

This Report has been cleared for submission to the Board by Senior Inspector, Sean O'Donoghue,

Signed: *Doogan Learey*

Date: 25/05/2016



OFFICE OF ENVIRONMENTAL SUSTAINABILITY

INSPECTOR'S REPORT ON A LICENCE APPLICATION

To: Directors

From: ORLA HARRINGTON

- LICENSING UNIT

Date: 25 MAY 2016

RE: Application for review of an Industrial Emissions Licence from ELI LILLY S.A., TRADING AS ELI LILLY S.A. – IRISH BRANCH Licence Register P0009-04

Application Details

Class of activity (First Schedule of EPA Acts 1992 as amended):

5.16: The production of pharmaceutical products including intermediates

11.2 (b) (c) & (e): Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving one or more of the following activities:

(b) Physico-chemical treatment

(c) Blending or mixing prior to submission to any of the other activities listed in paragraph 11.2 or 11.3;

(e) Solvent reclamation or regeneration.

11.3 (b): Disposal or recovery of waste in waste incineration plants or in waste co-incineration plants – For hazardous waste with a capacity exceeding 10 tonnes per day

11.6: Temporary storage of hazardous waste, (other than waste referred to in paragraph 11.5) pending any of the activities referred to in paragraph 11.2,

	<i>11.3, 11.5 or 11.7 with a total capacity exceeding 50 tonnes, other than temporary storage, pending collection, on the site where the waste is generated.</i>
Category of Activity under IED (2010/75/EC):	4.5, 5.1, 5.2, 5.5
Title of BREF Document (main):	<i>Reference Document on Best Available Techniques for the Manufacture of Organic Fine Chemicals</i>
Notice for the purposes of Section 82A(3) (IE transposition) of the EPA Act (as amended):	17 February 2014
CRO Number:	902873
Section 87(1)b notice issued	28 October 2011
Licence review form received:	17 August 2012
Section 90(7) notices issued:	28 October 2011, 08 March 2012, 11 October 2012, 23 January 2013,
Information under Section 90(7) received:	17 August 2012, 19 October 2012, 21 November 2012, 06 February 2013
EIS received:	17 August 2012 (revised 04 June 2015)
Notices under Regulation 10(2)(b)(ii) issued:	17 February 2014, 26 August 2015, 10 December 2015
Information under Regulation 10(2)(b)(ii) received:	04 June 2015, 19 October 2015, 22 April 2016
Submissions received:	12 September 2012
Site notice inspected:	13 August 2015
Site visit:	27 October 2015

1. Installation and applicant

Eli Lilly S.A., trading as Eli Lilly S.A. – Irish Branch (hereafter referred to as Lilly) is located, in Dunderrow, 17km south of Cork City and 4km northwest of Kinsale. It is a subsidiary of the Eli Lilly International Corporation which has its headquarters in Indiana, USA. The site covers an area of approximately 62.7 ha and was used primarily for agricultural purposes prior to its purchase by Lilly in 1981.

Lilly are engaged in the chemical manufacture of bulk pharmaceuticals including anti-depressant, ulcer treatment, cancer treatment, central nervous system disorders and antibiotic agents. While this focus continues on site, the installation is expanding to develop new medicines. In 2006, Lilly announced that the Kinsale site would become the main centre for manufacture and supply of active ingredients for its new biopharmaceutical medicines. Since then commissioning of a new biopharmaceutical

manufacturing plant (Building IE42) has been completed. In 2011 further expansion was announced with the addition of Building IE43, which will also be a cell culture based process.

Both IE42 and IE43 are three storey manufacturing buildings located at the north eastern part of the site, with IE43 located to the east of IE42. They have a combined ground floor area of approximately 29,330m² which serve as the utilities/services area. The upper floors are used in process and administration with scope for expansion if needed in the future. Both buildings comprise of 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 and utility support. Buildings IE42 and IE43 will be used to produce biotechnology products in bulk form, for the treatment of cancers and other ailments.

The site also consists of a range of support facilities including solvent storage, laboratories, warehousing, utility generation offices and cafeteria. Abatement equipment onsite includes two incinerators; two thermal oxidisers (one of which is on standby), two carbon absorbers, two wastewater treatment plants, solvent recovery plant (currently not in use) and one firewater retention pond.

This installation was first licensed by the Agency in 1995. Revised licences were issued in 2002 and 2005 to ensure compliance with the Council Directive on the incineration of hazardous waste (Directive 2000/76/EC), provide for an additional manufacturing building, additional boiler capacity and upgrading on site incinerators including the provision of heat recovery. The current licence (reg no. P0009-03) was technically amended on the 16 July 2007 to cater for a biopharmaceutical plant at the site (IE42). This involved amending the licence to take account of a heat treatment unit by virtue of the fact that it denatures active ingredients and other cell by-products. A further amendment issued on the 07 September 2010 which related to boiler emissions to air.

In 2011 the Agency initiated a review of P0009-03 under the European Communities Environmental Objectives (Surface Waters) Regulations 2009, SI 272/2009, as amended (hereafter referred to as Surface Waters Regulations) and the European Communities Environmental Objectives (Ground Water) Regulations 2010, SI 9/2010 (hereafter referred to as Groundwater Regulations). On the 06 February 2012 the Agency received a request for a licence review. This was on foot of an Agency decision that the proposed IE43 building expansion could not be accommodated under the existing licence or under the limited review scheduled under the EO Regs. The expansion was considered significant due to the fact that an Environmental Impact Statement (EIS) was submitted to Cork County Council in support of the planning application (ref: 11/06594).

On the 19 December 2013 the company was issued with an amendment to the licence under Section 82A (11) of the EPA Act 1992, as amended in order to achieve necessary conformity with the Industrial Emissions Directive (IED).

