12**.

Table 8.12 2014 Link Flows during the Construction Phase

Link	Year 2014 Without Development			Year 2014 With Development		
	07:15 - 08:15	08:00 – 09:00	16:00 – 17:00	07:15 - 08:15	08:00 – 09:00	16:00 – 17:00
R605 (North of Ballydonaghy)	120 vph	121 vph	148 vph	284 vph	161 vph	312 vph
Ballydonaghy Road (L3025)	183 vph	130 vph	111 vph	306 vph	161 vph	234 vph
R605 (South of Ballydonaghy)	294 vph	234 vph	244 vph	581 vph	305 vph	531 vph
R605 (North of Ballyvrrin Road)	332 vph	399 vph	324 vph	619 vph	471 vph	611 vph
Ballyvrrin Road (West of Entrance)	76 vph	55 vph	37 vph	486 vph	157 vph	447 vph
Ballyvrrin Road (East of Entrance)	41 vph	43 vph	34 vph	41 vph	43 vph	34 vph
R605 (North of Entrance 1)	306 vph	390 vph	322 vph	429 vph	420 vph	445 vph
R605 (North of Entrance 2)	212 vph	326 vph	269 vph	335 vph	357 vph	392 vph
R605 (South of Entrance 2)	183 vph	333 vph	239 vph	306 vph	363 vph	362 vph

It can be seen from **Table 8.12** that during the construction phase the roadways 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 junction of the R605/ Ballyvrrin Road has been carried out to include the additional traffic associated with the construction traffic. The junction of R605/ Ballyvrrin Road was again modelled using LINSIG and the results of the analysis can be seen in **Table 8.13** below.

Table 8.13 2014 'With' Development – R605/ Ballyvrrin Road

Roadway	AM Development Peak 07:15 -08:15		AM Network Peak 07:15 -08:15		PM Network Peak 07:15 -08:15	
	Capacity	Queue	Capacity	Queue	Capacity	Queue
R605 North	36%	3 vehs	21%	2 vehs	16%	2 vehs
Ballyvrrin Road	34%	2 vehs	17%	1 veh	41%	6 vehs
R605 South	19%	1 veh	11%	1 veh	41%	5 vehs

It can be seen **Table 8.13** above that the junction is expected to have sufficient capacity to accommodate the traffic associated with the proposed development during its construction phase.

In addition to the operation of the above junction, the junction of 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 R605/ Ballydonaghy Road has been assessed using PICADY which is a UK Department of Transport software application designed to model priority controlled junctions.

Table 8.14 2014 'With' Development – R605/ Ballydonaghy Road

Roadway	AM Development Peak 07:15 -08:15		AM Network Peak 07:15 -08:15		PM Network Peak 07:15 -08:15	
	Capacity	Queue	Capacity	Queue	Capacity	Queue
R605 North	0%	0 vehs	0%	0 vehs	0%	0 vehs
Ballydonaghy Road (L3025)	56%	1 veh	25%	0 vehs	6%	0 vehs
R605 South	7%	0 vehs	6%	0 vehs	49%	1 veh

It can be seen from **Table 8.14** above that the junction is expected to have sufficient capacity to accommodate the traffic associated with the proposed development during its construction phase.

8.7 Mitigation Measures

8.7.1 Local Road Improvements

As part of the IE30 project the Ballyvrin Road was widened between the R605 and the construction entrance. This widening has ensured that it is practical for two vehicles to pass each other on this stretch of road. The traffic management provision put in place during the IE30 project (i.e. traffic lights at the junction of Ballyvrin Road and the R650) will be maintained during the construction of the IE43 project. The existing construction entrance will be upgraded to include additional signage and bollards to discourage traffic from using Ballyvrin Road East for accessing/leaving the site.

8.7.2 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 the Local Authority. The construction traffic management plan will include travel restrictions on all Lilly traffic using Ballyvrin Road to the east of the existing construction entrance. 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.

8.7.3 Parking Provision

As part of the development proposals all the parking needs of the construction staff will be facilitated within the Lilly complex with a total of 550 parking spaces provided for construction personnel.

8.8 Residual Impacts

The proposed development is expected to generate increased traffic during the construction phase of the IE43 project. However, all junctions in the vicinity of the development are expected to operate within capacity.

Following the construction of IE43 there will be little change to prevailing traffic conditions in the area as the IE43 facility is expected to be staffed by personnel already employed at Lilly. The Ballyvrin Road west of the existing construction entrance is expected to experience some increase in traffic as staff transfer from the car parks at the front of the facility (accessed from the R605) to the new car park provided to serve the staff of IE43, this section of road is adequate to cater for the increase in traffic expected along this roadway.

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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 on the ambient environment, proposes mitigation measures where necessary, and considers the residual impact.

9.2 Methodology

9.2.1.1 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.

9.2.1.2 Limits and Standards

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

BS5228 2009 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 9.1** sets out construction noise criteria presented in BS5228.

Table 9.1 BS5228 (Part 1) ABC Assessment Categories and Thresholds (BSI, 2009)

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 44 to 53dB, (refer to **Table 9.4**) the A category is applicable as specified in **Table 9.3**. Therefore the limits outlined in **Table 9.2** below will be applied at the nearest sensitive receptor to the works.

Table 9.2 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.

No significant vibration sources are envisaged during the construction or operational phases.

Operational Phase

During the operational phase of the development, the noise from the facility must comply with the IPPC Licence Limits. Schedule B.4 of the IPPC 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.

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 9.3**).

Table 9.3 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

Traffic Impacts

The impact of the proposed development during the operation and construction phases due to the traffic generated by it is also considered based on the significance criteria outlined in **Table 9.3** above.

9.3 Receiving Environment

9.3.1 Noise

Lilly personnel currently conduct annual noise monitoring at a number of monitoring points in the vicinity of the site. Monitoring is carried out in accordance with the IPPC 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 IPPC 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 9.4**. The noise levels shown in **Table 9.4** are logarithmic averages of triplicate samples taken during 2010.

Table 9.4 Noise Monitoring Results (2010)

Name	Location	L_{Aeq} (30 mins) Noise Level (dB)	
		Daytime	Night-time
M1	Old School NE of site	44	36
M2	Site Boundary N of site	53	43
M3	Site Boundary NW of site	51	43
M4	Site Boundary SW of site	46	43
M5	Site Boundary S of site	45	38

The 2010 monitoring results are within the licensed noise daytime and night-time limits and consequently the impact of noise from the facility on the nearest residences is currently not significant.

9.3.2 Vibration

No vibration monitoring is conducted to determine the existing vibration environment as there are no activities on site which give rise to vibration to any appreciable degree.

9.4 Noise Impact of the Proposed Development

9.4.1 Construction Phase Impact Assessment

The proposed construction works is expected to take approximately 30 months with hours of construction from 07:00-19:00 Monday to Friday and 08:00 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 generation of noise.

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.

For the purposes of the calculation in **Table 9.5**, it has been assumed that plant and equipment will be at the location of the north eastern boundary of the site; closest to the nearest noise sensitive locations.

However, plant and equipment will not remain in the one place for the duration of the construction period and it is likely that they will be positioned at greater distances from the nearest noise sensitive location for the majority of the works. This consequently will generate a lesser impact. However, as discussed previously, the assessment has been conducted to be representative of a worst-case scenario.

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.

Noise levels were predicted at four sensitive receptors, refer to **Figure 9.2**. The results of the modelling assessment are summarised for the worst-case receptor (N4) in **Table 9.5**.

Table 9.5 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

Phase	Plant Item	Maximum Plant Noise Level at 10m Distance (dB L _{Aeq,1hr}) ¹
	Dump truck	76
General Construction	Circular Saw	84
	Diesel Hoist	78
	Compressor	75
	Generator	74
	Crane	78

¹: BS 5228-1, 2009 (BSI, 2009)

Table 9.6 details the results from the modelling of noise emissions during construction phase. Levels are provided for the worst-case receptor, N4.

Table 9.6 Construction Noise Modelling Results

Construction Phase	Predicted L _{Aeq,1hr} at worst-case sensitive receptor - N4 (top floor) (dB)	Total Noise (dB) L _{Aeq,1hr} (predicted + baseline)
Site clearance and preparation	50	51
General Construction	51	52

During site construction works, the maximum predicted total noise level due to the construction phase of the IE43 facility of 52dB is predicted to comply with the BS5228 daytime limit and the IPPC licence daytime limit of 55dB. No works likely to result in significant noise emissions 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 and IPPC Licence daytime 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 facility was also undertaken based on traffic information provided in Chapter 8. No variation in noise levels was predicted in the assessment so the impact is considered imperceptible based on the criteria outlined in **Table 9.3**.

Construction works are not anticipated to give rise to any appreciable vibration.

9.4.2 Operation Phase Noise Assessment

The noise prediction models undertaken for this report evaluate the impact of operations of the facility on surrounding noise sensitive locations. The input to the model was an updated electronic AutoCAD map showing the proposed building details and details of the main noise sources associated with the development. These inputs were used to update the existing site noise model developed for the facility. Jacobs Engineering Ltd provided details of the noise sources and their relative locations.

There are a number of internal noise sources proposed as part of the IE43 development. However, as these sources will be contained within the building, breakout noise will be minimal and no impact on the noise environment is envisaged.

The main external noise sources associated with IE43 biotech manufacturing facility are:

- Condensate return pumps (5 no.).
- Cooling towers (4 No.), adjacent to IE30.
- Cooling water pumps (4 no.), adjacent to IE30.

Details of the noise sources modelled are presented in **Table 9.7**.

Table 9.7 Details of Noise Sources Modelled

Source	Location	Comments	Sound Power Level (dB) of each Source
Condensate return pumps	External to IE43	5 No.	75
Cooling tower	South-east of IE30	4 No.	85
Cooling water pumps	South-east of IE30	4 No.	75

The impact of noise from the proposed facility was determined by comparing the existing baseline noise environment to the proposed situation with the above noise sources in operation. The baseline levels used in the assessment for the sensitive receptors were based on the nearest monitoring point. Predicted values are compared to the baseline level for daytime and night-time in **Tables 9.8** and **9.9** respectively.

Table 9.8 Summary of Daytime Noise Level Model Outputs at Sensitive Receptors

Location	Existing Measured Noise levels	Predicted Noise levels with IE43	Increase in Predicted Noise Level	Impact
	dB(A) L_{Aeq}	dB(A) L_{Aeq}	dB(A) L_{Aeq}	
N1	44	44	0	No impact
N2	51	51	0	No impact
N3	45	45	0	No impact
N4	44	44	0	No impact

Table 9.9 Summary of Night-time Noise Level Model Outputs at Sensitive Receptors

Location	Existing Measured Noise levels	Predicted Noise levels with IE43	Increase in Predicted Noise Level	Impact
	dB(A) L_{Aeq}	dB(A) L_{Aeq}	dB(A) L_{Aeq}	
N1	36	36	0	No impact
N2	43	43	0	No impact
N3	38	38	0	No impact

Location	Existing Measured Noise levels	Predicted Noise levels with IE43	Increase in Predicted Noise Level	Impact
	dB(A) L _{Aeq}	dB(A) L _{Aeq}	dB(A) L _{Aeq}	
N4	36	36	0	No impact

As can be seen from the above tables, there is no increase in noise levels predicted at the noise sensitive locations due to the operation of IE43 and levels will continue to comply with IPPC licence limits.

An assessment of the changes in traffic volumes due to the operational phase of the proposed development was also undertaken based on traffic information provided in Chapter 8. No variation in noise levels was predicted in the assessment so the impact is considered imperceptible based on criteria outlined in **Table 9.3**.

9.5 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, 2009) 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 IPPC 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.
- 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.

9.6 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.

9.7 References

EPA, *“Guidance Note for Noise in relation to Scheduled Activities”*

ISO 1996 *“Description and measurement of environmental noise”*.

ISO 9613 *“Attenuation of sound during propagation outdoors”*

BS 5228 *“Noise and vibration control on open and construction sites”*

BS 4142 *“Rating industrial noise affecting mixed Residential and Industrial Areas”*

National Roads Authority *“Guidelines for the Treatment of Noise and Vibration in National Roads Schemes”*

10 Air Quality and Climate

10.1 Introduction

This chapter presents an assessment of the impact of the proposed IE43 biotech manufacturing facility on air quality in the vicinity of the Lilly plant. The impact of the project on climate is also addressed.

10.2 Assessment Methodology

10.2.1 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 publicly 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
SO ₂	Human Health	1-hour	350	≤24 exceedances p.a. (99.73%ile)	1 January 2005
		24-hours	125	≤3 exceedances p.a. (99.18%ile)	1 January 2005
PM ₁₀	Human Health	24-hours	50	≤35 exceedances p.a. (90%ile)	1 January 2005
		Calendar year	40	Annual mean	1 January 2005

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
PM _{2.5}	Human Health	Calendar year	25 ¹	Annual mean	1 January 2010
		Calendar year	20 ²	Annual mean	1 January 2020
Benzene	Human Health	Calendar year	5	Annual mean	1 January 2010
CO	Human Health	8-hour running mean	10,000	Max. daily 8-hour mean	1 January 2005

¹ Target value

² Limit value to be reviewed by the Commission in 2013 in light of further information on health and environmental effects, technical feasibility and experience of the Target Value in Member states.

The UK Highways Agency Design Manual for Roads and Bridges (DMRB, 2007) model, predicts the annual mean concentration for carbon monoxide (CO). This cannot be directly compared with the Air Quality Standards as it is an 8-hour mean concentration. However, the DMRB states that if the annual mean CO concentration is below $2,000 \mu\text{g}/\text{m}^3$ then it is 'currently unlikely' that the maximum daily running 8-hour mean concentration will be exceeded. The UK Department for Environment, Food and Rural Affairs (DEFRA) concurs in its Local Air Quality Management Technical Guidance (DEFRA, 2003) that:

'Authorities may assume that where the predicted annual mean concentration is below $2\text{mg}/\text{m}^3$, there is little likelihood of the maximum daily running 8-hour mean concentration exceeding the objective.'

A guideline value has been derived by University College Cork for Total Organic Carbon (TOC) of $20\mu\text{g}/\text{m}^3$. This TOC guideline of $20\mu\text{g}/\text{m}^3$ is based on extensive TOC measurements at non-industrial county sites. It is referred to as the *desirable TOC maximum*.

10.3 Existing Environment

Lilly is located in a rural area, in a zone referred to by the Environmental Protection Agency 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. The EPA reports that air quality in this zone is 'Good', with reference to the parameters PM₁₀, nitrogen oxides, sulphur dioxide, carbon monoxide and metals.

University College Cork carried out extensive ambient air monitoring in the vicinity of the Lilly plant from 1990 to the end of 2009. Since 2010, Lilly carried out the monitoring using in-house resources. The monitoring programme has been streamlined as the data indicated that there were no detectable ambient effects

from the plant operations based on almost 20 years of operation and due to the much reduced usage of organic solvents at the Lilly site. Additionally, the last two major expansions of the plant are enabling bio-pharmaceutical manufacturing which has negligible attributable air emissions. With the agreement of the EPA the monitoring of oxides of nitrogen and particulate fine matter (PM₁₀) were discontinued at the end of 2009.

The most recent monitoring period covered 2010 and the air quality parameters measured were total organic carbon (TOC) and sulphur dioxide (SO₂). Monitoring is carried out at one location offsite as shown on **Figure 10.1** at the old national school. In the first quarter of 2011, the use of heavy fuel oil for steam generation was replaced with natural gas. This eliminated the need to monitor for Sulphur and Nitrogen Oxides, a condition specified in the IPPC licence. This was agreed with the EPA. Lilly continue to monitor the ambient air quality for TOC. However, there is no licence requirement to do so. The results for 2010 are outlined below and are taken from the 2010 AER which is available on the EPA website – www.epa.ie.

10.3.1 2010 Air Quality Monitoring Parameters

In general, based on the monitoring of levels of Total organic carbon (TOC) and sulphur dioxide, ambient air quality in the vicinity of the Lilly plant is what would be expected in a rural area.

The air quality parameters measured were as follows:

- Total organic carbon (TOC) or volatile organic carbon, monitored as a weekly average, and analysed by capillary gas chromatography with flame ionisation detection.
- Sulphur dioxide (SO₂) measured hourly by an approved ultraviolet detection system for twelve months.

10.3.2 2010 Air Quality Monitoring Parameters Results

The mean weekly TOC concentration at the Old School monitoring site was 2.4 microgram/m³ (µg/m³) with a range of 0.1 to 5.3 microgram/m³ (µg/m³). There was no exceedance of the *desirable TOC maximum* of 20 microgram/m³.

Sulphur dioxide was measured for twelve months at 1-hour intervals at the Old School as set out in EU legislation. Hourly values for the concentration of SO₂ in the ambient air were in compliance with the conditions of the EU Directive (2008/50/EC) on ambient air quality.

10.3.3 2010 Air Quality Monitoring Conclusions

Ambient air quality in the vicinity of the old school monitoring site showed that there was full compliance with the respective guideline and EU Directive limits for the two parameters of air quality measured in 2010. There has also been full compliance with the Directive limits on all parameters since the inception of the programme in 1990.

10.4 Existing Emission Sources

10.4.1 Introduction

Potential sources of existing emissions to atmosphere from the site include the following:

- emissions from processing equipment,
- emissions from one waste incinerator,
- emissions from the regenerative thermal oxidiser or the standby thermal oxidiser,
- emissions from the three boilers,
- fugitive emissions from storage tanks and production buildings, and
- dust emissions.

There are a number of licensed emission points on the site. These are listed below in **Table 10.2** below and shown on **Figure 10.1**.

Table 10.2 Licensed Emission Points to Air

Item	Licence Ref.	Description
1	4-1	Boiler Stack
2	7-1(b)	John Zinc Incinerator
3	7-1(c)	Thermal Incinerator (no longer in use)
4	A3-24	Carbon Absorber (no longer in use)
5	A3-30	Carbon Absorber (no longer in use)
6	7-1 (a)	Resco Regenerative Thermal Oxidiser Incinerator
7	IE08 EF10	(General and Pharmaceutical Dust from Bagging unit)
8	IE08 EF23	(General and Pharmaceutical Dust)
9	IE16 S/S DEF3	(General and Pharmaceutical Dust from mill operation)
10	IE16L/S EF7	(Dust from dry end production)
11	IE16 S/S EF2	(Dust from milling and sieving)
12	IE1 – V3	(Extract from Dispensing Room)
13	IE3 EF19-HF1	(Dust from Ractopamine Annex) (no longer in use)
14	IE16 L/S EF8	(Future) (Pharmaceutical Dust)
15	IE16L/S EF9	(Future) (Pharmaceutical Dust)
16	IE16L/S EF10	(Future) (Pharmaceutical Dust)
17	IE16L/S EF11	(Future) (Pharmaceutical Dust)
18	IE30 EV1	(Future) (Pharmaceutical Dust)
19	IE30 EV2	(Future) (Pharmaceutical Dust)

Items 3, 4, 5 and 13 are not in use, and the associated equipment has been dismantled. However, they remain licensed emission points, should the need arise for future use.

Other emissions to air associated with the operations at Lilly come from traffic movements around the site and traffic travelling to and from the site.

Background sources of emissions to the atmosphere in the vicinity of the Lilly plant include dust from land-dressing and harvesting, odours from the use of silage and the land spreading of slurry, and direct gaseous emissions particularly methane from grazing farm animals. Emissions from fuel burning and traffic in the area also contribute to emissions to the atmosphere. However, only emissions from the plant are addressed in this section.

It is Lilly's objective that the emissions from the site comply with all relevant air quality standards. Consequently emissions to atmosphere are reviewed periodically to identify potential reductions. This objective was included in the Schedule of Objectives and Targets in the 2010 Annual Environmental Report, which was submitted to the EPA in 2011. The AER 2010 is available to view on the EPA website – www.epa.ie.

To further minimise impacts on air quality, the use of heavy fuel oil for steam generation has been replaced by natural gas. The use of Liquid Petroleum Gas (LPG) as a support fuel for the incinerators was also replaced by natural gas. The feasibility of a Combined Heat and Power (CHP) plant is still under active consideration and provision has been made for a future gas supply.

10.4.2 Processing Equipment

The wet processing operations in the chemical synthesis buildings at Lilly produce solvent vapours and inorganic vapours. Control of these emissions is a multi-stage process. Most reactors and stills are equipped with dedicated condensers for the return of condensed solvent vapour to the vessel. Most condensers can operate at -17°C . Off-gases from process vessels are directed through the condensers. From the condensers, the off-gases are sent to appropriate scrubbers, in which any acid or alkaline gases are neutralised, and then are routed to a regenerative thermal oxidiser. Other off-gases are sent directly to the regenerative thermal oxidiser.

10.4.3 Regenerative Thermal Oxidiser

Process and scrubber off-gases, ducted from the production buildings, are routed to the regenerative thermal oxidiser. A second regenerative thermal oxidiser is available as a back-up. A process flow diagram of the regenerative thermal oxidiser system is presented in **Figure 10.2**.

Continuous monitoring of Volatile Organic Compounds (VOCs) and hydrogen chloride is carried out on the exhaust gases emanating from the regenerative thermal oxidiser and caustic soda scrubber system prior to entering the stack. In addition periodic monitoring is carried out for sulphur dioxide, nitrogen oxides, dioxins, hydrogen fluoride and hydrogen bromide. The site continues to maintain a full compliance record to the IPPC limits for the regenerative thermal oxidiser.

10.4.4 Waste Incinerator

In accordance with the site's philosophy, Lilly has a policy of treating the waste streams it generates onsite and where possible utilising the waste management

hierarchy of waste avoidance, reduction and recovery and finally treatment. The site only processes waste generated on its own site. As described in section 12.2.5, solvent wastes generated by production processes are treated in a waste incinerator, manufactured by John Zink. The John Zink incinerator and regenerative thermal oxidiser discharge through one stack. A Process flow diagram of the John Zinc is presented in **Figure 10.3**.

Continuous monitoring of carbon monoxide, total organic carbon, hydrogen chloride, particulate and sulphur dioxide levels is carried out on the exhaust gases of the incinerator as required by the IPPC licence. The monitoring is undertaken prior to the gases entering the stack. The unit is also monitored periodically, as required by the IPPC licence for hydrogen fluoride, hydrogen bromide, dioxins and heavy metals.

The site maintains an excellent compliance record to the relevant IPPC limits.

Refractory waste from the incinerator is sent off site to controlled and approved landfill sites. Liquid waste generated in the incinerator is treated on site, as described in Chapter 11, *Effluent Generation and Treatment*.

10.4.5 Boilers

At present, steam is generated on the site by means of three fire-tube boilers located in IE4. Two of these are completely new units and all three units have had the burners replaced with state of the art systems. The boilers each have a nominal capacity of 9 tonnes. Normal demand is met by running two boilers simultaneously, with the third boiler on standby. The boilers run on natural gas. The emission generated is primarily carbon dioxide. The boilers exhaust to atmosphere through a single stack which is a licensed emission point. There is adequate steam generating capacity on site for the new IE43 facility.

10.4.6 Carbon Absorbers

The site has licensed emission points for two carbon absorbers. These licensed emission points remain as licensed vents in the event that they may be needed in the future. Carbon absorbers were used in the past as part of a recovery process for solvents.

10.4.7 Dust Emissions

The site has 16 licensed dust emission points. The IPPC licence emission limit value for these emission points is $0.1\text{mg}/\text{m}^3$ particulates, as active ingredient.

Dust emissions can arise on site from activities such as bagging, dry end production, raw materials handling, milling and sieving. Filters are provided at many points that have the potential to release pharmaceutical dusts. These comprise pre-filters, in the form of bag filters, combined with high efficiency particulate air filters, which act as a secondary filtering source removing 99.97% of dust. Typically pre-filters and secondary filters are installed in series. For areas with a low dust potential, pre-filters are used. The air handling units have panel filters as a pre-filter combined with bag filters. Usually a number of panel and bag filters are installed in series. Glovebag (bag over bag) technology is also used

within the production areas where high levels of containment are required to protect the operators from contact with product.

10.4.8 Fugitive Emissions

Each process building is provided with a ventilation system designed to ensure a specified number of air changes per hour and to ensure a safe operating environment for the operators in the building. Minor drips of solvent can lead to solvent vapours in the process area, which are extracted by the ventilation system and discharged to atmosphere. Sources of fugitive emissions include equipment such as regenerative thermal oxidiser duct trips, spills, rupture disk releases, building ventilation fans, solvent storage breathing losses, leaks from valves and pumps, cleaning operations and emissions from waste water treatment. Due to the low amounts of solvents and high air volumes it is impractical to purify this airflow. A number of measures are taken to minimise fugitive emissions both within and outside the process buildings.

Gaseous emissions to the atmosphere including fugitive emissions have reduced considerably over the past years as the solvent usage has decreased significantly. The emphasis is to eliminate or reduce emissions at source, i.e. repair of leaks, purchase of high specification equipment, etc. The abatement equipment includes condensers, vapour scrubbing devices, vapour capture and incineration. Fugitive emissions are managed under the Environmental Management Programme (EMP) as agreed with the EPA and reviewed on an ongoing basis.

10.4.9 Total Monitored Emissions

A summary of the total emissions to atmosphere, monitored on site in 2010 is presented in **Table 10.3**. The total mass emissions to atmosphere from the site in 2010 were well within the licensed mass emission limits.

Table 10.3 Summary of Emissions to Atmosphere (AER, 2010)

Emissions to air				
Parameter	Unit	Max. Licensed Emission per year	2009 Mass Emission	2010 Mass Emission
Total Particulates	Kg/yr	2,565	177.5	152
VOC	Kg/yr	2,565	42.9	30
Hydrogen Chloride	Kg/yr	2,565	9.9	16
Hydrogen Fluoride	Kg/yr	257	0.9	0.8
Hydrogen Bromide	Kg/yr	513	0.9	0.8
Sulphur Dioxide	Kg/yr	295,109	59,369	103,419
Dioxin (TEQ)	Kg/yr	6.39×10^{-5}	1.451×10^{-6}	6.663×10^{-7}
Cadmium & Thallium	Kg/yr	13	0.07	0.02
Mercury	Kg/yr	13	0.07	0.10
Antimony, Arsenic, Lead, Chromium, Cobalt, Copper, Manganese, Nickel, Vanadium	Kg/yr	128	1.25	0.43
Carbon Monoxide	Kg/yr	12,827	123	36

Emissions to air				
Parameter	Unit	Max. Licensed Emission per year	2009 Mass Emission	2010 Mass Emission
TA Luft Organics Class I	Kg/yr	7,647	204	578
TA Luft Organics Class II	Kg/yr	38,237	343	1,635
TA Luft Organics Class III	Kg/yr	57,356	2,451	3,375
TA Luft Inorganics Class II	Kg/yr	1,912	2	3
TA Luft Inorganics Class III	Kg/yr	11,471	7	46
Nitrogen Oxides (as NO ₂)	Kg/yr	219,066	48,054	58,369
% Compliance	%		100	100

Source: Annual Environmental Report, 2010

10.4.10 Odour Emissions

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 this plant.

10.5 Identification of Potential Impacts from IE43

10.5.1 Construction Impacts

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 significant 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.

Air emissions from the exhausts of the construction plant and machinery and haulage trucks will be mainly nitrogen oxides and particulate emissions from the diesel engine exhausts.

10.5.2 Construction Traffic Methodology

The UK Highways Agency Design Manual for Roads and Bridges (DMRB, 2007) states that if daily traffic flows change by less than 1,000 annual average daily traffic (AADT) or Heavy Duty Vehicle flows change by less than 200 AADT then the impact on air quality can be considered neutral.

As the predicted change in traffic volumes for the construction phase is less than the DMRB criteria, no significant impact on air quality is envisaged.

10.5.3 Operational Impacts

The products, which will be manufactured in IE43 biotech manufacturing facility will be aqueous based and will not contribute to any significant increase in air emissions.

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. Solid wastes will be treated in the incinerator. 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 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 discharged to the wastewater treatment plant along with other liquid wastes from the facility. The process air emissions from the building will be classified as minor emission points and will be discharged directly to atmosphere.

Lilly have discussed the IE43 project with the EPA and the EPA has confirmed that the current IPPC licence will not need to be reviewed. The limits on emission to air from the plant, set out in the IPPC Licence will continue to be met when this facility is commissioned. The site Genetically Modified Microorganisms Register will have to be updated with an addendum to include the IE43 facility.

It is not envisaged that the proposed IE43 facility will result in the generation of odours.

As a consequence of the IE43 biotech manufacturing facility, the number of service vehicle trips will increase by one to two trucks per week. The resulting increase in traffic is not expected to result in significant increase in emissions to air.

10.6 Proposed Mitigation Measures

10.6.1 IE43 Operational Phase

Air emissions from the IE43 biotech manufacturing facility will be filtered as appropriate and will be discharged directly to atmosphere. There will be no further abatement required.

10.6.2 Construction Activities

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.

- Topsoil and other 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 details of dust mitigation measures.

10.6.3 Odours

No mitigating measures are deemed necessary as the generation of odours on site is not expected.

10.7 Residual Impacts

If the mitigation measures outlined above are implemented, the effect of construction on air quality will not be significant. No residual operational impacts are envisaged.

10.8 Micro Climate

10.8.1 Receiving Environment

The site is located in Dunderrow, Kinsale, Co. Cork, in a rural area. The environs are largely agricultural land with residential development.

10.8.2 Temperature

According to Met Éireann, the mean daily air temperature in Cork Airport (the nearest meteorological station to the proposed site) is 7.6°C in January and 11.1°C in July, a year-round average of about 9.4°C.

10.8.3 Rainfall

According to Met Éireann, the mean annual rainfall is about 1200mm, and on 151 days in the year the rainfall is more than 1mm.

10.8.4 Wind

According to Met Éireann, the mean annual wind speed for the Cork area is 11.1 knots. The prevailing wind comes from the southwest and west. Winds from the north and east are less frequent.

10.8.5 Sunshine

According to Met Éireann, the mean daily duration of sunshine amounts to about 3.8 hours.

10.8.6 Characteristics of the Proposal

The parameters of the proposed development of relevance to local climate or microclimate are size of the building and heat losses.

The proposed IE43 biotech manufacturing facility is a split level building with heights ranging from 9m to 30m. The ground floor area of the proposed new building will be approximately 9,120m².

10.8.7 Potential Impact of the Proposal

The effects of structures on the climate in their area (known as the microclimate) can be considered under three headings:

- modification of atmospheric composition,
- modification of heat balance, and
- modification of surface roughness and composition.

10.8.8 Modification of Atmospheric Composition

The scale of the development together with the type of operation is such that it is extremely unlikely that the emissions could result in the formation of photochemical smog.

10.8.9 Modification of Heat Balance

Large groups of buildings and paving, such as are found in an urban area, can have an impact on heat balance, and hence on micro-climate, due to:

- changes in thermal radiation balance due to changes in atmospheric composition,
- changes in thermal balance due to albedo (the ratio of the energy received to the energy given up), heat conductivity and thermal capacity of urban surface materials, and
- the production of heat by human activities - increased heat generation from the waste heat from heating systems, and heat lost through the thermal fabric of buildings.

The net effect of these thermal processes is to make city temperatures generally higher than those in surrounding rural areas. For example, Met Éireann data show that the outdoor temperature in the inner Dublin area is some 1 - 1.5°C higher than in County Dublin. This is mainly due to the turbulent diffusion of sensible heat from warm buildings and the absorption of long wave radiation emitted by the city surface and its pollution blanket. This is known as the 'heat island' effect, and can, in extreme cases, raise city temperatures by as much as 6 - 8°C in the early hours of calm, clear nights in large cities.

However, the scale of the existing buildings on the Lilly site and of the IE43 building is such that no measurable impact on the heat balance in the area will occur.

10.8.10 Modification of Surface Roughness and Composition

Modifications of surface roughness and composition can be considered with respect to airflow and moisture.

10.8.11 Airflow

Urban structures can have considerable effects on the movement of air, both by producing turbulence as a result of their roughening of the surface, and by the channelling effects of the urban canyons. However, the height and mass of the proposed IE43 building is relatively insignificant, and there is no significant potential for funnelling, because of the layout. It is not expected that the IE43 project will have any detectable influence on the area beyond the site boundary in terms of exaggerating local wind conditions.

10.8.12 Moisture

The rapid removal of surface water run-off through drains reduces local evaporation. However, due to the relatively small area of the development site, there will be only a small reduction in evaporation.

10.8.13 Mitigation Measures

Because of the low impact on the micro climate, mitigation measures will not be required.

10.8.14 Residual Impact

No significant residual impacts are envisaged with respect to the micro climate.

10.9 Global Climate

Carbon dioxide, a greenhouse gas, will be emitted by the fuel burning equipment on site, such as the boilers and other heating appliances, the thermal oxidiser and the incinerator. The emissions are minimised by the conservation of energy use on site. The installation of a heat recovery boiler as part of the upgrade of the John Zink has led to more fuel-efficient generation of steam on site and helped reduce the consumption of fossil fuels.

Lilly has a Greenhouse Gas Emissions Permit, number GHG023-3. The EPA has given Lilly the following allocation for emissions of carbon dioxide:

Year	Allocation (tonnes CO ₂)
2008 - 2012	12,877

The site emission of CO₂ for 2010 was 16,549 tonnes somewhat over the allowance. This was largely due to the increased production activities on site. It is

anticipated that at the end of the current phase in 2012, the emissions will be only slightly, if at all, over the allocation. Significant reductions in CO₂ emissions from the site are expected in 2011 and 2012 due to the use of natural gas. The carbon dioxide emissions from the entire site represent approximately 0.018% of the emissions of carbon dioxide equivalent for Ireland in 2009. The latest estimate by the EPA is that Ireland's emissions were 62.32million tonnes carbon dioxide equivalent in 2009. The estimated emissions from the plant following the commissioning of IE43 biotech manufacturing facility will be within the allocation provided by the EPA. Therefore, the emissions from the Lilly plant with the IE 43 facility operational are not expected to have a significant effect on the global climate.

10.10 References

Air Quality Standards Regulations 2011 (S.I. No. 180 of 2011), Government Publications, Dublin, Ireland.