The site has been certified to the ISO 14001 Environmental Management Systems standard. The licensee is a legal entity of normal status and the associated company's registration office (CRO) number is 902873. The site is operated 24 hours per day 7 days per week and currently employee numbers are approximately 470 staff.

2. Reason for Licence Review

The purpose of this review of the licence is to achieve compliance under the Surface Waters Regulations and the Groundwater Regulations. In addition, the review proposes to allow the company to achieve the following aims:

- The operation of a new biopharmaceutical manufacturing facility (Building IE43).
- To revise the licensed site boundary.

The licensee proposes to extend the existing boundary of the installation to encompass an greenfield area of 44 acres to the east of the site as shown in drawing no IE0Y – A01-04-000049, revision 04, entitled *Eli Lilly Site Boundary & Surrounding Lands Dunderrow Kinsale* with the proposed additional land shaded in green (refer to appendix 1 of this report). The portion of land to be included in the site boundary may be used in the future to provide for additional expansion of production facilities but at present the licensee has confirmed that there is no plan for further development. Any further use of the proposed area will be subject to condition 1.4 (material change) of the licence. The site boundary change has been addressed through amending condition 1.3 of the RD.

- The licensing of two new main air emission points from a proposed gas fired combined heat and power plant (CHP) and boiler.
- The flexibility to use the scrubber (Sc-10) on the exhaust gases from the regenerative thermal oxidiser as required.
- Operation of the incinerators at a reduced temperature when the halogenated organic substance, expressed as chlorine, is $\leq 1\%$ of the hazardous waste content.
- Increase the pH range on the storm water discharge (SW3) from 6-9 to 6-10.
- In an effort to limit the need for possible future licence reviews retain emission limit values (ELVs) for three air emission points namely, A2-3 (Thermal incinerator), A2-4, A2-5 (carbon absorbers) that have been decommissioned and demolished in the RD for possible replacement units.
- To include a new class of activity (class 11.2(b)) to facilitate the on-going operation of an existing Nano-filtration plant.

There are no changes to waste generated on the site as a result of this review. The Agency approved a request to operate a Nano-filtration plant (ref: M726/ap03mo) on 11 March 2006 and its activity was covered under class of activity 11.1 (allowing the recovery or disposal of waste at an installation). The licensee has now reclassified this activity, following the transposition of the Industrial Emissions Directive 2010/75/EU, as requiring authorisation under Class 11.2(b) *Physico-chemical treatment*. The application of this technique allows active pharmaceutical ingredient to be removed from the waste water stream. BAT is to provide relief to the biological WWTP and the receiving waterbody from a poorly degradable load by the application of a separation technique e.g. membrane processes. At present, the plant is out of service but is being maintained for possible future use. The Class 11.2(b) activity is included in the RD.

Finally, the RD takes into consideration all changes at the installation that have been approved under condition 1 by the Office of Environmental Enforcement (OEE) since the last review in 2005 (P0009-03). All main emission points have been renamed in accordance with EPA guidance.

3. Process description

There are five main production buildings dealing with the bulk manufacture of human health drugs on the site, namely IE2, IE3, IE8, IE16 and IE30. This is the site's traditional business, and unit operations were outlined in detail in the previous licence application (P0009-03). These processes will not be amended by the licence review.

Biopharmaceutical commercialisation and supply (Building IE42 and IE43):

The installation uses GM cell lines, in particular Chinese Hamster Ovary (CHO) cells that are genetically modified to produce different proteins for medical uses. They are classified as Class 1 Genetically Modified Micro-organisms (GMMs) (activities of no or negligible risk) under EU GMO legislation. This technology has been used in the biopharma industry for over three decades with a history of safe use.

The manufacturing process starts by thawing vials (usually 1-2 ml) containing the GMM, inoculating their content into a series of shaker flasks (125ml to 3L), scaling up to glass bioreactors (12L) and seed bioreactors of increasing size (50L, 250L and 1000L) which are in turn used to inoculate large scale production bioreactors (>1000 litres). To ensure sterility the small scale GM culture inoculations are carried out in a bio-safety cabinet using aseptic techniques.

The cells are held in the production bioreactor, provided with oxygen and growth media and maintained at the desired pH, temperature, pressure and agitation for a multi week cell culture cycle to enable production of the desired protein. The growth media solutions are prepared by mixing a pre-purchased mixture of solids with water on a batch basis in a separate area. These solutions are transferred to the bioreactors on a predetermined schedule to support the growth of the cells at different volume stages.

Following production of the protein, the fluid is centrifuged to remove suspended solids and is then passed through retentive filters to remove residual cell debris. There are a number of chromatography purification steps to produce a purified concentrated product, which is then dispensed into suitably sized containers. The final steps are bulk filling and freezing prior to shipping off site for formulation into final product.

All atmospheric vents from the process equipment will be equipped with sterile vent filters capable of retaining particles smaller than 0.2micron in size.

Under normal operating conditions, there is no liquid waste from the bioreactors. Any in-process leaks, spills, cell contacted liquid waste that could potentially contain activated cells (from cell culture, harvest and equipment wash areas) is sent to a holding tank where it is heat treated for a set period of time (typically, $\geq 90^{\circ}\text{C}$ for ≥ 60 seconds) to inactivate the GMM cells prior to being pumped to the WWTP for further treatment. These inactivation parameters are established as part of a validation/verification system.

Liquid waste which does not contain cellular material (such as residual buffer, nutrient feed) is discharged directly to the WWTP. All contaminated solid waste including cells are sent off site for incineration. The processing of all liquid and solid biowaste is controlled by the GMO permit (licence register G0267-02). The RD takes account of the heat treatment for the inactivation of cells by validated means and specifies temperature as a control parameter in the licence schedule. The GMO permit requires the licensee to validate annually the chosen method of inactivation

under normal working conditions. Any breach of the GMO consent is immediately reported to the Agency in accordance with the provisions of the GMO (Contained Use) Regulations 2001 to 2010.