Environmental Protection Agency (2010) Air Quality Monitoring Annual Report 2009 Environmental Protection Agency, Wexford

Environmental Protection Agency (2010) Ireland's Emissions Of Greenhouse Gases in 2009, EPA October 2010

Irish Meteorological Service Online www.mets.ie

Lilly (2010) *Annual Environmental Report*

Official Journal of the European Communities Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste

Official Journal of the European Communities Directive 96/61/EC of 24 September 1996 concerning Integrated Pollution Prevention and Control

UK Highways Agency, 2007 *Design Manual for Roads and Bridges (DMRB)*, Highways Agency, London, UK.

11 Effluent Generation and Treatment

11.1 Introduction

This chapter of the EIS details the effluent and effluent management systems which will be generated and utilised by the new IE43 facility. The section also details the capacity of the system and its regulatory status. The impact of the emissions of treated effluent on the receiving waters is also addressed. The site has considerable effluent treatment capacity available for the project which is compliant with EU and National requirements.

11.2 Overview

Because the Lilly site has been subject to IPPC 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 IE43 project falls within the same category of licensable activity under Integrated Pollution Prevention and Control (IPPC) licensing, and can be accommodated within the scope of the current IPPC licence (Ref. P0009-003).

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 – IPPC Bureau in Seville, Spain, and the relevant Irish BAT Guidance Note.

This project is also required to comply with the relevant effluent pre-treatment requirements for thermal or chemical inactivation of biotic material appropriate to a Class 1 activity under the GMM Regulations.

There is already sufficient organic and hydraulic treatment capacity available in the Lilly plant to accommodate the project and to ensure that the effluents 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 effluents which may be characterised as:

- Process wastewater – arising directly and indirectly from manufacturing
- Utility wastewater
- Sanitary wastewater
- Surface water
- Incinerator quench water

11.3.1.1 Process Wastewater (Direct)

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) 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 effluent load arising from the process.

11.3.1.2 Aqueous Effluent (Indirect)

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 solvents. Laboratory wastewater is included also in this category.

Rainwater run-off, which is potentially at risk of contamination by process or utility materials, is also directed to the effluent system rather than the surface water system.

Only effluents proven to be biodegradable are directed to the waste water treatment plant as described in section 11.3.2.

11.3.1.3 Utilities

The utilities include 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.

11.3.1.4 Sanitary

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 effluent is discharged directly to the aeration tanks. The micronutrient content is of benefit to the treatment of the process effluents. This effluent is collected in the sanitary sump, T6, and is pumped directly to the aeration basins.

11.3.1.5 Surface Water

The existing and proposed surface water drainage systems are described in Chapter 14 of this EIS.

11.3.1.6 Incinerator quench water

The site's incinerator and thermal oxidisers generate scrubber waters and quench waters, which are made up from utility, groundwater and mains water intake. These quenches typically contain inorganic salts but no organic load.

11.3.2 Process Wastewater Source Segregation

Process and utility effluents 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 (solvent content normally greater than 80% or primary mother liquors).
- Secondary (solvent content between 80 – 20%).
- Aqueous (solvent content less than 20%).

This initial classification is used primarily to determine the most likely processing route, which might be followed.

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 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.

Subject to compliance with the waste acceptance criteria, aqueous wastewater from processes and utilities is currently treated on-site in a purpose designed biological wastewater treatment plant. The operation of the biological treatment plant is described in Sections 11.4.2 and 11.4.3 below.

The quench water from the incinerators is treated in an inorganic wastewater treatment plant. Refer to **Figure 11.3**.

11.3.3 Effluent 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 of final effluent is not impaired.

This screening and assessment procedure optimises the use and reuse of resources, water and energy in particular.

The process schematics and process flow diagrams are shown in **Figures 11.1a** and **11.1b**.

As will be seen from the description of the biological wastewater treatment plant in section 11.4.3 below, the plant has an inherent capacity and flexibility to handle a wide variety of hydraulic and organic effluent 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 48% 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.

11.3.4 Aqueous Wastewater Hydraulic and Organic Load

The individual contribution, which each site activity makes to the total volume of 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.

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		646	320

Note 1: estimate

At present the biological 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 IE43 Facility

The project will generate direct process effluent primarily from highly biodegradable growth media for mammalian cells and from waste from purification operations (which contains mainly inorganic chromatography buffers) materials. The main effluents will be accompanied by cleaning solutions using acidic, caustic and degradable detergents.

The utility waste water from IE43 can be accommodated in the existing water management systems associated with IE30 and 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.

The indirect aqueous streams from IE 43 will contain clean-in-place (CIP) solutions and the chromatography waste which comprises the bulk of the organic load. The main constituents of the aqueous waste 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 IE43 expansion as proposed will add a maximum of 164m³/day of aqueous wastewater at peak production.

Table 11.2 Constituents of Aqueous Waste Stream

	Process Waste Grams/Lot	mg/L	Cleaning Waste Grams/Lot	Total mg/L	Total kgs per lot	Average kgs/day	Worst Case/day
Total dissolved solids	4654950	19732.9	0	6.3	4655	1037	1266
Total suspended solids	19549	82.9	0	0.0	20	4	5
Total solids	4674499	19815.8	0	6.3	4674	1042	1271
Ash	2511475	10646.5	0	3.4	2511	560	683
Chemical Oxygen Demand (COD:mg O ₂ /L)	3014596	12779.3	0	4.1	3015	672	820
Total Kjeldahl Nitrogen (TKN:mg/L)	130328	552.5	0	0.2	130	29	35
Ammonia Nitrogen (NH ₃ -N: mg/L)	131746	558.5	0	0.2	132	29	36
Phosphorous-ortho	31030	131.5	5511	0.0	37	8	10
Chloride	1050463	4453.1	0	1.4	1050	234	286
Sulfate	514507	2181.1	0	0.7	515	115	140
Sodium	998952	4234.7	0	1.4	999	223	272
Potassium	3836	16.2	11637	0.0	15	3	4

Litres

Process Waste Volume/lot	235900
Cleaning Volume/lot	501300
Total Aqueous Waste Volume/lot	737200
Average Aqueous Waste/day	164300
Worst Case Aqueous Waste/day	200500

The above rates are plant generation rates. The effluent will be routed to the IE43 aqueous waste tank and pumped out to the wastewater treatment plant at an average rate of 350 litres per minute. The direct process wastewater from the IE43 facility, or biowaste as it is called, will have similar characteristics to that arising currently in IE42 in that the growth media and chromatography elution materials are essentially compatible with mammalian cells, are highly biodegradable and

are akin to domestic effluent. The IE43 expansion as proposed will add a maximum of 6m³/day of biowaste at peak production. The main constituents of the biowaste stream are shown below in **Table 11.3**.

Table 11.3 Constituents of (Direct) Biowaste Stream

	Grams per Lot	mg/L	Total kgs per lot	Average kgs/day	Worst Case kg/day
Total dissolved solids	37290	1530.8	37.3	8.3	21.4
Total suspended solids	42576	1747.8	42.6	9.5	24.5
Total solids	79867	3278.6	79.9	17.8	45.9
Ash	10051	412.6	10.1	2.2	5.8
Chemical Oxygen Demand (COD:mg O ₂ /L)	88400	3628.9	88.4	19.7	50.8
Total Kjeldahl Nitrogen (TKN:mg/L)	7332	301	7.3	1.6	4.2
Ammonia Nitrogen (NH ₃ -N: mg/L)	3642	149.5	3.6	0.8	2.1
Phosphorous-ortho	850	34.9	0.9	0.2	0.5
Chloride	1810	74.3	1.8	0.4	1.0
Sulfate	884	36.3	0.9	0.2	0.5
Sodium	1060	43.5	1.1	0.2	0.6
Potassium	1155	47.4	1.2	0.3	0.7

Litres

Biowaste Volume/lot	24360
Average biowaste volume/day	5430
Worst Case biowaste/day	14000

The above rates are plant generation rates. These will be routed to the IE43 biowaste tank and pumped out to the wastewater treatment plant at average rate of 100 litres per minute. The IE43 effluent which will be similar to the existing effluent streams from IE42 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 effluent mix. The addition of the proposed IE43 plant will be accommodated without causing any net increase in organic effluent emissions from that already licensed.

When the IE43 facility is operational, the combined loads from the site will still only utilise 19.8% of the installed organic load capacity of the plant and 77% of the hydraulic capacity.

11.5 Wastewater Treatment Plant

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 effluents.

These include:

- Inorganic effluent treatment.
- Biological effluent treatment - activated sludge with air stripping, aerosol and off-gas management.
- On-site biosolids dewatering and incineration.
- Solids / process metal recovery.

These give a great degree of flexibility and modular response for a multi product organic synthesis site.

11.5.2 Biological Wastewater Treatment Plant 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 270m³ /day containing 476 kg COD. The plant can conservatively cater for the anticipated expanded load of 460m³ /day containing up to 646 kg/COD /day when all current projects are commissioned. The existing items of plant can be configured to provide treatment for up to 600m³/day containing up to 3,263 kg COD.

Therefore, the current loads only utilise approximately 14.6% of total available biological capacity and this uptake will only increase to 77% hydraulic capacity and 19.8% organic capacity when the IE43 project is operating at peak capacity.

In addition to the process effluents, a small but beneficial sanitary waste component is added from the sanitary sump directly to the aeration basins. This currently contributes approximately 75 m³ /day containing 26 kg COD and is designed for twice that load and a maximum input of up to 24 m³ / hour. The domestic waste provides micronutrients not available in the pure process effluents but which will now be enhanced by the addition of the IE43 effluent.

11.5.3 Biological Treatment Plant Process Configuration

Figure 11.2 is a process flow schematic showing the current equipment trains and capabilities of the biological treatment plant. The biological treatment plant is described below.

11.5.3.1 Equalisation, pH Correction and Emergency Dump Tank Capacity

TK -14 is the balancing / pH correction system. This has a working volume of 1200m³, which provides >5 days hydraulic balancing at present and will still provide >2 days balancing when the current expansion projects have been completed. This is a very conservative position as 24 hour balancing is more than adequate. Emergency dump tank capacity is also provided for off line diversion of unsuitable materials or excess loads. pH correction to between 6.5 - 8.5 as registered in the aeration basins is the normal objective. Correction in both directions is undertaken by addition of 96% Sulphuric acid or 25% caustic.

11.5.3.2 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 2,300m³ of available aeration volume. The tank configuration are 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.

11.5.3.3 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.

11.5.3.4 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 3263 kg COD /day and at a modest increase in efficiency would increase to 4000 kg COD /day. With the aeration system operating at an MLSS concentration of 6000 mg/l and a COD F/M ratio of 0.3 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.

11.5.3.5 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 only 50% 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.

11.5.3.6 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.

11.5.3.7 Final Biological Treatment Plant Effluent Discharge

The effluent 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 biopant 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 quench system, which has been through the cooling ponds.

The discharge is provided with flow measurement and flow proportional composite sampling prior to discharge.

11.5.3.8 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 effluent. This maintains a healthy sludge population, and greatly aids the treatment process.

11.5.3.9 Summary of Biological Treatment Capacity

The treatment capacity of the biological treatment plant is summarised in **Table 11.4**.

Table 11.4 Summary of Biological Treatment Capacity

Type:	Activated Sludge
Aeration Tank Capacity:	2300 m ³
Average Daily Operation Capacity:	600m ³ /day
Licensed Flow:	3000 m ³ /day 125 m ³ /hour
Average BOD	1600kg/day
Average COD	3263 kg/day
Capacity Uptake Projected	19.8% organically 77% hydraulically
% Removal Efficiency:	> 98 % BOD Removal > 93 % COD Removal

11.5.4 Cooling Ponds (with prior Filtration)

The clarified or filtered effluent 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 effluent and discharged to the Sandy Cove outfall.

11.5.5 Process Control

Process control for both treatment plants is achieved using the plant wide Fox I/A Distributed Control System. This means that the effluent plant is an integral part of the process reporting and control on site.

11.5.6 IPPC Effluent Emission Requirements and Compliance

The monitoring point for the discharge from the biological treatment plant is designated emission point 6-1 in the IPPC licence. The licensed limits for 6-1 are shown in **Table 11.5** and are the relevant compliance limits pertaining to the wastewater treatment plant emission once IE43 facility is operational. A technical amendment to the IPPC licence will be sought from the EPA which will require control of the biowaste stream from the IE43 facility by means of a thermal inactivation step (the biowaste wastewater will be subject to a heat inactivation step which inactivates any potential living cellular material as a precaution prior to biological treatment).

Table 11.5 IPPC Licence Emission Limit Values for the Discharge from the Biological Treatment Plant under Licence Ref. P0009-003

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	600
COD	1500
Suspended solids	500
Total Nitrogen	100
Total Ammonia (as N)	50
Total Phosphorous (as P)	100
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.

11.6 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.

11.6.1 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 offgas 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.

11.7 Compliance with Regulatory Requirements

The site is fully compliant with the requirement under the Protection of the Environment Act 2003, for existing plants, which operate under IPPC licences, to implement Best Available Techniques (BAT) in the treatment of emissions. This means that the element of the treatment process utilised by the IE43 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.

11.7.1 BAT Status of the Effluent Treatment Plant

In the case of effluent 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 effluent 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 effluent treatment system and procedures comprising:

- effluent screening criteria and upfront pretreatment,
- scale of operation,
- osmotic and pH stability,
- support analytical capability,
- physiochemical pretreatment,
- 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 active pharmaceutical ingredient 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 effluent will increase the ratio of highly biodegradable effluent and will further enhance the stability of the effluent treatment process.

11.8 Storm Water Management

Storm water management is addressed in Section 14.3.

11.9 Residual Impact of Effluent on Receiving Waters

Treated effluent is discharged through a pipeline to a diffuser about 500 m offshore near Sandy Cove Island in the outer Kinsale harbour. Refer to **Figure 11.4**. 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 biologically treated effluent discharged is circa 9% of the licence limit. This will rise to approximately 15% when IE 43 is fully operational.

Effluent dispersion at the outfall location provides a dilution factor of approximately 100,000 as determined by the most recent dye dispersion tests.

The licence requirement is for a dilution factor of 30. The measured dispersion capability is mainly generated through wave and tidal action.

In terms of organic and other parameter assimilative capacity, this level of dilution in the mixing zone would mean that a conservative organic assimilative capacity of approximately 300,000kg BOD /day is theoretically available at a permitted background rise of 1.0mg/L BOD.

Essentially this means that the discharged treated effluent would only take up approximately 5kg /day BOD which would be 0.3 % of the permitted load and 0.002% of the available assimilative capacity at the discharge point.

This post treated residual load would not be detectable in the receiving environment and the change in receiving water concentration would be below the detection limit of the test. The same applies to the other parameters and as a result the discharged effluent is not expected to have any effect on achieving the objectives of the 2009 Surface Water Regulations.

The analyses, toxicity testing, treatment performance indicates potential to impact the receiving environment. This has been consistently borne out by routine biotic monitoring.

Ongoing monitoring has 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 introduction of the IE43 project.

11.10 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

Lilly (2010) Annual Environmental Report

Environmental Protection Agency *Lilly IPPC licence (Ref. P0009-003)*

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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 IE43 Biotech Manufacturing Facility and assesses the likely impact of the waste generated.

Lilly has a well-developed 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 Characterisation of Wastes and their fate for the Existing Facility

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 Annual Environmental Report. Wastes generated at Lilly are categorized as either hazardous or non-hazardous for disposal, in accordance with the EU European Waste Codes and the Basel Convention. Lilly undertakes monitoring of certain wastes, as required by *Schedule C.4 Waste Monitoring* of the IPPC licence.

12.2.1 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
- 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 2010.

12.2.2 Non-Hazardous Waste

Non-hazardous wastes generated on site include the following:

- general refuse, 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 2010. Lilly actively pursues means of reuse, recovery and recycling throughout the facility. The 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 treatments 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.