4. Planning Permission, EIS and EIA Requirements

4.1 EIA Screening

In accordance with Section 83(2A) of the EPA Act 1992, as amended, the Agency must ensure that before a licence or revised licence is granted, that the application is made subject to an environmental impact assessment (EIA), where the activity meets the criteria outlined in Section 83(2A)(b) and 83(2A)(c). In accordance with the EIA Screening Determination, the Agency has determined that the activities are likely to have a significant effect on the environment, and accordingly is carrying out an assessment for the purposes of EIA.

The EIS pertaining to planning ref: 11/06594 (pharmaceutical biotechnology manufacturing facility (IE43)) was submitted to the Agency with the licence application and was considered by the Agency for the purposes of EIA. Please refer to the EIA section (Section 13) of this report for further information and discussion on EIA.

4.2 Planning status

A number of planning applications have been made by the licensee for the site of the activity since 2005 (date of last review). Details of these planning applications and permissions have been provided in the licence review application form and are available to view on the Cork County Council website.

The licensee has provided a determination by Cork County Council that the CHP plant associated with the licence review is exempted development. There is a planning application in place for a new boiler (planning ref: 16/04799).

Cork County Council has determined that the development associated with planning application Ref: 11/06594 which is the development associated with the biopharmaceutical manufacturing facility (Building IE43), is likely to have a significant effect on the environment and that an EIA was required.

Cork County Council required an EIS in support of two planning applications. The applicant has submitted the most recent EIS required by Cork County Council. This EIS relates to planning permission ref 11/06594. Having reviewed the (planners) reports for previous planning permissions, it is considered that the EIS submitted with the licence application adequately identifies, describes and assesses the direct and indirect effects of the entire activity and that an EIS relating to previous planning permissions (ref: 079929) is not required for the Agency's assessment. Having specific regard to EIA, this report is intended to identify, describe and assess for the Agency the direct and indirect effects of the proposed activity on the environment, as respects the matters that come within the functions of the Agency, including any interaction between those effects and the related development forming part of the wider project, and to propose conclusions to the Agency in relation to such effects. The EIS submitted, the licence application, the submissions and observations received from third parties, the assessment(s) carried out by the planning authority, the relevant planning decisions and any additional information submitted by the licensee have been examined and assessed and are considered below for that purpose.

4.3 Content of EIS and licence application

I have considered and examined the content of the licence application, the EIS and other relevant material submitted with it.

It was considered that the EIS and licence application did not adequately address the following areas and this information as requested under Regulation 10(2)(b)(ii) of the EPA (Industrial Emissions)(Licensing) Regulations 2013:

1. Full description, including design specification and projected emissions from the CHP plant and additional boiler.
2. List of all planning permissions relating to the site, clarification as to whether EIS was required, confirmation in writing from planning that an EIS was not required.
3. Provide a revised site boundary to clearly identify the proposed extension to the existing licensed site boundary.

On receipt of further information under Regulation 10 of the Licensing Regulations, all of the documentation received was examined and I consider that the information as submitted contains a satisfactory description of the project, the alternatives studied by the licensee, the aspects of the environment likely to be significantly affected by the activity, the likely effects of the activity on the environment, the forecasting methods used, the prevention and mitigation measures envisaged, the lack of difficulties and deficiencies encountered and a non-technical summary.

I consider that the EIS, when considered in conjunction with the additional material submitted with the application, also complies with the requirements of the *EPA (Industrial Emissions) (Licensing) Regulations 2013*.

I have considered and examined the documents furnished by Cork County Council in relation to the impacts assessed by it; in particular the planners report and the decision dated 20 March 2012 (ref 11/06594).

I have considered the issues that interact with the matters that were considered by the above authorities and which relate to the activity in Section 13 of this report. Having considered the application and EIS, the submissions by members of the public, the submissions of state and public authorities and the matters resulting from the planning authority, I consider that the likely significant effects of the activity on the environment are as set out in Section 13 below.

4.4 Consultation with Competent Authorities

Consultation was carried out between Cork County Council and the Agency as follows:

Table 1

Consultation	Date
Notice under Section 87(1I)(g)(i) issued:	28 November 2015 to Cork County Council 21 October 2015 to Cork County Council
Response to Section 87(1I)(g) Notice received:	05 December 2012 from Cork County Council 03 November 2015 from Cork County Council

Cork County Council did not provide any additional observations to the Agency on the licence application and EIS.

5. Submissions

One valid submission was received by the Agency in relation to the licence application.

This submission was received from Declan Hamilton, Principal Environmental Health Officer, Health Service Executive, Impact Building, Fr. Mathews Quay, Cork. In his correspondence, Mr Hamilton stated that '*during the operational phase of the development the noise from the facility must comply with IPPC licence limits*'.

Response: Standard noise conditions and emission limit values have been set in the RD, which provides for a noise survey to be carried out in accordance with Agency guidance. *Schedule B.4: Noise Emissions* of the RD sets daytime, evening and night time noise ELVs from the activity at noise sensitive locations. In view of that, if the activity is carried out in accordance with the RD and the conditions attached, the operation of the activity will not cause a noise nuisance. A noise modelling assessment of noise sources was carried out and indicated that there will be no additional impact by the expansion of the activities. Given the foregoing, it is not anticipated that there will be any breach of noise limits, day or night.

6. Consideration of Best Available Techniques (BAT) and BAT conclusions

Section 86A(3) of the EPA Act 1992 as amended, requires that the Agency shall apply BAT conclusions as a reference for attaching one or more conditions to a licence or a revised licence. BAT for the installation was assessed against the BAT Conclusions contained in the following documents:

- *BREF Document for the Manufacture of Organic Fine Chemicals (OFC) (August 2008)*
- *BREF Document on Best Available Techniques in Common Waste Water and Waste Gas Treatment / Management Systems in the Chemical Sector (Feb 2003 and Draft 2 of 2011)*
- *BREF Document on Best Available Techniques for Waste Incineration (2006)*

BAT was also assessed against the *BAT Guidance Note for the Pharmaceutical & Other Speciality Organic Chemicals (EPA 2008)*.

The assessment has demonstrated that the installation will comply with all applicable BAT Conclusion requirements specified in the above BREF Documents and BAT note. Regard was also had to relevant BAT Conclusions requirements for Environmental Management Systems set out in recently published Commission Implementing Decisions (CIDs).

I consider that the applicable BAT Conclusion requirements are addressed through: (i) the technologies and techniques as described in the application; (ii) the standard conditions specified in the RD; and (iii) where applicable, the inclusion of additional specific conditions.

In the absence of a CID or 'potential BAT' for the sectoral BREF, BAT associated emission levels (AELs), are taken from the current national BAT note for the sector (In this case the BAT Guidance Note for the Pharmaceutical & Other Organic Chemicals).

7. Emissions

7.1 Emissions to Air

7.1.1 Main Emissions

There are three boilers onsite, each with a thermal input rating of 7.2MW. A maximum of two boilers are operated at any one time. These boilers are operated on natural gas, discharge through one stack (A1-1) and are considered significant.

There is provision in the current licence for two incinerators (KEU and Thermall) to handle all onsite liquid waste. Process and scrubber exhausts are ducted from the production buildings and routed to the regenerative thermal oxidiser (RTO) for treatment. A back up RTO (Reeco 2) was installed in 2007 to increase the fume abatement reliability onsite. Continuous monitoring of relevant parameters is carried out on the individual exhaust gases from each unit as required by the licence before these gases are combined into a single emission that is vented through one stack.

Normal operation of the RTO assumes the presence of chlorinated solvents in the vapours being fed to the RTO, albeit intermittently, thus requiring the use of the scrubber 10 to remove acid by-products. A carbon adsorption system (separate to the carbon absorbers mentioned below) is available as abatement in the event that bypass of the RTO system is necessary. This abatement applies only to a specific chlorinated solvent vapour stream (dedicated to one priority production process). It is noted that the current licence does not provide for correct thermal treatment controls for the combustion of chlorinated solvents. In order to minimise the risk of dioxin formation, key criteria must be met which includes a 2 second residence time at 1100°C. This has been incorporated into *Schedule C: Control & Monitoring* of the RD. If $\leq 1\%$ halogenated organic substances, expressed as chlorine, are combusted this operating condition need not apply.

There is provision in the current licence to duct solvent emissions from a product that is no longer manufactured on site for treatment to carbon absorbers. These carbon absorbers have reached their end of life cycle and have since been demolished.

As part of the licence review, the licensee proposes to install two new main emission points (refer to table 2 below). The table also outlines the proposed renaming of emission points in accordance with EPA guidance.

Table 2: Emissions to Air

Current emission point ref no:	Description	Proposed emission point ref no:
	Current	
4-1	Onsite boilers	A1-1
7-1 (a)	Regenerative thermal oxidisers (Reeco RTOs)	A2-1
7-1(b)	KEU incinerator	A2-2
7-1(c)	Thermall incinerator ^{Note 1}	A2-3
A3-24, A3-30	Carbon absorbers ^{Note 1}	A2-4, A2-5
	Proposed	
	Combined Heat and Power (CHP) plant	A2-6
	Additional boiler ^{Note 2}	A1-2

Note 1: Emission points decommissioned and demolished but ELVs retained for possible future use

Note 2: Emission point is in place and may be operated once planning permission is granted.

Proposed CHP and Boiler

The licensee proposes to increase heat and electricity supply capability onsite, to cater for demand from the biopharmaceutical expansion, by installing a Combined Heat and Power (CHP) plant (emission point A2-6) and an additional boiler (emission point A1-2), both of which will operate on natural gas.

The CHP will have a nominal thermal input of 9.7MW, generating 4.4MW of electrical output and recovering thermal energy of up to 2MW of hot water and 2MW of steam. The licensee anticipates that commissioning of the CHP plant will begin sometime in 2016. The boiler has a thermal input of 7.2MW. The RD makes provision for the operation of the CHP and additional boiler by means of inclusion of emission points in *Schedule B.1 Emissions to Air*. Final installation details i.e. flow rates and details of emission were provided during the licensing process and the licensee undertook air dispersion modelling of all current and proposed main emissions to confirm that there will be no exceedances of air quality standards (AQS) for Nitrous oxides (NO_x) from the installation. This is discussed further under the heading *Impact of Air Emissions on the Receiving Environment*.

Directive (EU) 2015/2193 of the European Parliament and of the Council of 25 November 2015 on the limitation of emissions of certain pollutants into the air from medium combustion plants (MCP Directive) applies to combustion plants with a rated thermal input equal to or greater than 1MW and less than 50MW irrespective of the type of fuel they use. The deadline for applying the ELV of 190mg/m³ is 2025, however based on application information this ELV can be met for the CHP plant from date of grant of licence and this is reflected under condition 4 and *Schedule B* of the RD.

An ELV of 250mg/Nm³ NO₂ will be applied to the proposed boiler. This is based on modelling input and is within the BAT guidance range. However in line with the MCP Directive a limit of 200mg/l for NO_x will apply to the boiler from the 01 January 2025. The current licence contains ELVs for existing boilers and these will be retained in the RD.