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Table 12.1 Hazardous Waste Management in 2010

Waste material	EWC Code	Main source	Quantity Tonnes	Further treatment	Recovery, reuse recycling	Final disposal
Aqueous washing liquids and mother liquors	07 05 01	Production	4.0	Incineration in Germany	Energy recovery	Ash from incineration land-filled
Organic halogenated solvents washing liquids and mother liquor	07 05 03	Production	117.5	Incineration in Denmark & Germany	Energy recovery	Ash from incineration land-filled
Organic halogenated solvents washing liquids and mother liquor	07 05 03	Production	83.1	Incineration on site	Energy recovery	Ash from incineration land-filled
Other organic solvents washing liquids and mother liquor	07 05 04	Production	32.4	Incineration in Belgium, Germany & UK	Energy recovery	Ash from incineration land-filled
Other organic solvents washing liquids and mother liquor	07 05 04	Production	9,298.5	Incineration on site	Energy recovery	
Other organic solvents washing liquids and mother liquor	07 05 04	Production	314.7		Reclamation	
Other filter cakes and spent absorbents	07 05 10	Production	58.2	Recycling in Holland and Belgium	Recycling	
Solid wastes containing dangerous substance	07 05 13	Production	143.4	Incineration in Belgium & Germany	Energy recovery	Ash from incineration land-filled
Packaging wastes containing residues of or contaminated with dangerous substance	15 01 10	Production	29.0	Incineration in Germany	Energy recovery	Ash from incineration land-filled
Packaging wastes containing residues of or contaminated with dangerous substance	15 01 10	Production	10.5	Metal recycling in Ireland	Recovery of metal	
Linings and refractories from non-metallurgical processes containing dangerous substances	16 11 05	Production and maintenance	5.9	Incineration in Germany	Energy recovery	Ash from incineration land-filled

Waste material	EWC Code	Main source	Quantity Tonnes	Further treatment	Recovery, reuse recycling	Final disposal
Alkalines	20 01 15	Production	0.1	Incineration in Germany	Energy recovery	Ash from incineration land-filled
Acids	20 01 14	Production	0.02	Incineration in Germany	Energy recovery	Ash from incineration land-filled
Absorbents, filter material contaminated by dangerous substance	15 02 02	Production	6.3	Incineration in Belgium & Germany	Energy recovery	Ash from incineration land-filled
Spent catalysts contaminated with dangerous substance	16 08 07	Production	31.8	Recovery of catalyst components in UK	Recovery	
Paints and resins containing dangerous substance	21 01 27	All areas	1.0	Incineration in Germany	Energy recovery	Ash from incineration land-filled
Discarded electric and electronic equipment containing dangerous components	20 01 35	All areas	0.2	Metal recycling in Ireland	Recycling	
Lead Batteries	16 06 01	All areas	1.1		Recovery	
Fluorescent tubes	20 01 21	All areas	1.1	Recovery in Ireland	Recovery	
Waste oil	13 01 11	Maintenance	2.7		Recovery	
Fuel oil and diesel	13 07 01	Maintenance	0.5	Incineration in Germany	Energy Recovery	

Table 12.2 Non-Hazardous Waste Management in 2010

Waste material	EWC Code	Main source	Quantity Tonnes	Further treatment	Recovery, reuse recycling	Final disposal
Mixed municipal waste	20 03 01	All areas	58.5			landfill
Mixed municipal waste	20 03 01	All areas	39.0		Recycling	
Biodegradable kitchen and canteen waste	20 01 08	Canteen	1.7		Recycling	
Spent activated carbon	19 09 04		0.8		Recycling	
Saturated or spent ion exchange resins	19 09 05		6.2	Recycling in Belgium	Recycling	
Bulky waste	20 03 07		136.5			landfill
Bulky waste	20 03 07		15.2		Recycling	
Mixture of concrete, bricks, tiles and ceramics	17 01 07	Construction on site	895.7		Recycling	
Wooden pallets	15 01 03	All areas	113.8		Recycling	
Paper and cardboard	20 01 01	General office waste	56.3		Recycling	
Metals	20 01 40	Construction on site	176.3		Recovery	
Organic sludge	07 05 12	Effluent treatment plant	211.5		Recycling	
Waste printing toner	08 03 18	Offices and laboratories	0.2		Recycling	
Glass	20 01 02	All areas	3.1		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	

Waste material	EWC Code	Main source	Quantity Tonnes	Further treatment	Recovery, reuse recycling	Final disposal
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	
Alkaline batteries	16 06 04	All areas	0.3		Recycling	

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12.2.3 Solvent Waste Management

Solvent wastes and wastes containing solvents are produced on site in significantly greater quantities than any other waste. 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 waste water treatment plant on site.

12.2.4 Incineration on Site

Solvent wastes for disposal on site are categorised as primary and secondary wastes as indicated in **Table 12.3**.

Primary wastes typically have a high calorific value and can be used to fuel the incinerators.

The on-site incinerator is used to treat solvent wastes generated by production processes. The John Zink unit is used for liquid wastes only. Both primary and secondary wastes are treated in the John Zink 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 annual throughput capacity of the John Zink incinerator is circa 5.7 million litres of primary waste and 8.2 million litres of secondary waste, with the current product mix and depending on the calorific value.

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%< <80%	Incineration	low calorific value
Aqueous wastes	<20%	wastewater treatment plant, subject to treatability, API content; otherwise incineration	very low calorific value

12.2.5 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.

12.2.6 Off-site Waste Contractors

Lilly uses only contractors with the necessary permits and / or licenses 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 Solid Waste Management in IE43

12.3.1 Introduction

The solid waste material from IE43 will either be incinerated off-site or recycled where suitable. 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 are discussed below in Section 12.3.2.

12.3.2 Process Solid Wastes

The solid waste generated by production processes in the IE43 biotech manufacturing facility can be linked to the following functions:

12.3.2.1 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.

12.3.2.2 Cell Culture and Primary Recovery (or harvest)

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, autoclaved and drummed. These items will have come in contact with cells and the purpose of the autoclaving is to de-activate any cell material. It is likely that this solid waste will be incinerated.

12.3.2.3 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, such as the buffer solution bags, may be considered for recycling after a washing step. It is likely that the solid waste such as product solution bags, which has been in contact with product solution, will be incinerated.

This packaging solid waste from IE43 when the plant is fully operational is estimated to amount to circa 30 tonnes per annum, when the plant is fully up and running, of which it may be feasible to recycle circa 6 tonnes per annum.

12.3.3 Other Wastes

There will also be general wastes from offices and break areas in IE43, which will typically include paper, cardboard, plastics, ink cartridges and general refuse.

12.4 Waste Minimisation throughout the Site

12.4.1 Main Objectives

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.

12.4.2 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 10 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.

12.4.3 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.

12.4.4 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 incinerator.
- Upgrading of the wastewater treatment plant.
- Membrane filtration capability to remove active ingredients from process waste streams.

12.5 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 solid wastes arising from the operation of this plant which will be mainly packaging type materials.

12.6 References

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

United Nations Environment Program (1989) *Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal Secretariat of the Basel Convention, Geneva.*

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13 Flora and Fauna

13.1 Introduction

Dixon.Brosnan Environmental Consultants prepared this chapter as part of an Environmental Impact Statement for the construction and operation of a new biotechnology manufacturing facility, to be known as IE43 within the existing site boundary of the Lilly bulk pharmaceutical manufacturing plant, located at Dunderrow, Kinsale, Co. Cork. Details on the proposed development are given in Chapters 1 *Introduction* and 3 *Site and Scheme Description* of this EIS.

This chapter describes and evaluates the habitats with their associated flora and fauna in order to describe and assess the impacts that would result from the proposed development. The chapter follows the structure and protocols detailed in *Advice notes on current practice in the preparation of Environmental Impact Statements* (EPA, 2003) and *Guidelines on the information to be contained in Environmental Impact Statements* (EPA, 2002). The classification scheme used in the NRA publication *Guidelines for assessment of ecological impacts of National Road Schemes* (NRA, 2006) was also used in this report. Refer to **Appendix A13.1**.

13.2 Methodology

13.2.1 Introduction

This flora and fauna impact assessment is based on previous desktop studies carried out by Fehily Timoney in 2003 and by DixonBrosnan in 2004. Recent surveys of the site were carried out in May, June, July and August 2011 by Dixon.Brosnan Environmental Consultants. Reports on previous studies and surveys are provided in **Appendix A13.2**.

In 2011, habitats on site 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 *Draft Habitat Survey Guidelines: a Standard Methodology for Habitat Survey and Mapping in Ireland* (Heritage Council, 2002). In broad terms, the habitat map is based on the methodology outlined in the British JNCC publication (1993) on Phase 1 habitat surveys. It should be noted that some of the habitats are transitional and where this occurs they were placed in the category they most resemble. A habitat map summarising the results of habitat surveys above is shown in **Figure 13.1**. The classification scheme used to define impacts is based on a classification scheme used by the National Roads Authority (NRA) *Guidelines for the assessment of ecological impacts of National Road Schemes* (NRA, 2006a). This is detailed in **Appendix A13.1**. Surveys for fauna were carried out in conjunction with habitat mapping surveys.

13.3 Existing Environment

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 Ballyvryn 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 Inishannon. The N71 national secondary route passes through Inishannon and Bandon to the north of Dunderrow. A stream flows in an approximate northeast-southwest direction through the Lilly 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. The proposed IE43 biotech manufacturing facility will be located at eastern end of the Lilly site as shown on **Figure 3.2**.

13.3.1 Designated Sites

The Lilly site does not form part of, nor is it in the vicinity of any Special Area of Conservation (SAC), Natural Heritage Area (NHA) or Special Protection Area (SPA). There are seven proposed designated areas within 10km of the site. The nearest of these, 'Bandon Valley below Inishannon pNHA', site code 1515 is 3km to the west of the Lilly site. As this pNHA is located a considerable distance from the proposed development site and up-gradient on the main channel of the Bandon River, no impact on this designated site is envisaged.

A Natura Impact Statement Stage 1 Screening report (**Appendix A13.3**) was prepared to determine the likely impact on Special Areas of Conservation (SACs) and Special Protection Areas (SPAs) which could potentially be affected by the proposed IE43 biotech manufacturing facility. This report concluded that no significant impacts are expected to occur. The designated sites are listed below and shown in **Figure 13.2**.

- Bandon Valley Below Inishannon pNHA (1515)
- Bandon Valley Above Inishannon pNHA (1740)
- James Fort pNHA (1060)
- Garrettstown Marsh pNHA (1053)
- Garrylucas Marsh pNHA (0087)
- Courtmacsherry Estuary pNHA (1230), SAC and SPA
- Sovereign Islands pNHA (0105) & pSPA (124)
- Bandon Valley West of Bandon pNHA (1034)

13.3.2 Habitats and Flora

13.3.2.1 Introduction

Habitats identified during the May, June, July and August 2011 surveys, which are relevant to the proposed IE43 development, are summarised below and shown on **Figure 13.1**. The habitat classification scheme is based on the scheme outlined in *A Guide to Habitats in Ireland* (Fossit 2000). The habitat types identified on site are detailed below.

13.3.2.2 Habitat Types

Habitat types identified by DixonBrosnan in 2011 are shown on **Figure 13.1**.

- Eroding River (FW1)
- Treelines (WL2)
- Hedgerows (WL1)
- Recolonising bare ground ED3
- ED2 Spoil and bare ground
- Improved agricultural grassland GA1
- Amenity grassland GA2
- Drainage ditch FW4
- Wet Willow-Alder-Ash Woodland (WN6)

13.3.2.3 Eroding River (FW1)

A stream flows in an approximate northeast-southwest direction through the Lilly site as shown on **Figures 13.1**. 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 is part of the Bandon catchment, which is a salmonid river. It 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 stream has a natural riffle-pool sequence and stable banks, which protect against erosion. The stream and surrounding vegetation are shown on **Figure 13.1**. There is no published information available on fish stocks in this stream. However, examinations by Dixon.Brosnan in 2004 and 2011 found that adult brown trout were present.

According to Inland Fisheries Ireland (IFI), the stream supports and allows safe unhindered passage of Brown Trout and possibly Sea Trout. It is proposed that a new section of stream channel will be created to replace the section of channel which would be removed by the proposed development.

Certain parts of the stream provide habitat for adult trout with undercut, stable banks and riffle-pool habitat. Areas suitable for spawning were also noted. There are two bridges over the stream within the Lilly site – one is located towards the eastern side of the site and the other is at a point approx 300-400m further downstream.

The EPA does not conduct surface water monitoring of the freshwater stream associated with this site. Currently the EPA only records the estuarine water quality within this area, which is displayed in **Table 13.1**.

Table 13.1 EPA Estuarine Water Quality

River / waterway	Location	Approx. distance from development site	2009 Q values
Bandon river	Lower Bandon estuary	1 – 1.5km downstream of the proposed development	Eutrophic

13.3.2.4 Treelines WL2

The treeline of primary concern for the purposes of this assessment is the treeline which runs along the northern boundary of the stream in the western section of the site. There is a high bank on the northern side of the stream, which stabilises the stream channel thus this habitat is generally dry and not susceptible to flooding. This habitat consists of mature trees including oak, sycamore and ash with hazel, hawthorn, alder and holly. The understory includes hartstongue fern, hard fern, foxglove and dog violet. Certain sections are heavily shaded and contain fewer species and in these circumstances ivy is often dominant.

13.3.2.5 Hedgerows (WL1)

Most of the hedgerows within the overall land holding on the internal and external boundaries are quite dense with a mixture of species, which attracts nesting birds. Typical hedgerow species noted include hawthorn and blackthorn, which form the bulk of the hedgerows on site. Elm is also common in sections and ash and holly are scattered in the hedgerows as mature or semi-mature trees. Other woody species include elder, bramble, ivy, wild rose and honeysuckle. Where there is no buffer between the arable land and the hedgerow, species such as nettle, ryegrass and hogweed are often dominant. In heavily shaded areas, the heavy growth of ivy leads to a restricted under storey flora, with relatively few species. Species such as bindweed, old man's beard and cleavers are common on some sections of hedge.

The highest diversity of under storey plants generally occur where shade is low and where the hedgerow is not affected by the drift of fertiliser and/or herbicides from the adjoining arable fields. On this site many of the hedges are associated with high earth/stone banks, which increase the range of habitats available. Typical species noted include hartstongue fern, male fern, foxglove, dog violet, wood avens, herb robert and umbellifers such as cow parsley and hogweed.

One area of internal hedgerow, located on the north side of the river and joining the hedgerow that runs along the north-western boundary of the site, includes hawthorn, holly and ash with hartstongue, bramble, ivy and lord and ladies in the understory. Although it supports native species, it a small remnant of a larger hedgerow system which is now isolated within the overall Lilly site. Other sections of hedgerow are dominated by non-native species such as Leyland cypress and are thus of low ecological value.

13.3.2.6 Recolonising bare ground ED3

Graveled areas support little vegetation although older tracks on soil support early successional species such as bittercress, greater plantain and willowherb. On some older areas scrub species such as willow and bramble are becoming established.

13.3.2.7 ED2 Spoil and bare ground

An area which previously supported a mixture of Scrub WS1 and Marsh GM1, located to the south of the stream has recently been cleared of all vegetation to the edge of stream bank. This area is therefore of minimal ecological value at present.

Three additional small areas of spoil were observed and are the result of ongoing site development works. The heaps have been colonized with species such as rosebay willow herb and creeping thistle. As with the previous spoil heaps created on site, it is anticipated that these will be leveled and planted with an agricultural grassland seed mix.

Improved agricultural grassland GA1

Parts of the land holding are still held as agricultural lands. Improved agricultural grassland has also developed on areas of spoil that were deposited south of the stream during previous construction works.

Amenity grassland GA2

Within the proposed development area there are areas of amenity grassland some of which support planted immature trees. Both types of grassland are dominated by common species and are of low value.

Drainage ditch FW4

A small drainage ditch runs along the northern boundary of the stream and its riparian strip of trees. It is largely overgrown with brambles. It is often dry and has been culverted under the new bridge. A second dry drainage ditch occurs south of the river.

13.3.2.8 Wet Willow-Alder-Ash Woodland (WN6)

The majority of the wet willow-alder-ash woodland (WN6) is in the southwestern section of the site which will be unaffected by the proposed development. The section closest to the proposed development is located to the southeast of the stream in a mosaic with scrub.

A number of small feeder streams, which are probably derived from springs arising within the marsh in the south-eastern part of the site drain into the watercourse. This side of the stream is also more low-lying and there are obvious indications of periodic flooding of the riparian zone. The presence of wetter conditions due to periodic inundation during floods and the presence of springs encourages a more typical riparian vegetation including willow, hemlock water dropwort, meadowsweet, golden saxifrage, brooklime, fool's watercress and ivy.

13.4 Fauna

Dixon.Brosnan surveyed for mammalian, amphibian and avian fauna in 2004 and 2011.

13.4.1.1 Mammals

Otters

Although no specific signs of otter were recorded during the Dixon.Brosnan survey, the site has the potential to support otters. Given the presence of a stream which contains a population of brown trout, it is likely that otters are present at least periodically. However, no holts were recorded.

Bats

All bat species in Ireland are protected under the Wildlife Act 1976, as amended 2000 and the Habitats Directive which was transposed into Irish law in the European Communities (Natural Habitats) Regulations (S.I 94 of 1997), as amended. The Irish government is also a signatory to the Bonn convention (Convention on the conservation of migratory species of wild animals, Bonn 1979) and the Bern Convention, 1982 (The convention on the conservation of European wildlife and natural habitats) and has a commitment to the “Eurobats” agreement (Agreement on the Conservation of bats in Europe, 1991) (NRA 2005a).

The area to be developed which is located to the south of the river consists of recently cleared ground which is of no value for bats at present. The area to the north of the river consists of low value and highly modified habitat which may occasionally be used by feeding bats but is not a critical resource. The small section of hedge in this area is the remnant of an old field boundary and does not have value as a commuting route.

The primary concern in relation to bats is the potential impacts which could ensue from the removal of a part of the existing stream and in particular the treeline that runs along it. Streams are used by a number of bat species including soprano and common pipistrelle and Daubenton’s bat for feeding and treelines such as this one can be used by bats commuting between roosts and feeding grounds.

A bat activity survey was carried out by Carl Dixon M.Sc. on September 6th 2011 commencing approximately 1 hour before dusk and finishing approximately 2 hours after dusk. The survey was carried out using a Batbox Duet heterodyne and frequency division detector (Batbox Ltd. Steyning, U.K.). Although conditions were dry and it was relatively warm, winds were moderate to strong immediately prior to and following sunset. This may have delayed emergence. However, approximately 50 minutes after dusk, winds died down and conditions became suitable for bat feeding activity.

The objective of the study was to determine whether any of the trees along the stream have potential for bat roosts, whether the treeline forms an important commuting route for local bat populations and whether bats feed along the stream and treeline.