The installation does not fall within the scope of Chapter III of the Industrial Emissions Directive (2010/75/EU) (or class 2.1 of schedule 1 of the EPA Acts 1992, as amended). The total rated thermal input on site once the CHP and additional boiler are operational will be approximately 38MW. The RD specifies that combustion of fuels at the installation shall not exceed a total rated thermal input of 50MW. Given that the rated thermal input of the installations boilers is in excess of 20MW, the installation is subject to the carbon emissions trading scheme (S.I. No. 437 of 2004). Lilly have been granted a greenhouse gas emissions permit by the Agency (no IE-GHG023-10352-4) (refer to section 9 of this report).

Impact of Air Emissions on the Receiving Environment

The Air Dispersion Modelling assessment was carried out using the AERMOD software to predict the ambient pollutant concentrations resulting from the proposed CHP and boiler emissions, as well as all major emissions at max. ELVs as proposed in the application. Five years of meteorological data (2004 – 2008) from the synoptic station at Cork Airport was assessed in the modelling analysis. Each individual met

data year was modelled and examined to ascertain which year resulted in the highest predicted process contribution (PC). The worst case was deemed to be 2008. For background air quality, the modelling used an average of 2008, 2009 and 2010 Agency air monitoring data (Zone D¹). The licensee conducted continuous air monitoring in 2006 and 2007 with average concentrations ranging from 4.9µg/m³ – 6.2µg/m³ for NO_x which was used in the model rather than EPA data. Building downwash effects have also been taken into consideration.

The dispersion model was used largely to predict the impact of emission of oxides of nitrogen resulting from the increased combustion sources onsite and the impact of this on the ambient air quality. All other main air emission limits remain unchanged since the previous licence review in 2005 which were reassessed in line with the Waste Incineration Directive 2000/76/EC (WID).

The modelling approach is based on the adoption of the following 'worst case' scenario:

- All main emission points operating simultaneously at the ELVs proposed in the RD, 24 hours a day, 7 days a week, and 365 days a year. The Thermal incinerator has been demolished but emissions were included in the modelling, as the emission point (A2-3) will be retained in the RD. Similarly, the emissions (A2-4 & A2-5) from the carbon absorbers are included.
- The licensee modelled the continuous operation of four boilers (proposed & current); in reality one boiler is always on standby.

The assessment was undertaken in accordance with the *EPA Air Dispersion Modelling from Industrial Installations Guidance Note (AG4), 2010*, which requires that the PC from the industrial installation is added to the background concentration (BC) to obtain the predicted environmental concentrations (PEC). In order to assess the impact, each PEC is compared with an appropriate environmental assessment level (EAL), which in this case is the Air Quality Standards 2011, SI 180 of 2011.

Table 3: Air Dispersion Model.

Parameter	Averaging Period	Process Contribution (µg/m ³)	Max PEC (µg/m ³) Predicted Environmental Conc. = Process contribution (PC) + Ambient Conc. (AC)	EAL (µg/m ³)	PEC as % of EAL
Nitrogen Oxides (as NO ₂)	99.8%ile hourly	169	175	200	87
	Annual	8	15	40	37.5

The annual and short term NO_x as NO₂ predicted environmental concentration (PEC) from the installation is 37.5% and 87% of the AQS respectively. The emissions from the site have been modelled based on worst case, although in all cases the actual

emissions from the installation are likely to be significantly less than these levels, based on previous AER reports. Since the previous review (2005) all onsite boilers have been upgraded to low NO_x units.

With regard to NO_x emissions, it is recommended that the licensee is requested to include NO_x emission reduction as part of their 'Schedule of Objectives and Targets' under condition 2 of the RD. The RD also requires the licensee to establish, implement and maintain a programme for monitoring and assessment of Nitrogen Oxides (as NO₂) concentrations in ambient air, within six months of date of grant of the licence. Given the conservative nature of the modelling, it is expected that this monitoring will demonstrate that the installation is not causing any breaches of the relevant AQS.

Modifications to Air Emissions

Request: the licensee proposes to operate the incinerators at a reduced temperature of 850°C when the halogenated organic substance, expressed as chlorine² is ≤ 1% of the hazardous waste content. This would be a new aspect to the operation of the abatement system. The current license (P0009-03) conditions relate to the incineration of waste at 1100°C only. The profile of solvent waste being generated on site is changing such that the halogenated content could be ≤ 1% for extended periods of time, depending on production schedules.

Recommendation: The use of operating temperatures in excess of those that are required for efficient destruction of the waste should generally be avoided. When the use of operational temperatures below the 1100°C (850°C as specified for ≤1% of halogenated organic substances) have been demonstrated to provide for similar or better level of overall environmental performance, the use of such lower temperatures is considered to be BAT. The RD permits the licensee to operate the incinerators under two modes of operation (i) to incinerate waste with > 1% halogenated organic substances, expressed as chlorine, at a minimum operating temperature of 1100°C with a minimum 2 seconds residence time, and (ii) to incinerate wastes with ≤1% halogenated organic substances, expressed as chlorine, at a minimum operating temperature of 850°C with a minimum 1 second residence time, subject to condition 3.16. This flexibility will minimise the requirement for auxiliary fuel.

Request: The normal operation of the RTO under current licence conditions assumes a presence of chlorinated solvent in the vapours being fed to the unit thus requiring the operation of a packed bed scrubber (scrubber 10) to remove the acidic by-products of combustion. As the process generating chlorinated vapours is no longer running continuously on site and will be phased out entirely in the coming years, the licensee proposes not to operate scrubber 10 when treating non-chlorinated vapour streams. The licensee anticipates that this will lead to significant energy savings on site.