This habitat consists of mature trees including oak, sycamore and ash with hazel, hawthorn, alder and holly in the understorey. A preliminary survey of the trees along the stream indicated that there were no over mature trees with sufficient cracks or crevices to provide significant bat roosts. Whilst the presence of a small number of individuals cannot be completely excluded it is considered unlikely that the trees along the stream are of value for bat roosts.

Apart from two isolated signals from overflying bats (common pipistrelle) no significant bat activity was recorded until approximately 50 minutes after dusk when winds dropped. However, there was strong feeding activity along the

treeline from that time onwards with an estimated 3-4 common pipistrelle moving along the stream.

Based on the results of the survey, it is considered unlikely that the stream and treeline provide significant roosting habitat or function as a particularly important commuting routes within the local landscape. However, results indicate that the stream and treeline do provide a local feeding resource for common pipistrelle bats.

Other mammals

During the Dixon.Brosnan survey in 2004, the only species recorded were rabbits and fox. However, it was considered likely that species such as brown rat, field mouse, house mouse, pigmy shrew and bank vole were present. Other species, such as hedgehog and stoat were considered likely to be present on occasions. No signs of badger activity were noted during the survey and no setts were located. However, it is possible that badgers do visit the site.

13.4.1.2 Amphibians and Reptiles

The common frog was noted in the marsh habitat during the Dixon.Brosnan survey in 2004. Tadpoles were also noted in temporary pools of water that had formed in small depressions on the edge of a track within the development site area in 2011. Lizards may be present at low densities, although the habitat is not of particular value for this species. It was considered that a variety of invertebrate species will be present at the site, however a specialised survey was not considered necessary.

13.4.1.3 Birds

During the Dixon.Brosnan survey in 2004 and 2011, the bird species noted, or likely to occur, were broadly associated with either aquatic and riparian habitats or intensive farmland with woodland/scrub and dense hedgerows.

Certain bird species are associated with rivers including dipper, grey heron, grey wagtail, kingfisher and mallard however only grey wagtail was noted near the stream. No potential kingfisher nesting sites were recorded. Snipe was noted in the marsh close to the river.

Typical woodland birds noted on site included dunnock, swallow, wren, great tit, song thrush, pigeon, robin, greenfinch, blackbird, jackdaw, hooded crow and rook. A single mallard was recorded in an open section of the stream. Typical hedgerow species such as song thrush, chaffinch and blue tit were noted in the scrub. Predatory species, which were not noted, but which may occur include kestrel and sparrow hawk. Other birds likely to occur, but not noted, include goldfinch, long tailed tit, bullfinch, willow warbler, treecreeper, starling, jay, magpie chiffchaff and redwing.

Native, dense hedgerows are important for many breeding birds and the stream and its associated habitats will also attract certain bird species. Notwithstanding this the birds noted on the overall site are common in mixed farmland and no rare or endangered species were detected during the surveys or are likely to occur.

13.5 Characteristics of the Project

To facilitate the construction of the IE43 facility, bulk excavation works will be undertaken within the IE43 footprint. All of the excavated material will be retained on site, either being reused as fill or used for landscaping purposes in the fields to the south of the existing stream. A section of the existing stream will be permanently diverted to facilitate the development of the IE43 facility. As part of the stream diversion works, a number of trees and hedgerows will be removed. Refer to Chapter 3 *Site and Scheme Description* for more details of the proposed development.

Treated effluent is discharged through a pipeline to a sea outfall close to Sandy Cove Island, near Kinsale. Refer to **Figure 11.4**. The IPPC licence provides limits which ensure environmental protection of the receiving waters. There will be no change to this arrangement and effluent will comply with the licence limits.

As detailed in Chapter 14 of this EIS, surface water from the Lilly plant currently discharges to the stream which runs through the site via a containment pond. The discharge is continually monitored for pH and Total Organic Carbon.

As noted in Chapter 14, it is envisaged that the IE43 process activities will require commissioning of four new wells and reactivation of two existing wells.

13.6 Identification of Potential Impacts

13.6.1 Potential impact on Habitats and Flora

The habitats on the site are not rare or threatened nor do they require any special protection under existing or pending legislation. The proposed works will impact primarily on low value habitats where ground levels were previously disturbed and in places raised with soil and excavated material from previous construction projects within the Lilly site. However, an area of marsh and scrub will be removed and a section of the existing stream infilled as part of the proposed stream diversion. Although this area of marsh was identified as being of local ecological value by the 2004 survey, in the absence of grazing, natural succession has allowed scrub to dominate this area. A repeat survey of this area in 2011 did not record any rare or uncommon species in the marsh area and found that it has been significantly reduced in size. A treeline which supports a number of mature trees along the river will also be affected. A section of the stream will be removed and a new length of channel constructed.

The portion of the stream extending downstream from the proposed IE43 development would be potentially vulnerable to any effects arising from the proposed development works, particularly due to its small size and consequently its low dilution capacity. This stretch is approximately 1km in length. Upstream sections are not vulnerable.

There is a potential for silt or spillages (of construction related materials) to enter surface waters during the IE43 construction phase. This would lower the overall quality of the stream and its biological diversity. Chapter 14 addresses control of emissions to waters during operation of the plant. Increased discharges of surface water from the plant could potentially impact on water quality in the stream if it has high nutrient levels or chemical contamination.

13.6.2 Potential impacts on Terrestrial Fauna

Impacts to fauna could include disturbance of movement routes by construction fencing and limited loss of habitat. There may also be some disruption of fauna due to increased levels of noise and disturbance. The stream diversion could potentially impact salmonid populations and on local bat populations.

Tadpoles were noted in shallow temporary depressions within the development area. As common frog is protected under the Wildlife Act, 1976 & 2000, it is recommended that any tadpoles present in these habitats during construction works be relocated to appropriate habitat in consultation with the NPWS prior to commencement of construction works. Spawn/tadpoles can occur between January and July although the habitat noted on site is ephemeral and likely to dry up.

13.7 Proposed Mitigation Measures

13.7.1 Habitats and Flora

Where possible, boundary hedges should be retained and enhanced. NRA guidelines on the protection of trees and hedges prior to and during construction should be followed (NRA, 2006c). It is recommended that new hedgerows and treelines be planted as soon as possible to replace those lost during construction and to connect with existing hedgerows in the wider environment. Where practicable, the planting should be predominantly of Irish native species that reflect the existing vegetation of the area.

Although species such as elm and blackthorn are difficult to plan into a formal planting scheme; species such as oak, willow, holly, alder, ash, hazel and hawthorn should be incorporated into the planting scheme. As there may be some genetic variation between trees from different areas it is preferable that the trees planted are derived from local seed sources where this is possible. This is particularly important for willow and for this species it may be necessary to use cuttings from native trees on site.

13.7.2 Birds

The Wildlife Amendment Act 2000 (S.46.1) provides that it is an offence to cut, grub, burn or destroy any vegetation on uncultivated land or 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. None the less it is recommended that hedgerow habitat be removed outside of the breeding season where possible.

13.7.3 Otters

The NRA publication *Guidelines for the treatment of Otters prior to the construction of national road schemes* outlines the mitigation measures described below (NRA, 2005b).

In line with the mitigation measures outlined in the NRA guidelines it is recommended that a preconstruction survey for the presence of otters should be conducted no more than 10-12 months in advance of construction. The objective of the survey is to ensure that no new holts have been constructed since the previous survey and to specifically check for breeding holts. It is noted that no evidence of a breeding holt was detected at the site of the proposed development in 2011 and no active holts were located in the area to be directly affected. However if active holts are detected in the area to be affected, specific measures will be required. Removal of otters or holts can only be carried out under a Section 25 derogation under the 1997 Habitats Regulations. In addition, derogations are also required for any works likely to cause significant disturbance i.e. blasting and piling when this occurs within 150m of a breeding holt. Where works are proposed within 150m of a breeding holt appropriate mitigation measures such as screening or reduced working hours may be required. There will be no blasting carried out as part of the proposed development.

Other mitigation measures may include timing of works to avoid impact on breeding females or young cubs which can use a breeding holt for approximately 21 weeks. Exclusion of Otters from holts and provision of alternative holts may also be required using similar methodologies to those employed for badgers.

If such mitigation measures are required detailed methodologies will be agreed with the National Parks and Wildlife Service prior to commencement of works which could impact on Otters.

13.7.4 Bats

The diversion of the existing stream and creation of new a stream channel will recreate suitable feeding habitat for bats over time. Native trees will be planted along one side of the stream to ensure that similar habitat is recreated. Where possible either fast growing species or semi-mature specimens will be used to replace feeding habitat in as short a time as possible.

Where mature trees are to be removed, this should be done in accordance with NRA guidelines (NRA, 2005a). The removal of trees or hedgerows as part of a development can have a significant impact on bats. As well as providing roost sites they also provide a valuable source of insect prey. Therefore, the removal of such trees reduces the availability of shelter and feeding sites for bats. Tree-felling poses an immediate risk of injury or death to bats and a number of measures can be taken to reduce this risk to a negligible level.

To proceed with tree felling, a licence must be obtained from the National Parks and Wildlife Service (NPWS). Tree felling should ideally be undertaken between the months of August to late October/early November. Trees should be examined immediately prior to felling for the presence/absence of bats. This should include a visual daylight inspection as well as a night-time detector survey. Where an autumn examination of a tree does not find the presence of bats, it is safe to proceed with tree felling the following day. Where the presence of a bat roost is unconfirmed, a close inspection of the tree immediately prior to felling should be undertaken. Where the presence of bats is confirmed on the day which felling is planned for, felling must be postponed until it is known that the bats have left the tree. Where bats are still present within an identified roost following repeated postponement of felling, it will be necessary to undertake exclusion procedures.

These will allow bats to exit from a tree but not to return. The bat specialist will advise on the steps necessary for exclusion and the likely time period required, under licence from the NPWS.

All potential entry points to the tree should be blocked off to prevent bats returning to the roost. The exit site will require a means of creating a one-way valve to allow bats to leave but not to return. Where it has proved impossible to exclude the bats, the tree should be felled in stages. If a tree known to contain bats must be felled outside the optimum season, a bat specialist must endeavour to remove all bats safely.

13.7.5 Aquatic Ecology - Freshwater

There will be no direct discharges to surface waters, subsurface soils and groundwater during the construction phase of the project. In the event of spillage of any polluting substance and/or pollution of the stream, Cork County Council and the Inland Fisheries Ireland shall be notified immediately. As noted in Chapter 14, it is envisaged that the IE43 process activities will require commissioning of four new wells and reactivation of two existing wells. To assess potential impacts on the stream flowing along the south of the site, water levels were measured at two locations over the five day pumping test. No change was detected to the water level in the stream. Thus, 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 was concluded therefore that the drawdown from the additional wells is unlikely to impact on surface water and surrounding off site wells. The water levels in the stream will be monitored as described in Chapter 14. Pumping from the wells will be controlled to ensure that there will be no impact on the water levels in the stream. These mitigation measures will ensure that there are no adverse impacts on the stream or the local groundwater due to the groundwater abstraction activities. All fuels and oils and other chemicals used in the execution of the works shall be stored in secured bunded areas. Particular care shall be taken during the refuelling and maintenance of plant equipment to avoid spillage. Machinery will be kept in good working order. See Section 3.5.2.2 for other measures to protect waters. A containment pond has been installed to prevent any potential impact on the freshwater system.

It is recommended that solids be settled from any surface water draining from the site. In particular any discharge containing heavy mineral solids and soil particles, which could consolidate on the riverbed and affect salmonid spawning should be avoided. Possible siltation from excavated soil will be prevented by siltation traps.

In relation to the proposed stream diversion works, the design and construction methodology are outlined in Chapter 4 *Construction Activities*. The design will ensure that the flow capacity of the new channel is maintained, that meanders and riffle pool habitat is created and that a minimum flow maintained.

13.8 Residual Impacts

13.8.1 Residual impacts on habitats

The relative values of habitat are detailed in **Table 13.2**. It should be noted that the value of a habitat is site specific and will be partially related to the amount of that habitat in the surrounding landscape. The evaluation scheme used in **Table 13.2** is based on the scheme detailed in the NRA publication *Guidelines for assessment of ecological impacts of National Road Schemes* (**Appendix A13.1**).

Table 13.2 Terrestrial habitat values and predicted impacts

Habitat Type	Relative Habitat Value	Impacts
Treelines WL2	Moderate value D	The closest treeline of value to the proposed development runs along the northern boundary of the stream. This will be removed and the impact will be moderate negative .
WL1 Hedgerows	Low value E to Moderate value D	One small section of hawthorn, holly and blackthorn hedge will be removed. This section is isolated from other hedgerows in the area is unlikely to function as an important commuting route for bats and other species. The impact will be minor negative .
Recolonising bare ground ED3	Low value E	Low value habitats within the development area. The impact of their removal will be minor negative .
ED2 Spoil and bare ground	Low value E	Low value habitats within the development area. The impact of their removal will be minor negative .
Improved agricultural grassland GA1	Low value E	The impact on this habitat will be minor negative .
Amenity grassland GA2	Low value E	This habitat is outside of the development area. This habitat will not be affected.
Drainage ditch FW4	Low value E	The impact on this habitat will be minor negative .
Wet Willow-Alder-Ash Woodland (WN6)	Moderate value D	This habitat will not be affected.

13.8.2 Residual impacts fauna

There will be a net loss of breeding and feeding habitat for birds and mammals due to the loss of a small section of treeline and hedgerow habitat and to a lesser extent, areas of grassland. In particular there will be a net loss of feeding habitat for bats along the stream although it not considered likely that roosts or significant commuting roosts will be affected. The impact will be reduced in the longer term by the diversion of the stream channel and the creation of new feeding habitat along the new channel. However there will be a moderate to high local impact on feeding bats in the short-term and a minor to moderate negative impact in the long term. The increase in noise and disturbance will lead to short-term disturbance of common birds and mammals. There will be a net loss of sub-optimal breeding habitat for common frog. Overall the impact on fauna will be localised and no

significant impact on bird, mammal and amphibian populations is envisaged in the long term.

13.8.3 Residual Impacts on aquatic ecology

As detailed in Chapter 14 surface water is discharged to the stream via a containment pond. An online pH and TOC monitoring system is in place for storm water discharge. Controls are in place whereby discharge is only allowed if the TOC value is less than 30mg/l and pH value is between 6 and 9. A daily visual inspection of the storm water discharge is also carried out. As this system will remain in place no significant impact from surface water discharges during the operation of IE43 is envisaged.

As detailed in Chapter 14, abstraction of additional water is not expected to impact on water levels within this stream.

Chapter 4, which outlines the specified methodology for construction of the new section of stream notes the following:

- The construction of a channel with meanders, pools, riffles and other in channel structures will aid the re-oxygenation of the river.
- The re-designed channel will provide improved habitat for flora and fauna.
- The diverted will should not alter the existing sedimentation rates as the key hydraulic/hydrologic parameters have been maintained or improved.

On the basis of the above, the impact on the stream, which is classed as being of moderate valued under the NRA classification scheme, is expected to be moderate negative in the short term and minor negative in longer. Provided standard mitigation measures are implemented during construction works no significant impact on water quality in the stream is likely to occur. The new channel has been designed to be suitable for resident salmonids and will allow migration of salmonids. Similarly no significant impact on water quality from the operation of the finished development is envisaged.

13.8.4 Residual impacts on Estuarine Ecology

The current location of the estuarine discharge will not be altered. The current discharge limits are specified by the IPPC licence and have been designed to protect the estuarine and marine environment. A benthic survey was carried out in 2010 to assess if changes in benthic habitat quality has occurred (Summary Report on Kinsale Benthic Survey Ryan Institute, March 2011). The report concluded:

- *Habitat quality in the Harbour area is generally Good or High ecological status in accordance with the Water Framework Directive (WFD).*
- *The area has been sampled on an almost annual basis since 1981. Long term analysis of habitat quality in Kinsale Harbour in previous years has shown that the area has been of consistently good habitat quality and that what change has occurred in the area can be attributed local and regional meteorological events.*
- *Overall, there was no evidence of a deleterious impact from the Eli Lilly outfall or substantial impact from any source in the Harbour area.*

As outlined in Chapter 11 there will be no significant increase in discharge volume or discharge concentrations and the discharge will continue to meet the relevant IPPC limits. As the available evidence indicates that the current discharge is not impacting significantly on water quality, no significant additional impact is envisaged. Although there are Designated Shellfish Areas within the estuary they occur upstream of the existing discharge point, although downstream of the confluence of the stream which runs through the site and the estuary. The limits applying to surface water draining from the site to this stream during construction and operation will ensure that no negative impacts on shellfish occur. It is noted that shellfish are naturally able to survive in estuaries with extreme fluctuations in levels of suspended solids and nutrients. Any impact from surface water discharges associated with the proposed development will be minimal.

13.9 References

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14 Soils, Geology, Surface Water and Groundwater

14.1 Introduction

This chapter describes the soils, geology, surface water and groundwater at the site of the proposed IE43 biotech manufacturing facility. The description 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, and a geotechnical site investigation for the proposed IE43 facility, which was undertaken in December 2010.

The impact of the construction and operation of the development on the underlying soils, geology, surface water and groundwater is assessed and mitigation measures are proposed, where required.