Recommendation: The request will not make a substantial change to the nature or extent of the emission from the RTOs. Continuous monitoring is carried out on the exhaust gases emanating from the RTO prior to entering the stack for VOC's, HCL, NO_x and SO₂ which will continue whether the scrubber is offline or online. The current licence requires continuous monitoring of scrubber liquid. The RD includes an

² Halogenated organic compounds (AOX). AOX stands for 'adsorbable organically bound halogens' expressed as chlorine.

annotation under Schedule C to require monitoring of scrubber liquid only when scrubber 10 is in operation.

Further requirements in the RD

Solvent usage and Chapter V of the Industrial Emissions Directive

The use of solvents at the installation falls within the scope of Chapter V Annex VII³ of the IED 2010/75/EU as *manufacturing of pharmaceutical products*, where solvent consumption exceeds 50 tonnes/annum. The installation uses over 2000 tonnes of solvent annually. The Directive sets an ELV of 20mg/m³ TOC on waste gases for this activity (Activity 20). This limit is stipulated in the existing licence and will be retained in the RD. The requirements of other areas of Chapter V are included in the RD; fugitive emissions shall not exceed 15% of the organic solvent input per calendar year (condition 5), preparation of a solvent management plan (SMP) in line with Annex VII Part 7 of the IED, and replacement as far as possible of certain hazard statements by less harmful ones. For all main emissions potentially containing volatile organic compounds with specific hazard/risk phrases, the RD also specifies ELVs in accordance with the requirements of Part IV of Annex VII.

RTO bypass events

Any bypass of the RTO is dealt with in accordance with an OEE approved response procedure (Ref: KIN-ED-011). In 2006, the licensee got agreement from OEE to consider a bypass event as significant, hence reportable, when it exceeds certain criteria (Ref: P0009-03/ap08mo). Only bypass events greater than the thresholds agreed would be reportable to the Agency. Following consultation with OEE, condition 11.1 (ii) of the RD requires the licensee to notify the Agency of any bypass to atmosphere deemed significant in accordance with Agency Guidance. It should be noted that the Agency has recently published guidance to industry on actions required should breakdown or a malfunction occur relating to air abatement equipment entitled *Agency Protocol for the Bypass of Air Emissions Abatement Equipment V2 (May 2016)*. Condition 6.18 requires the licensee to maintain a detailed log of all bypass events, including date, time, duration, operational activities at the time of bypass and time taken to shut down all relevant processes.

Future Emission Points

Emission points with reference numbers A2-1, A2-3, A2-4 & A2-5 which are proposed for future use have been provided for in the RD. Those that have been decommissioned and demolished but the ELVs retained for possible future use (A2-3, A2-4 & A2-5) are one Thermall incinerator and two carbon absorbers. There is one emission point (A2-1) that relates to a boiler which has been installed but has not yet been granted planning permission (ref: 16/04799). All four emission points have been considered from an environmental viewpoint in this licence review and have been listed in the licence (condition 5.8) and in the licence schedules subject to the need for a technical amendment of the licence once planning permission has been obtained. Condition 6 of the RD requires a test programme for any new abatement equipment installed (incinerator, carbon absorbers) for main emissions to air to be conducted within three months of the commencement of operation of the abatement equipment.

³ Frequency asked questions from the European Commission on the wording and intent of the IED 2010/75/EU.

7.1.2 Minor Emissions

There are currently fifteen minor emission points on site namely exhaust fans and vent points on various production buildings. Biotechnology manufacturing is aqueous based and will not contribute to any significant increase in air emissions. All biowaste gas streams (e.g. CO₂ from microorganism respiration) are discharged directly to atmosphere via 0.2 micron microbial hydrophobic retentive HEPA filters. The RD requires that all emissions containing active ingredients shall pass through a HEPA filter prior to discharge.

7.2 Emissions to Sewer

There will be no emissions to sewer.

7.3 Emissions to Water

The following table summarises the emissions to water from the installation.

Table 4. Emissions to water

Current emission point ref no:	Source of emissions	Proposed emission point ref no:
6-1	Treated effluent from the site	SW1
W2	Wastewater from incinerator	SW2
W3	Site storm water runoff	SW3

Process Effluent

Process effluent arises directly and indirectly from manufacturing (equipment cleaning, floor washing etc.), utilities, sanitary, contaminated surface water, incinerator quench water and biowaste (growth media & chromatography elution materials). All wastewaters are segregated and routed appropriately for treatment based on characterisation. All biowaste (arising from Buildings IE42 and IE43) will be first treated in a thermal inactivation unit to render all cells inactive before being directed to the on-site biological WWTP, which can accommodate the additional loading. There are two WWTP's operating in parallel on site namely;

- a) Biological WWTP has a design capacity of 270m³/day and 476kg COD/day. The plant can be configured to provide treatment for up to 600m³/day containing up to 3,263kg COD. The current loads utilise approximately 14.6% organic capacity which will increase to 19.8% when the IE43 is operating at full capacity. Treatment consists of activated sludge treatment, including off gas and sludge management. Aqueous waters from process, utilities and sanitary are treated here.
- b) Incinerator Process WWTP treats quench water and scrubber blow down from the incineration process and is routed through a three step process based on maximum treatment capacity (design value) of 1600m³ per day. Treatment includes pH adjustment, two clarifiers operating in parallel and three sand filters are installed post clarifiers as polishing for further solid removal.

Waste water from the incineration activity is monitored separately for WID compliance before it joins the effluent from the biological WWTP in a final holding tank. Monitoring of the combined effluent occurs at the holding tank. The current licence sets limits for this discharge (SW1) including a volumetric flow limit of 3,000m³/day i.e., inclusive of the 1,500m³/day of wastewater from SW2 (refer to appendix 2 of this report for the location of the outfall).