14.2 Existing Environment

14.2.1 Regional Geology

The bedrock underlying the site is of Lower Carboniferous age, and is thought to belong to the Kinsale and the Courtmacsherry Formations. The Kinsale Formation consists mainly of calcareous mudstones or muddy limestones, while the Courtmacsherry Formation comprises calcareous mudstone, calcareous siltstone and limestone. Refer to the Geological Survey of Ireland geology map presented in **Figure 14.1**. These formations are known collectively as the Cork beds 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.

The quaternary deposits consist of glacial sands, gravels and tills whilst the soils are principally brown podzolics and acid brown earths. Brown podzolics 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.

14.2.2 Local Geology

The geotechnical investigatory works undertaken in December 2010 have revealed the ground conditions at the proposed site of the IE43 facility is comprised of:

- Made ground.
- Glacial deposits
- Siltstone, shale, calcareous siltstone and limestone bedrock units.

Made ground was encountered in the majority of the boreholes and has a thickness of up to 3.60m. It comprises a reworked grey or grey brown sandy clayey gravel or gravelly clay with concrete constituents.

The indigenous soils comprise 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, and was as identified during the earthworks phase of IE 42.

The rock cores taken during the site investigation confirm that bedrock in the area of the proposed IE43 facility consists of a complex sequence of laminated siltstone, calcareous siltstone, shale and mudstone.

14.2.3 Surface Water

A stream flows in an approximate northeast-southwest direction through the Lilly site as shown on **Figures 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 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.

Refer to Section 14.3 below for a description of the site storm water drainage systems.

14.2.4 Groundwater

The site is located within the South Western River Basin District which covers most of counties Cork and Kerry, parts of Limerick, South Tipperary and Waterford and all of Cork City as shown in **Figure 14.3**. 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 site and surrounds is (PI) Poor Aquifer – bedrock which is Generally Unproductive except for Local Zones. Refer to **Figure 14.4**.

Groundwater movement in the bedrock is concentrated in fractures and fissures, and along bedding planes. These occur predominantly close to the bedrock surface. Ground water movement beneath the site has been interpreted as being in a south westerly direction. Groundwater was not encountered in any of the boreholes drilled during the December 2010 site investigation and groundwater in the bedrock appears to be confined by the overlying low permeability glacial till. Small or minimal groundwater inflow(s) is therefore anticipated during excavation works.

14.2.4.1 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 (sand/gravel aquifers only)	Karst Features (<30m radius)
	High Permeability (sand/gravel)	Moderate permeability (e.g. sandy subsoil)	Low permeability (e.g. clayey subsoil, clay, peat)		
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 in the site is ‘High (H)’ as shown on **Figure 14.5**.

The combination of poor aquifer and high vulnerability gives a resource protection zone rating of PI/H. The risk to groundwater from a potentially polluting activity such as a landfill would be considered acceptable, subject to certain conditions, in this situation. In the context of groundwater protection, the IE43 biotech manufacturing facility would not be regarded as a potentially polluting activity.

14.2.4.2 Groundwater Use

A substantial proportion of the water used in the Lilly plant is supplied by ground water from a series of onsite boreholes. In 2010, 276,461m³ of groundwater was used in the plant.

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.

14.2.4.3 Groundwater Monitoring

The IPPC Licence conditions require monitoring of five ground water wells on site. Monitoring is undertaken as follows:

Table 14.2 Groundwater Monitoring

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.

Results are reported to the Agency in-line with the requirements set out in the Annual Environmental Report (AER) as available on the EPA website, www.epa.ie. There is no significant impact on groundwater quality from ongoing site operations.

14.3 Onsite Drainage

14.3.1 Introduction

There are separate collection systems on the Lilly site for process effluent, floor drainage, utility wastewater, sanitary effluent and storm water. The generation, management and treatment of process, utility and sanitary effluents are addressed in Chapter 11, *Effluent Generation and Treatment*. The management of storm water run-off is addressed below.

14.3.2 Storm Water Drainage Systems

14.3.2.1 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 drainage system. This drainage system drains into the containment pond. Refer to section 14.3.3 below for details of the containment pond.

14.3.2.2 Storm water monitoring

The inlet flow and outlet flow from the containment pond passes through chambers, in which there is continuous monitoring for Total Organic Carbon and pH. The IPPC licence requires weekly monitoring at the storm water outfall for pH and total organic carbon and a daily visual inspection.

14.3.2.3 Runoff from bunds

Rainwater run-off from bunded areas and some process building roofs is collected and routed to the biological treatment plant. This is considered necessary as the bunds are acting as secondary containment of the materials stored in the tanks in the bunds.

14.3.2.4 Storm Water Receiving Waters

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 **Figures 14.2**.

14.3.2.5 Treated Effluent Receiving Waters

Treated effluent is discharged through a pipeline to a diffuser about 500 m offshore near Sandy Cove Island in the outer Kinsale harbour. Refer to **Figure 11.4**. The receiving waters are used for water sports and fishing and there are beaches within 2km of the emission point.

14.3.3 Designated Shell Fish Waters

The Shell Fish Waters Directive is implemented in Ireland by the European Communities (Quality of Shellfish Waters) Regulations 2006 (SI No 268 of 2006), which designated 14 shell fish harvesting or aquaculture sites for protection or improvement of the water quality. The European Communities (Quality of Shellfish Waters) (Amendment) Regulation 2009, SI 55 of 2009 designated a further 49 sites. The closest designated sites are in Kinsale Harbour, approximately 3km upgradient of the treated wastewater discharge point and Oyster Haven, approximately 7km upgradient of the discharge point.

14.3.4 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 stricter 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 2011 a total of 135 bathing waters were identified by the relevant Local Authorities.

The nearest designated bathing waters to the effluent outfall are Garrylucas, White Strand and Garryvoe which are approximately 6 km from the outfall.

14.3.4.1 Zoning

The storm water drainage system was re-configured when IE30 development came onstream in 2005 so that the 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.

Normally runoff from the entire site drains through the pond. In the event of a fire or incident in part of the site, runoff from the other parts will be diverted around the pond, while run-off from the affected area will continue to flow into the pond. This will reduce the total flow to the pond and increase the available containment capacity for potentially contaminated water.

14.3.5 Fire-Water Containment

Chemicals are used in all process areas on site and are stored in tank farms, and warehouses. A fire could rupture chemical containers and cause a release of hazardous chemicals. Activation of sprinkler, deluge and foam fire-fighting systems could create contaminated firewater that may run off from the location of the fire into the storm water drainage system.

The containment pond will 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 2.5-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.

The outflow from the pond is automatically monitored for TOC and pH. In the event that the preset 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 effluent treatment plant or the final effluent holding tank/wet well, depending on the need to treat the pond water.

14.4 Sub-Surface Characteristics of the Proposed Development

As described previously in Chapter 4, 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. Some surplus excavated material from the construction of IE42, which is coming to the end of the construction and commissioning stage, is stored on this land.

The site of the proposed IE43 development is located to the east of IE42 as shown on **Figure 3.2**. It is proposed to undertake bulk excavation which will create two platforms, one at circa 38.000mOD and a lower one at circa 29.000mOD, in a similar manner to the two platforms created as part of the IE42 construction project.

To achieve this, approximately 157,000m³ of material will be excavated. 50,000m³ of this material is expected to be stockpiled material from previous projects on site, with the remainder being new excavation, consisting of sandy, gravelly clay with cobbles and occasional boulders, and weathered and intact rock. The stockpiled material contains some inert construction and demolition waste. The bedrock, underlying the clay, consists of thinly laminated mudstones and siltstones, the top 0.6m of which is weathered. The bedrock element to be excavated will contain approximately 16,000m³ of weathered rock and intact rock.

All excavated material will be retained on site. The excavated bedrock will be re-used as engineering fill where possible. Material not suitable for engineering fill will be used to provide improved landscaping to the open fields at the southern boundary of the site as shown in **Figure 3.2**. The inert construction and demolition waste will be disposed of, off-site, at a permitted or licensed facility, as appropriate.

It is proposed to permanently divert the course of a section of the existing stream which flows through the Lilly site to facilitate the proposed development of the IE43 facility. Refer to **Figure 3.2**.

Two existing concrete pads will be demolished and the arising concrete will be crushed and reused on site as fill or removed off-site to a suitable waste facility. The bridge crossing over the stream, constructed to facilitate the IE 42 construction works will be used to access the areas to be landscaped on the southern side of the stream.

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.

It is envisaged that the IE43 process activities will require approximately 148,500m³/year (400m³ per day), thereby increasing overall water consumption to 551,078m³ per annum (1500m³ per day). The water supply will be provided by existing council water supply (up to 500m³/day) and on site abstraction wells, including commissioning of four new wells and reactivation of two existing wells.

14.5 Identification of Potential Impacts

14.5.1 Construction Phase Potential 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 in Section 14.4 above. The foundations will be constructed above the water table and therefore will not impact on groundwater.

It is expected that piling will not be required.

The excavation and removal of spoil associated with the IE43 building and the proposed stream diversion and the proposed landscaping works in the southern fields will create the risk that silt or mud will enter the stream, which runs past the southern part of the IE43 site, either directly or carried in surface water run-off.

14.5.2 Operational Phase Potential Impacts

The handling, use and storage of the small quantities of solvents and hazardous chemicals which will be in the IE43 facility 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 get into the ground and groundwater or into the streams which flow through and past the site.

Eli Lilly retained a consultant to carry out an assessment of hydrogeological groundwater development in 2011. 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 14.3** 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 14.3 Sustainable Yield Calculations

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 14.3 indicates that 1,800m³/day can be extracted from the aquifer on a sustainable basis in drought conditions. The projected total water demand for the operational site with IE43 online of up to 1,500m³/day is well within this range. 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 proposed use is within the range of historical extractions from the site aquifer with no offsite impacts being reported historically.

The water levels in the stream flowing along the south of the site was 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 level 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.

The drawdown from the additional wells is unlikely to impact on surface water and surrounding off site wells.

14.5.3 Geophysical Risk

While the project involves the construction of short lengths of relatively low retaining walls, these pose no significant engineering challenges. Given the ground conditions on the site and the nature of the IE43 project, the risk of a landslide or other geophysical risk is regarded as negligible.

14.6 Proposed Mitigation Measures

14.6.1 Construction Phase Mitigation Measures

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. The guide is written for project promoters, design engineers and site and construction managers. It addresses the main causes of pollution of 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 guide addresses developments on green field and potentially contaminated, brownfield sites.

The construction management of the site will take account of the recommendations of the CIRIA guide to minimise as far as possible the risk of soil, groundwater and surface water contamination.

Site activities, for which recommendations are provided in the CIRIA guide, include the following:

- demolition,
- excavation,
- earthmoving,
- dewatering of excavations and operating below the water table,
- piling and grouting,
- concreting operations,
- spreading of topsoil,
- road surfacing,
- site drainage, and the control and discharge of surface water run-off from the site,
- works in and adjacent to watercourses and in special areas of conservation,
- oil and fuel delivery and storage,
- plant maintenance.

The protection measures recommended in the CIRIA guide include:

- training of site managers, foremen and workforce, including all subcontractors, in the pollution risks and the preventative measures,
- written procedures to address activities where there is a particular risk of pollution,
- emergency response plan,
- spill control equipment readily available,
- persons with responsibility for emergency response identified at the start of the project,
- control of site drainage and surface water runoff to remove silt and other potential contaminants,
- maintaining the site clean and tidy, with proper collection and storage of waste,
- storage of oils and fuel in bunds,
- drip trays for stationary plant,

- regular maintenance, and removal from site of leaking plant or equipment,
- dedicated refuelling locations for mobile plant.

Implementation of the CIRIA guide's recommendations will ensure that the risk of pollution of groundwater, soils and surface waters, resulting from the construction activities, is minimised.

Runoff from the construction works will be discharged via the settlement pond to the stream. The outlet from this pond will contain a double row straw bale filter, a membrane, and be configured to ensure that the anticipated discharge parameters are met. Regular monitoring and testing of this discharge will be undertaken twice weekly for TOC, pH, suspended solids and total hydrocarbons.

Rain water run-off from the IE43 construction site will be controlled in a temporary system comprising land drains, swales (ditches) and settlement ponds. The system will essentially be an extension of the system put in place for the recent IE42 and earlier IE30 construction projects. 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.

The land drains and swales provide the rain water capture mechanism while the settlement ponds allow suspended soil particles to settle out. The settlement ponds will contain outlet filters to filter out any remaining suspended particles and any flotsam.

This system will be arranged to discharge to the stream at a single point within the site.

The entire 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 rain fall. Written procedures will be maintained and a log recorded for the inspections, sampling and testing of the discharge and maintenance.

At the point during the construction phase when the hardstandings have been created rain water collection in these areas will be facilitated by the applicable portion of the new permanent rain water system. For the remainder of the construction phase, until the rainwater system is completed and commissioned the water collected from these hardstandings will be routed to the final settlement pond on the swale system via a hydrocarbon interceptor.

As part of the stream diversion works, a swale will be constructed to the immediate south of the proposed riparian zone. This swale will collect all surface water runoff from the proposed earth embankments located to the south the river. This runoff will be diverted to the existing surface water settling pond prior to discharge into the stream.

The stream diversion has been designed to ensure no potential for upstream flooding and to minimise the potential for entrapment of debris which could result in localised flooding.

14.6.2 Operational Phase Mitigation Measures

The detailed measures and standard operating procedures in place on site currently will be extended to cover the IE43 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 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 IE43 facility, where there would be potential for spills or leaks, will be bunded to contain and divert spills and firewater.

The storm water system for IE43 will be designed using the same parameters as the IE42 design, i.e. to accommodate 1 in 5 year storm return period with a time to concentration of 15 minutes. There is enough capacity in the existing system to cater for flows from IE43. The water discharges via the containment pond to the stream after passing through the monitoring chamber. The development is not expected to have a significant impact on surface waters.

In relation to the commissioning of additional abstraction wells, mitigation measures and controls which will be put in place, from the outset, to protect the 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, a water supply will be obtained from Cork County Council, which in the past has supplied in excess of the volume required.

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 Foras Taluntais (1980) Soil Map of Ireland

A.G.Sleeman, M. Pracht, Geology of South Cork Geological Survey of Ireland (1994)

Construction Industry Research and Information Association (2001) *Sustainable urban drainage systems - best practice manual for England, Scotland Wales and Northern Ireland*, CIRIA, London

Environmental Protection Agency and Geological Survey of Ireland (1999) *Groundwater Protection Schemes Department of Environment and Local Government, Dublin*

Geological Survey of Ireland (GSI). Groundwater Protection Responses for Landfills

Geological Survey of Ireland National Draft Bedrock Aquifer map

Geological Survey of Ireland Groundwater Database

IGSL (2011) Eli Lilly IE43 *Geotechnical Site Investigation Report* (Project No. 15026)

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15 Archaeological, Architectural and Cultural Heritage

15.1 Introduction

This chapter comprises an archaeological, architectural and cultural heritage assessment of the proposed IE43 biotech manufacturing facility at the Lilly site. The purpose of this assessment is to evaluate the potential impact such a development would have on the cultural heritage of the entire area. The term cultural heritage in this chapter encompasses the following topics: archaeology, folklore/tradition/history, architecture/settlements and monuments/features.

This report was prepared by Sheila Lane and Avril Purcell, Lane Purcell Archaeology on behalf of Arup. The proposed development site is owned by Eli Lilly S.A. (Ireland Branch), Ballythomas, Dunderrow, Kinsale, Co. Cork.

15.2 Methodology

The care of archaeological monuments in Ireland has its beginnings in the 19th century with the establishment of the Ancient Monuments Protection Act of 1882. This was the first piece of legislation in the United Kingdom that sought to protect monuments of archaeological importance. This Act was upgraded in 1892 to provide legal protection to a wider range of monuments, including medieval structures. Various Acts followed (The Local Government Act, 1898, The Land Acts of 1903 and 1923) which sought to broaden the scope of what was considered to be of archaeological importance and to give more protection to these sites. The National Monuments Act 1930 repealed all previous Acts and is at present the principal statute which governs the care of monuments in the state. Various amendments have been made to the Principal Act of 1930; 1954, 1987, 1994 and 2004. Archaeology and architectural heritage are protected under the National Monuments and National Monuments (Amendment) Acts 1930-2004, and the Planning and Development Acts 2000-2001.

The methodology employed to complete this assessment comprised the following:

- A desktop assessment of the proposed development site and an area within a 2km radius of that site.
- A site inspection of the proposed development site carried out by Sheila Lane in May 2011.