All treated effluent travels 9km from the installation in a purpose built pipeline of approximately 25cm in diameter. It is discharged from a multiport subtidal diffuser

east of Sandy Cove Island, outside Kinsale Harbour, which is designated as coastal water by the EPA. Monitoring results in the licensee's 2014 AER indicate that the effluent quality is in compliance with the ELVs specified in the current licence (P0009-03).

Receiving waters and impact

Kinsale Harbour forms part of the South Western River Basin District. The following table summarises the main considerations in relation to the receiving waters.

Table 5: Receiving waters

Characteristic	Classification	Comment
Receiving water name and code	Kinsale Harbour (IE_SW_080_0000)	Coastal waterbody
WFD Status	Good (2010 – 2012)	Objective is to Protect.
WFD Risk (Overall)	2b (2008)	Strongly expected to achieve good status
Coastal Water Quality (tropic status)	Unpolluted	2014
EPA Coastal Monitoring stations	BN120 – East of Sandycove (Kinsale Harbour) BN130 – Outer Kinsale Harbour: Courlaparleen	located 0.3km southeast of the diffuser Located 1km southeast of the diffuser.
WFD Protected Areas (within 10km of the outfall) (see section 11.2)	Sovereign Islands SPA (site code 004124) Old head of Kinsale SPA (site code 004021) <u>Shellfish Waters</u> Kinsale (IE_SW_080_0100) Oyster Haven (IE_SW_070_0100)	3.8 km east of the outfall 6.8km South of the outfall 6km upgradient of the outfall. 7km west of the outfall
WMU Action Plan	<i>Bandon/Stick Water Management Unit Action Plan (WMUAP)</i>	9 IPPC licensed activities are identified as being a point pressure (specific sites are not mentioned).

It is noted from Table 5 that the installation does not discharge directly into any SPA or SAC. According to the Transitional and Coastal Action Plan (TrAC) published by the South Western River Basin District (SWRBD) in 2010, the overall status of Kinsale Harbour is 'Good' with no parameters considered less than good (DIN, MRP, DO, BOD). The overall objective is to 'Protect'. On-going monitoring of the area (Kinsale Harbour) has been conducted since 1978 by University College Galway, (hereafter NUIG), including monitoring of the benthic and coastal environments. Results have indicated that there is no evidence of a measureable impact from the discharge.

Designated shellfish areas are on the list of protected areas under the Water Framework Directive (WFD). Having regard to the distance from the shellfish area (7km) and the water quality in Kinsale Harbour (unpolluted) it is considered unlikely that the installation is affecting water quality in the shellfish area.

A conservative assumption included in the modelling produced a minimum dilution of 2,080 at 200m⁴ from the outfall. The median salinity of Kinsale Harbour is approx. 34 practical salinity units (psu) as reported in the application (attachment I.2). The EPA Water Quality in Ireland 2010 – 2012 (published 2015) reported the lowest median winter DIN values (below 0.17mg/l) were found in the high salinity coastal waters of Kinsale Harbour.

Impact of discharges

NUIG were commissioned by the licensee to investigate if the receiving surface water body (Kinsale Harbour) would be compliant with *EC Environmental Objectives (Surface Waters) Regulations (S.I. No. 272/2009)* if emissions were discharged at the potential maximum limits permitted under the current Licence (P0009-03).

Dissolved inorganic nitrogen (DIN)⁵ is the only parameter considered here as there are no other relevant parameters in Table 9 of the European Communities Environmental Objectives (Surface Waters) Regulations 2009, as amended, relating to coastal waters. Metals are dealt with separately below.

Table 6 Impact of Discharge

Parameter	<i>Current</i> ELV mg/l ^{Note 1}	Background Conc. mg/l	UM3 Model mg/l	Contribution from the discharge (mg/l)	EQS mg N/l ^{Note 2}
DIN - N	100 (Total Nitrogen)	0.200	0.232	0.032	0.25

Note 1: Assuming that all Total Nitrogen is discharged as DIN

Note 2: European Communities Environmental Objectives (Surface Waters) Regulations 2009, as amended (based on a salinity of 34.5psu)

The DIN in the receiving water is predicted to be 0.232mg/l which complies with the good status standard of <0.25mg/l N at 34.5psu salinity, in the Surface Waters Regulations. Table 6 above demonstrates that the sum of contribution from Total Nitrogen (TN) in the discharge at the current ELV would account for 13% of the water quality standard for DIN. The background concentration for DIN is elevated due to the Lower Bandon Estuary (1.5km upgradient of the outfall) which is classified as eutrophic because of high DIN levels.

In Kinsale Harbour, WFD monitoring indicates that the coastal waterbody is DIN compliant with the threshold (0.31 mg/l)⁶ both winter and summer. As discussed further on in the report, reducing emissions of total ammonia to 10mg/l (in line with BAT) would reduce the discharge contribution from 13% to 3% of the water quality standard for DIN rendering it insignificant in the context of Kinsale Harbour water body.

Section 86A (6)(a) of the EPA Act, as amended allows the Agency to specify less strict emission limit values than BAT, as described in BAT conclusions, where it is satisfied that the achievement of BAT associated emission levels (AELs) would lead to disproportionately higher costs compared to the environmental benefits under certain circumstances. As part of the licence review process, additional information was submitted detailing a rationale for the appeal against the imposition of the lower

⁴ Near field dilution and dispersion model of the Eli Lilly outfall, Kinsale Harbour, in relation to EC Environmental Objectives (Surface Waters) Regulations (*S.I. No. 272/2009*) by NUIG (31 May 2012).

⁵ DIN is the sum of the concentrations of nitrate, nitrite and ammonia.