An overview of the archaeological heritage in the vicinity of the site is provided in **Appendix A15.1**. The desktop study examined documentary sources for the area within a 2km radius of the Lilly complex. The desktop study included the following components:

15.2.1 Desktop Assessment

The desktop study provides a cultural heritage overview of the proposed development site and overall study area. During its compilation, the following sources were consulted:

- Record of Monuments and Places (RMP) - This record was compiled in accordance with The National Monuments Act 1994. It provides an updated list of all known archaeological monuments and places of archaeological interest, with an accompanying set of constraint maps. Many of the sites listed in the RMP were in the Sites and Monuments Record (SMR) which the RMP largely replaced and provided legal protection to the monuments included. It is an offence to interfere with any of the sites or monuments listed in the Record without first giving two months notice in writing to the National Monuments Service at the Department of Arts, Heritage and the Gaeltacht (DAHG).
- Sites and Monuments Database - The website of the National Monuments Service (NMS) at the Department of Arts, Heritage and the Gaeltacht at www.archaeology.ie, provides an updated list of new archaeological sites, discovered since the publication of the RMP.
- Archaeological Inventory of Co. Cork - this is the follow-up phase to the SMR where all the sites listed in the SMR were visited and a rapid survey of each site was carried out. Some of the SMR sites were found to be non-archaeological in nature and were not included in the Inventory. Sites discovered since the publication of the SMR are included. Many of these are now listed in the RMP. The Inventory for Co. Cork is published in five volumes. Volume 11: East and South Cork (published in 1994) and Volume V (2009) were used for this study. The relevant sites are listed in **Appendix A15.2**.
- Files of the Archaeological Survey of Ireland, – These files are held by the National Monuments Service at the Department of Arts, Heritage and the Gaeltacht. They are constantly updated and sometimes contain more information than that which is published, as well as new information. The relevant sites are listed in **Appendix A15.3**.
- National Museum of Ireland (NMI) – The relevant museum archives consist of a series of topographical files which record the recovery of archaeological artifacts throughout the country. These files were examined for information on finds from townlands that are directly impacted or close to the proposed development and no finds were noted.
- Excavation Bulletins and Excavations Database - This is an annual bulletin containing summary accounts of all excavations undertaken in Ireland. The bulletins are published for the years 1970 up to 2007 and can be accessed on the internet at www.excavations.ie. These sources were consulted for any excavations within the proposed development area.
- Documentary Sources – All available literary sources were consulted. These include local histories and relevant journals. The first, second and third editions of the Ordnance Survey six inch maps were also consulted. The Record of Monuments and Places has been superimposed on the 1939 edition of the 6" map at a reduced scale of 1:1250. The 25" map compiled between 1888 and 1913 was also consulted.
- Cork County Development Plan (2009) – The county development plans outline the county council's objectives with regard to the preservation of the archaeological and architectural heritage of the county. The county development plan also provides the Record of Protected Structures. There are no protected structures in the proposed development area.

15.2.2 Site Inspection

An inspection of the proposed development site was carried out by Sheila Lane in May 2011 in order to determine if any previously unrecorded archaeological remains or structures or features of cultural heritage interest were present.

15.3 Description of the Receiving Environment

15.3.1 Introduction

The area to be developed is located within the Lilly site. The Lilly site itself is located c.5km northwest of Kinsale, on the main road from Kinsale to Inishannon, Co. Cork as shown on **Figure 1.1**. It occupies the entire townland of Ballythomas West and a portion of the townland of Ballythomas East. The plant comprises a series of buildings and car parks at the west and fields at the east and southeast as shown on **Figure 3.1**.

The Lilly pharmaceutical manufacturing plant in Dunderrow was opened in 1981 and the plant has been gradually expanded during the past three decades.

15.3.2 Previous Archaeological Investigations

The following archaeological investigations have been carried out within the Lilly complex in recent years and nothing of archaeological significance was uncovered until a recent geophysical survey.

- **June 2000** (Planning Ref: S/00/1140) archaeological monitoring of extension to an existing warehouse (IE1).
- **May 2001** Archaeological monitoring under licence (01E1111) in southwest area of complex.
- **November 2001** (Planning Ref: S/01/3362) archaeological monitoring (01E1111). Construction of an electrical distribution building & material store, extension to Drum store & an environment treatment building.
- **July 2002** (Planning Ref: S/01 5197) archaeological monitoring (01E1111). Construction of office building & laboratory.
- **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 testing or monitoring.
- **May 2004** 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. 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.
- **November 2011** Geophysical survey (11R0150) was carried out by Target Geophysics on an area outside of and to the east of the proposed development. A circular ditched enclosure and some other anomalies were identified.

Cartographic sources indicate the area of the proposed development works has been under agricultural use since the mid 19th century. The 1842 (Fig. 4), 1902 and 1939 (Fig. 2) 6" OS maps show the area laid out as generally reasonably sized, rectangular fields. The 25" OS map of 1888-1913 shows the same picture. 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.

15.3.3 Archaeological Monuments in the vicinity of the site

There are four archaeological sites listed in the RMP in the Lilly land ownership and there are two other sites adjacent to Lilly land. These are shown on **Figures 15.1** and **15.2**. The four monuments within the complex are a bullaun stone (CO111-034), a fulacht fiadh (CO111-035), a souterrain (CO111-085) and a possible ringfort (CO111-089). The bullaun stone, fulacht fiadh and souterrain are published in the Archaeological Inventory for County Cork Vol. 2 – East and South Cork (see **Appendix A15.2**). The possible ringfort (CO111-089) is mentioned in the Files of the Archaeological Survey of Ireland (**Appendix A15.3**).

The souterrain (CO111-085) was located in the area of the main carpark for the factory and was investigated at the time of construction. No surface evidence of it now survives. The bullaun stone (CO111-034) is located in the reception area of a main Lilly administration building. According to the Archaeological Inventory (**Appendix A15.2**), the possible fulacht fiadh (CO111-035) was in reclaimed land east of the stream and there was no visible surface trace of the feature. This area has not yet been developed by Lilly.

The possible ringfort in Ballythomas East (CO111-089---) is not included in the Archaeological Inventory for Cork Vol. II – East and South Cork (Power 1994) or Volume V (Ronan *et al* 2009). There is no visible surface trace of this site and it is described as follows in the files of the Archaeological Survey of Ireland:

In gently undulating land on valley floor. No evidence of ringfort here. Surviving fence line to E of site is straight with angular bend rather than curving. Unlikely to have been ringfort.

Two other recorded archaeological sites lie outside but in close proximity to the Lilly complex. These are a graveyard (CO111-033---) in the townland of

Horsehill More (North) and a possible fulacht fiadh (CO111-090---) in the townland of Ballyvrrin Lower. The possible fulacht fiadh lies just east of the proposed development works area. It is not included in the Archaeological Inventory for Cork Vol. II – East and South Cork (Power 1994) or Volume V (Ronan *et al* 2009). It is described as follows in the files of the Archaeological Survey of Ireland:

On undulating ground on valley floor. No site located. Area where site is marked on working map is one of a number of undulations in the area. Soil slightly darker, but no burnt stone. Most likely not a Fulacht fiadh.

A Geophysical Survey, carried out by Target Archaeological Geophysics (2011: License No. 11R0150) in a field at the eastern end of the Lilly lands (not forming part of this planning application) identified a circular ditched enclosure. This is most likely to have been a ringfort, dating to the Early Medieval period. It is not visible on the ground nor is it marked on any of the OS maps and it is not visible on any of the available aerial photographs of the area.

There are also a number of recorded archaeological monuments within the wider area surrounding the proposed development site. All relevant archaeological monuments have been detailed in **Appendix A15.2** and **Appendix A15.3**.

An archaeological and historical overview of the area within a 2km radius of the proposed development shows that the earliest evidence for human activity in the region dates to the Bronze Age (c.2400-500BC) (**Appendix A15.1**). The study area has been occupied, used and constantly altered since its earliest occupation up to the present time.

The recorded location of the 1601 Battle of Kinsale, where the Gaelic forces were routed by a numerically weaker English detachment is in the Millwater Ford area, c. 1.8km to the southeast of the development site. It has been noted that there is the potential for carrying out a systematic metal-detecting survey at the battlefield site but that such work becomes problematic in the surrounding area as equipment and projectiles would be more spread out (Shiels 2004, 347). The battlefield site at Millwater Ford is not listed in the RMP for Co. Cork. Sheils (2007, 4-7) has suggested an alternative site for the major engagement following the discovery of a map in Trinity College. The Kinsale Battlefield Project was set up in 2001 with the aim of locating all the battlefield sites associated with the Battle of Kinsale in 1601. Following further analysis of the available literature, contemporary eyewitness accounts and the Trinity map, Sheils has concluded that the battle may have taken place near the village of Dunderrow. It is possible, therefore, that some part of the battle may have happened within the proposed development site although to date no such evidence has been found.

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'.

There are no archaeological finds documented in the archives of the National Museum of Ireland for the area of the proposed development (**Appendix A15.4**).

The 1st edition Ordnance Survey (OS) map of 1842 as shown on **Figure 15.3**, shows a house (Ballythomas) and its farm buildings almost centrally located within the Lilly landownership. A roadway/avenue runs from the south side of the house southwestwards to the Kinsale to Inishannon road and another runs from the north side of the house northwestwards 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 and associated development are shown as fields with a stream flowing southwest though the land from the eastern boundary of the Lilly lands. The stream flows along the townland boundary between Ballythomas West and Ballythomas east along the eastern end of its course but further to the west it flows a short distance south east of this boundary.

The 2nd edition OS map of 1902 as shown on **Figure 15.4** 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. The house is named as 'Ballythomas House' and the roadways/avenues run southwest and northwest from it. The ground to the south and northwest of the house is depicted as marshy. The junction of the secondary road at the north of the house and the main Kinsale to Inishannon road is marked as 'Dunderrow Cross Roads'. The areas of the proposed IE43 and associated development are shown as fields. The course of the stream has been moved a short distance to the northwest to align with the 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 1938 as shown on **Figures 15.1** and **15.2** depicts a similar topography to the 2nd edition map. The stream is shown running from northeast to southwest along the southern townland boundary with marshy ground shown adjoining it in places. Watercourses run along the field boundaries to the northeast of the house. The areas of the proposed IE43 and associated development are shown as fields.

15.3.4 Architectural Heritage

Within the extent of the Lilly land ownership, no features of architectural merit have been recorded by the current record of protected structures (RPS) for the area in the Cork County Development Plan 2009. The nearest protected structure to the proposed development is that of White Castle (RPS no 00717) in Ardcloyne located approximately 1.8km to the southeast of the site. Similarly, there are no architectural conservation areas (ACAs) in the area. The nearest architectural conservation areas are in Bandon town.

15.3.5 Field Inspection

Sheila Lane (Lane Purcell Archaeology) visited the site in May 2011. The site of the proposed IE43 facility consists of an area steeply sloping downhill to the east. Ground levels have been raised within parts of this area in the recent past by the introduction of soil and excavated material from previous construction projects within the Lilly site. In other areas ground levels have been reduced to provide a level surface.

No finds or features of archaeological interest were noted during the site inspection.

15.4 Characteristics of the IE43 Facility

The new IE43 facility will provide production capacity for biotech products at the Kinsale plant. The proposed development area comprises the easternmost end of the Lilly property sloping downhill roughly north-south to a west-flowing stream, the area on the south bank of the stream and portions of four fields on the south side of the stream where soil will be placed as part of landscaping proposals. A section of the stream to the east of the existing bridge will be diverted. Refer to **Figures 3.2 and 15.4**.

The northern side of the stream may be divided into 4 areas as shown on **Figure 15.4**. Area 1 comprises a field in pasture. Geophysical Survey (10R0171) and archaeological testing (11E0115) were carried out in this area in the recent past and no features of archaeological significance were identified. Refer to **Appendix A15.5** for a copy of the archaeological testing and geophysical survey report.

Area 2 comprises a uniform raised area where soil from a previous development has been stored and topsoil was removed from this area in advance of this work. It is proposed to remove this soil as part of the proposed development. No archaeological intervention has taken place in Area 1. Refer to **Figure 15.5**.

Area 3 comprises a levelled compound where the ground has been disturbed by cutting and filling. No archaeological intervention has taken place at this part of the site. Refer to **Figure 15.6**.

Area 4 comprises a levelled compound on the north side with a fenced off building (part of the Lilly facility) and piled soil on the south side. Licensed archaeological monitoring was carried out on this part of the site in 2008 (License No. 07E0860) and nothing of an archaeological nature was noted. Refer to **Figure 15.6**.

Area 5 is a level area where it is proposed to erect cooling towers. This area was investigated under licence (03E0573) in April 2003. It now comprises a level grassed area.

A geophysical survey and archaeological testing were carried out in the sections of the site indicated on **Figure 15.4** as a temporary car park and a contractors laydown. No features of archaeological significance were identified. It is proposed to undertake landscaping in three fields to the south of the stream. Refer to **Figure 15.4**. Archaeological monitoring in all of these fields (Fields 1, 2 & 3) was carried out in 2008 during landscaping works as part of the construction of IE42 and no finds or features of an archaeological nature were noted. There is a possible

ringfort (CO111-089---) at the eastern end of Field 2. This site was first noted as a possible kink in a field fence on an aerial photograph (suggesting that it might be the eastern side of a ringfort) and it was added to the RMP. When the site was inspected by the Archaeological Survey of Ireland the fence was found to be angled and it was noted that this was 'unlikely to be a ringfort'. A more recent inspection and report by Lane Purcell Archaeology has also concluded that it is not a ringfort. An application has been made to the Department of Arts Heritage and the Gaeltacht to have the status of the site reviewed in order that it may be removed from the next publication of the RMP. A fence currently runs through the RMP site and a metalled track runs outside the fence connecting the Lilly plant by a bridge over the stream to the four fields.

The stream which runs southwest from the eastern boundary is to be diverted to the southeast for a distance of 243m into an area which was not accessible during the site visit. The diverted route of the stream will run adjacent to the northeastern boundary of Field 3 in an area which is depicted as marshy on the 1902 and 1938 OS maps.

15.5 Predicted Impact of the Proposed Development

The proposed development will not impact on any known sites of archaeological or cultural heritage significance.

The closest recorded sites to the proposed development works area are a possible ringfort (CO 111-089---) and a possible fulacht fiadh (CO111-090---). Both sites are described as unlikely to be archaeological sites in the files of the Archaeological Survey of Ireland and neither are therefore, included in the archaeological inventories for County Cork. The possible ringfort lies within the Lilly lands and the possible fulacht fiadh lies outside and to the northeast of these lands. The proposed development will not impact on the possible ringfort or the possible fulacht fiadh. As stated earlier, Lilly are currently preparing an application to the Department of Arts, Heritage and the Gaeltacht to have this site delisted as an RMP.

There are no protected structures within the area of the proposed development works.

A significant amount of archaeological investigation has been undertaken in the Lilly complex since it was opened thirty years ago. Other than the souterrain which was found during the initial site development, no features or finds of archaeological significance were identified during these investigations. Much of the land to be impacted by the current proposed development has been subject to archaeological investigations in the more recent past. Areas 1, 4 and 5 on the north side of the stream and Fields 1, 2 and 3 on the south side of the stream have been archaeologically tested or monitored since 2007 (Geophysical Survey 10R171, Testing 11E115, Testing and monitoring 07E860). Refer to **Figure 15.4**. The proposed development will not, therefore, impact on any known or unknown archaeology in Areas 1, 4 and 5 on the north side of the stream. Area 3 has been levelled in the recent past without archaeological intervention and it is likely that all known and unknown archaeology was removed. Soil has been stored in Area 2 and the topsoil was removed here in advance of storage. It is likely that the known and unknown archaeology in this area has been removed during this process. There will, therefore, be no impact on known or unknown archaeology in Areas 2

and 3. The area of the stream and its proposed diversion route were not available for inspection at the time of the site visit. The proposed diverted route of the stream is adjacent to the eastern side of the possible ringfort (CO111-089---) and the western side of the possible fulacht fiadh (CO111-090---). No archaeological investigation has previously been undertaken in this area and it is possible that previously unrecorded archaeological features may be present here. Given the marshy nature of the land (as depicted cartographically) it is possible that features associated with wetland environments such as fulacht fiadh or burnt mounds may be present. According to Target Archaeological Geophysics, this area is not suitable for geophysical survey.

On the south side of the stream the possible ringfort (CO111-089---) which is located north of Field 2 will not be impacted by the proposed development. An application has been made to the Department of Arts Heritage and the Gaeltacht to have the status of the site reviewed in order that it may be removed from the next publication of the RMP. It is hoped that its status will have been reviewed by the DAHG in advance of the development and that it will be removed from the next publication of the RMP.

15.6 Mitigation Measures

Extensive archaeological investigations have taken place on the Lilly site over the past eleven years and no archaeological finds or features have been uncovered. The most recent investigations comprised a geophysical survey followed by archaeological testing at the northern end of the site in Area 1. No features were identified during these investigations and no further archaeological intervention in this area is required. Likewise no further investigation is required in Areas 1, 4 and 5. Given that disturbance has taken place in the remaining Areas 2 and 3 it is unlikely that any archaeology is present in these areas and so no further intervention is required in these areas.

The existing route of the stream will be waded and metal detector surveyed in advance of proposed stream diversion works, following consultation with the National Monuments Service, Department of Arts, Heritage and the Gaeltacht. The adjoining land which was not accessible during the site inspection will be inspected and following consultation with the National Monuments Service, Department of Arts, Heritage and the Gaeltacht and Cork County Council archaeological investigation carried out. According to Target Archaeological Geophysics, this area is not suitable for geophysical survey. Archaeological testing will be carried out on this area. In the event of archaeological material being uncovered such material will be preserved in situ, or where possible, preserved by record following consultation with the National Monuments Service, Department of Arts, Heritage and the Gaeltacht. Preservation in situ will require the relocation of the element of the development beyond the area of archaeological sensitivity identified during archaeological testing. Preservation by record will require the excavation of the archaeological material identified during testing, such material will be fully resolved to professional standards of archaeological practice (Policy Guidelines on Archaeological Excavation – Department of Arts, Heritage, Gaeltacht and the Islands). This work will be funded by the developer.

15.7 Residual Impacts

No residual impacts are envisaged as all archaeological, architectural and cultural heritage issues will be resolved at the pre-construction and construction stages of the development.

15.8 References

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16 Material Assets

16.1 Introduction

In this section, the impacts which the proposed IE43 facility will have on material assets, including existing services, utilities, resources and material assets are evaluated.

16.2 Common Site Utilities

16.2.1 General

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

- Glycol (4°C) heat transfer medium
- Glycol (50°C) heat transfer medium
- Cooling water
- Plant steam
- Water (potable and water for operations)
- Carbon dioxide gas (bulk tank)
- Oxygen gas (bulk tank)
- Purified water
- Water for injection
- Clean steam
- Compressed air
- Electric power

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

- Steam
- Water
- Electric power

16.2.2 Steam

A new branch will be installed on the existing steam generation header from which a new steam line will be extended through the site on piperacks to IE43.

16.2.3 Water

16.2.3.1 Water Sources

The site has two sources of supply water. There is a municipal supply of potable water and groundwater is pumped from a number of wells at various locations around the site. A significant portion of the plant's requirements is supplied by the wells, with the balance coming from the municipal supply. Historically, the wells have supplied 30m³/hour on average.

Approximately half of the 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 including as water for filter cake washing, final rinsing of vessels and lines. 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.

16.2.3.2 Water Consumption

The water consumption on the site in 2010 was as follows:

Groundwater	276,461m ³
Municipal supply	126,117m ³
Total	402,578m ³

Water usage on site has been declining. In 2006 for example, the total water consumption was 488,608m³. There was an increase in 2010 mainly due to the commissioning of the new IE42 facility which has a significant water demand due to its water based production processes and the level of cleaning required to maintain regulatory clean room standards.

It is envisaged that the IE43 process activities will require approximately 148,500m³/year (400m³ per day), thereby increasing overall water consumption to 551,078m³ per annum (1500m³ per day). The water supply will be provided by existing council water supply (up to 500m³/day) and on site abstraction wells, including commissioning of four new wells and reactivation of two existing wells. Refer to Chapter 14 of this EIS for details of the proposed groundwater development.

The drawdown from the additional wells is unlikely to impact on surface water and surrounding off site wells.

16.3 Energy

16.3.1 Electricity

The site has a 38kV connection to the national power grid. In 2010, the site consumption of electricity was 52,339MWhr. This was an increase on the 2009

figure, which can be attributed to the additional power demand of the new IE42 production facility.

The estimated electrical load for IE43 facility will be 18,308 MWhr. There is sufficient capacity in the existing power supply to the site to cater for this demand. During construction, existing electrical services will be utilised with the exception of some portable welding plant.

16.3.2 Fuel

Currently the Lilly site boilers are fuelled by natural gas. Natural gas is used on site currently as the fuel for the incinerator and thermal oxidisers. Diesel is used for the emergency generators, some fork-lift trucks and the firewater pumps.

In 2010, the site used 4,525m³ of heavy fuel oil and 1,870m³ of diesel.

The fuel demands of the site show an increase on the 2009 figures attributed mainly to site expansion activities resulting in additional heating costs. The estimated annual increase in HFO fuel consumption due to the IE43 facility would be 427,800 litres which would be 10.6% over 2010 usage. However, natural gas has now replaced HFO on site.

The forecast natural gas usage for 2012 is circa 86 GWh. This is expected to reduce to circa 66GWh in 2015 as production on the existing Lilly site reduces. The proposed IE43 is forecast to increase natural gas demand by circa 50GWh. Hence, due to reduced production in the existing site there will be no net increase in natural gas usage.

16.4 Process Effluent

The generation, treatment, monitoring and discharge of process effluent is addressed in Chapter 11: *Effluent Generation and Treatment*.

16.5 Identification of Potential Impacts

No significant impact on material assets is predicted as a result of the proposed development.

16.6 Proposed Mitigation Measures

The design for the IE43 biotech project has specifically 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.

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

Lilly Annual Environmental Report, 2010

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 IE43 project development. This chapter also addresses environmental effects which have not been specifically addressed in the individual chapters of the EIS.

Only topics that 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 General

The requirement to address cumulative impacts, indirect impacts and interactions of effects comes from the Regulations and Environmental Impact Assessment directive 85/337/EEC as amended by 97/11EC and 2003/35/EC. Schedule 6 of the Planning and Development Regulations 2001, which mirrors Article 3 of the Environmental Impact Assessment directives, specifies the information to be contained in an EIS, including the information listed below (emphasis is the author's):

“A description of the aspects of the environment likely to be significantly affected by the proposed development, including in particular:

- Human beings, fauna and flora
- Soil, water, air, climatic factors and the landscape
- Material assets, including the architectural and archaeological heritage, and the cultural heritage and
- The inter-relationship between the above factors.”

*“A description is also required of the likely significant effects (including **direct, indirect, secondary, cumulative**, short, medium and long-term, permanent and temporary, positive and negative) of the proposed development on the environment resulting from:*

- The existence of the proposed development
- The use of natural resources.”

17.3 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 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 IE43 biotech manufacturing facility, 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.

The views of the statutory bodies and others, obtained during the EIS scoping and consultation process, were addressed. Reference was also made to the EPA Guidelines and, in particular, to the guidance given for the preparation of an EIS, in the EPA's *Advice Notes on Current Practice (in the preparation of Environmental Impact Statements)*, for the following project type:

Project Type 7 – Installations for the production of pharmaceutical products using a chemical or biological process.

17.4 Definitions

There are no generally agreed and accepted definitions of indirect impacts, cumulative impacts or inter-relationship of impacts.

The EPA Guidelines define cumulative impact thus: *The addition of many smaller impacts to create one larger more significant impact.*

The EPA Guidelines 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.*

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.

17.5 Effects in Other Environmental Media

17.5.1 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 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 ‘CO’ 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 of the EIS.

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Table 17.1 Potential Interaction of Effects Matrix (C = Construction, O = Operational)

	Noise and Vibration	Air Quality	Climate	Landscape And Visual	Archaeological Architectural & Cultural Heritage	Human Beings	Material Assets	Flora and Fauna	Soils & Geology	Surface Water & Ground-water	Road Network & Traffic
Noise and Vibration	-	-	-	-	-	CO	-	CO	-	-	-
Air Emissions	-	-	CO	-	-	CO	-	-	-	-	-
Emissions to water	-	-	-	-	-	-	-	CO	-	-	-
Landscape and Visual	-	-	-	-	-	CO	-	-	-	-	-
Archaeological Architectural & Cultural Heritage	-	-	-	-	-	-	-	-	-	-	-
Human Beings	-	-	-	-	-	-	-	-	-	-	CO
Material Assets	-	-	-	-	-	CO	-	-	-	-	-
Flora & Fauna	-	-	-	-	-	-	-	-	-	-	-
Soils & Geology	-	-	-	-	-	-	CO	-	-	CO	-
Traffic	CO	CO	CO	-	-	CO	-	-	-	-	-

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17.5.2 Potential Effects in Different Media

The impacts of noise and vibration during construction and operation on human beings and fauna are addressed in **Chapter 9, *Noise and Vibration***. Mitigation measures are proposed to ensure there will not be a significant impact.

In **Chapter 10, *Air Quality and Climate***, the potential effects of air emissions from the facility, including emissions from traffic, on human beings and the climate during the construction and operation phases are addressed. The assessment concluded there would not be a significant impact.

Emissions to water are described in **Chapter 11, *Effluent Generation and Treatment***. The potential impacts are addressed and mitigation measures are proposed to ensure there will not be a significant impact.

Landscape and Visual Impact was addressed in **Chapter 7**. 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. The IE43 building will be set into the landscape, will display colours/textures that assist its blending into the landscape, and only the upper parts will be visible and always against a backdrop of existing vegetation or buildings.

The main effect of the development on human beings will be increased employment and economic activity, which is not expected to lead to a significant impact on other media. This is addressed in **Chapter 6, *Human Beings***.

Impacts on Material Assets are addressed in **Chapter 16**. The interaction of impacts between material assets and the other environmental media are addressed in the individual chapters.

The soils and geology of the site have the potential to interact with human beings and surface water and groundwater. These issues are addressed in **Chapter 14, *Soils, Geology, Surface Water and Groundwater***. There is not expected to be a significant impact on other media.

Chapter 10, *Air Quality and Climate*, **Chapter 9, *Noise and Vibration***, and **Chapter 8, *Roads and Traffic***, address the effects which traffic from the construction and operational phases will have on air quality, the noise environment and human beings, respectively. Traffic from the proposed IE 43 project is not expected to have a significant impact.

17.6 Indirect Effects

No significant indirect effects are expected from the proposed IE43 project.

17.7 Cumulative Impacts

The cumulative impacts of the proposed IE43 project have been addressed in the relevant chapters of the EIS. Where relevant, the impact of the proposed IE43 development has been combined with the impact from the existing Lilly plant to determine the cumulative impact on the project.

To determine traffic impacts in **Chapter 8 Roads and Traffic**, the additional traffic generated by the proposed development, at the existing Lilly facility is combined with the baseline traffic generated by the existing users of the road network in the area. Thus, the cumulative traffic impacts are assessed and determined to be insignificant.

For the noise impact assessment in **Chapter 9, Noise and Vibration**, the noise emissions from the proposed IE43 project, during construction and operation are combined with background noise levels to determine the impacts. The resultant cumulative noise impact will not be significant at the closest noise sensitive locations to the proposed facility.

17.8 Other Impact Headings

In this EIS only topics that could logically be linked to the development have been examined in detail. Accordingly, when a topic is not mentioned, the author has concluded that no potential for impact exists.

17.8.1 Amenity

The impact of the proposed development on the amenities of the area has been addressed in a number of sections of this EIS.

Land use and amenity are addressed in **Chapter 6 Human Beings**. The impact of the development on traffic is described in **Chapter 8 Roads and Traffic**. The impact of the development noise and air quality is assessed in **Chapters 9 and 10** respectively. **Chapter 7 Landscape and Visual Impact** addresses the impacts of the proposed development on the landscape character of the site.

17.9 References

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

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

18 Summary of Impacts and Mitigation Measures

18.1 Introduction

This section summarises the potential environmental effects associated with the IE43 project at the Lilly site in Dunderrow, Kinsale. It lists the potential impacts associated with the physical presence of the project, atmospheric emissions, solid wastes and effluent emissions for both the construction and operations phases, and the proposed mitigation measures. For impact significance criteria refer to **Appendix A1.1**.

Table 18.1 (Sheet 1 of 5) Assessment of Potential Effects and Mitigation Measures

Source / Scale of Effect	Control and Mitigation	Environmental Consequence Significance Level
CONSTRUCTION PHASE		
Site Clearance and Preparation		
Moving of spoil deposited at IE43 site and re-depositing at another location Importation of equipment Noise from construction activities Vehicle and plant emissions	Construction traffic management plan Dust control measures Wheel wash - mud control measures Measures for control of rainwater and mud run off Measures for storage of fuels etc on site Reuse of spoil on site where feasible	Moderate Temporary increase in traffic in the vicinity of the site Temporary noise associated with construction machinery on site Re-use of spoil for landscaping at another location within the site
Generation of Waste		
Primary waste sources during construction: Construction waste Sewage Domestic type waste Disposal of waste will use up landfill space. Transport of waste will generate greenhouse gases	Construction waste management plan to minimise waste generation Disposal of sewage to site wastewater treatment system	Moderate Material not suitable for reuse will use up landfill space
Noise and Vibration		
Principal sources of noise and vibration: Earthworks plant and equipment Construction plant and equipment Construction traffic	Noise control measures in accordance with BS 5228	Slight Temporary slight increase in noise levels during the construction phase

Table 18.1 (Sheet 2 of 5) Assessment of Potential Effects and Mitigation Measures

Source / Scale of Effect	Control and Mitigation	Environmental Consequence Significance Level
Air Emissions		
Emissions from construction plant and vehicles Emissions from construction traffic Dust from movements on site in dry windy weather	Construction traffic management plant Plant and vehicles serviced regularly to minimise emissions Dust control measures	Imperceptible Very localised and temporary decrease in air quality in vicinity of vehicles and plant but well within air quality standards.
Climate		
Greenhouse gas emissions from construction plant and vehicles Greenhouse gas emissions from construction traffic	Construction traffic management plant Plant and vehicles serviced regularly to minimise emissions	Negligible No significant impact predicted
Soils, Geology, Surface Water and Groundwater		
Rainwater runoff which could contain silt Leaks or spills of fuel or lubricant from plant and equipment	Measures for control of rainwater run off Plant and vehicles serviced regularly to minimise leaks Fuels and lubricant stored in bunded areas Refuelling of plant in controlled areas only	Negligible No emissions expected to local watercourses, soil or groundwater
Flora and Fauna		
Site clearance will result in minimal loss of existing vegetation Re-deposition of spoil at another location within the site will result in loss of existing vegetation and impact on stream banks Construction operations will disturb fauna Diversion of section of stream	Measures for control of rainwater run off Measures to protect stream New section designed and constructed to provide replacement habitat for fish and invertebrate communities	Negligible Habitats cleared have low ecological value Habitats at areas to be landscaped have low ecological value
Archaeology, Architecture and Cultural Heritage		
Site clearance Re-use of spoil for landscaping at another location within the site Stream diversion	Archaeological testing at stream diversion area and spoil landscaping Wading and metal detector survey of stream in advance of proposed stream diversion works	Negligible No impact expected
Visual Impact		
Construction will require large cranes and other plant on site	None	Negligible No impact expected
Employment		
Average of 450, up to 550 jobs on site and additional jobs in off-site suppliers	None	Significant Beneficial Positive effect on employment

Table 18.1 (Sheet 3 of 5) Assessment of Potential Effects and Mitigation Measures

Source / Scale of Effect	Control and Mitigation	Environmental Consequence Significance Level
Impact on Local Residents		
Presence of construction operation	Careful management of site operations Construction noise	Slight No significant impact
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	Moderate Resource use will be typical for the type and size of project
Traffic		
Increased traffic during construction phase	Construction management plan Timing of extra large loads travelling by road	Negligible No significant impact predicted
OPERATIONAL PHASE		
Noise and Vibration		
Plant Operation	Noise controlled in accordance with IPPC licence	Negligible No significant impact predicted
Process Wastewater and Storm Water Emissions		
Additional organic and inorganic effluent	Organic and inorganic process wastewater treated and monitored before discharge to outfall, in accordance with IPPC licence Storm water monitored prior to discharge to stream Fire water containment	Negligible No significant impact predicted
Air Emissions		
Principal sources of air emissions are: Existing combustion processes (operation of boilers/incinerator and RTO) Building ventilation Traffic emissions	Energy efficient plant and equipment Use of BAT in treatment of emissions	Negligible No significant impact predicted
Climate		
Emissions of greenhouse gases	Energy efficient plant and systems Energy recovery from incinerator and RTO	Negligible No significant impact predicted

Table 18.1 (Sheet 4 of 5) Assessment of Potential Effects and Mitigation Measures

Source / Scale of Effect	Control and Mitigation	Environmental Consequence Significance Level
Flora and Fauna		
No effects	No mitigation necessary	Negligible No significant impact predicted
Waste Management		
Increased volumes of hazardous waste Increased volumes of non-hazardous waste	Waste minimisation Segregation of wastes to facilitate recycling Upgrade of incinerators for increased capacity to treat waste on site. Use of licensed waste management service providers	Slight Increased volumes of material sent off-site for recycling, recovery or disposal
Soils and Geology		
Increase site activities leading to marginal increased risk of spills and leaks	No emissions to ground Storage of liquids in bunded areas Fire water containment	Negligible No significant impact predicted
Surface Water and Groundwater		
Increase site activities leading to marginal increased risk of spills and leaks Additional groundwater abstraction	No emissions to ground Storage of liquids in bunded areas Baseline monitoring of levels in stream and ongoing monitoring of groundwater monitoring wells	Negligible No significant impact predicted
Archaeology, Architectural and Cultural Heritage		
No effects predicted	No mitigation necessary	Negligible No significant impact predicted
Visual Impact		
Primary visual features are: New buildings	Apparent mass minimised as a result of architectural detailing, construction materials and colour treatment	Slight Slight impact on some views
Material Assets		
Increased consumption of energy, natural gas, potable water, and electricity	Process water reuse where feasible Energy efficient electrical equipment	Slight Increased consumption of energy and water resources
Traffic		
Change in traffic patterns between site entrances	No mitigation required	Negligible No significant impact predicted

Table 18.1 (Sheet 5 of 5) Assessment of Potential Effects and Mitigation Measures

Source / Scale of Effect	Control and Mitigation	Environmental Consequence Significance Level
Employment		
Secure existing employment on site and increase in numbers of secondary jobs created in the wider economy Secures future of existing plant	No mitigation required	Significant Beneficial Improvement in employment rates in general area
Impact on Local Residents		
Greater site activity	Careful plant management Good house-keeping	Negligible No significant impact predicted
Wider Community		
Greater availability of important pharmaceutical products Lilly's support for and contribution to community activities	No mitigation required	Moderate Beneficial

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