⁶ Water Framework Status Update based on Monitoring Results 2007-2009, OEA, EPA Wexford (21 June 2011)

standard for Total Phosphorus (as P). This included a report on various phosphorus removal technology options along with the capital and operating costs associated with such an installation at the Kinsale site in order to achieve compliance with the BAT AELs.

A discussion on the emission levels associated with the best available techniques (BAT-AELs) in advance of the Commission Implementing Decision (CID) for the Organic Fine Chemicals BREF (sectorial BREF) or for Common Waste Water and Waste Gas Treatment as referenced by the licensee is premature. The BAT conclusions for the sector have not been published and are therefore not law. The Agency will ensure that all licence conditions and limits for the installation are reconsidered and where necessary updated to ensure compliance, once the relevant CID for the sector is published.

At present, in terms of ELVs it is appropriate to discuss national BAT Guidance for the sector and the requirements of the Surface Waters Regulations.

Under the Surface Waters Regulations, BOD, COD, suspended solids (SS), TN, Total Ammonia, and TP (as P) are not parameters of interest in coastal waters. However the current licence limits for these parameters are not in line with BAT for the sector as they were set before the National BAT note⁷ was published. Consequently, the ELVs will need to be reduced under this licence review.

Where the BAT ELVs can be met they will be included in the RD and are not discussed further (refer to Table 7 below). The RD proposes that these ELV reductions are effective from date of grant of licence.

It is noted that the licensee cannot meet the more stringent BAT ELVs for TP (as P) so the discussion will focus on that parameter.

Table 7 ELVs specified in the current licence (P0009-03) compared to the National BAT.

Parameter	Current ELVs (mg/l) (P0009-03)	National BAT Note (mg/l) ^{Note 1}	Achievement of BAT ELVs ^{Note 2}
BOD	600	20	Yes
COD	1500	250	Yes
SS	500	35	Yes ^{Note 3}
TN	100	25	Yes
TP (as P)	<u>100</u>	<u>2</u>	<u>No</u>
Total Ammonia	50	10	Yes

Note 1: BAT Guidance Note on Best Available Techniques for Pharmaceutical and Other Speciality Organic Chemicals.

⁷ BAT Guidance Note on Best Available Techniques for Pharmaceutical and Other Speciality Organic Chemicals, EPA 2008.

Note 2: Based on the Annual Environmental Reports (AER) 2013, 2014, 2015 and monitoring results for SW1 submitted in support of the licence review application (2013 results with the exception of nitrate, nitrite and MRP (as P) which was monitored for a period in 2011).

Note 3: A mass emission limit of 105kg/day BAT equivalent is proposed for SS based on monitoring results submitted in the licence application.

Total Phosphorus (as P): The licensee predicts a fivefold increase in the use of cleaning products and buffers when IE42 and IE43 are fully operational. This will impact on the phosphorus concentration of the aqueous waste streams for treatment in the biological WWTP. The licensee proposes a limit of 150kg/day TP (as P) on SW1 (effluent discharge) which represents a 50% reduction on the current licence limit.

There is no environmental quality standard specified for TP in coastal waters in the Surface Waters Regulations. National BAT guidance for the sector suggests that a concentration limit of 2mg/l TP (as P) should be achieved, depending on the sensitivity of the receiving waterbody. In this instance, the concentration limit does not apply, as the receiving water is not eutrophic. The trophic status of Kinsale Harbour is 'unpolluted' (2014).

Schedule B.2 of the RD sets an ELV of 150kg/day for TP to apply from date of grant of licence. When the CID is published, this issue will be addressed again, either by the application of a concentration limit or by way of derogation. It will be the Agency's responsibility to ensure all licence conditions for the installation are reconsidered in line with the relevant BAT conclusions within four years of its publication.

Condition 5 of the RD requires that the discharges from the installation shall not artificially increase the ambient temperature of the receiving water by more than 1.5°C outside the mixing zone (i.e. from a distance of 250m from the outfall). The dispersion model submitted indicates that this will not be an onerous requirement on the licensee. This condition is requirement of the Surface Waters Regulations to ensure that discharge from the outfall will not impact the free passage of fish and significantly affect the aquatic ecosystem. It is also noted that if there are no thermal discharges from the installation the requirements of this condition are likely to be already met.

Specific pollutants and Priority substances

The waste water from the incineration activities (1500m³/day) is limited in the existing licence for a number of parameters. These include specific pollutants (Cu, Zn) and dioxins/furans. The licensee reports that average emission levels based on 2014 monitoring data are compliant with these ELVs. Furthermore, given that there is significant dilution available in the receiving water (a minimum of 2,080 dilutions 200m metres from the outfall); this discharge will comply with the standards specified in the Surface Waters Regulations.

The discharge from combined WWTP's (SW1) is limited for Tin, Copper, Zinc, Toluene and Xylene (specific pollutants) and Benzene (priority substance). Monitoring of SW1 also includes waste water from the incinerator activities (SW2).

Modelling carried out predicted that concentrations at 100m from the outfall for copper, zinc, benzene, toluene and xylene are an order of magnitude below the relevant EQS when discharged at licensed limits.

Table 8 Mass balance for Specific pollutants and Priority substances

Parameter	Current ELVs (mg/l)	Background Conc. (mg/l) Note 3	Contribution from the discharge (mg/l) Note 1	Standard (mg/l) (AA) Note 2
Copper	0.5	0.001	0.0012	0.005
Zinc	0.6	0.004	0.0042	0.04
Benzene	0.1 (combined ELV for all 3)	0.001	0.0010	0.008
Toluene				0.01
Xylene				0.01

Note 1: Based on current ELVs.

Note2: European Communities Environmental Objectives (Surface Waters) Regulations 2009

Note 3: The background level was estimated to be 10% of the Environmental Quality Standard (EQS) from S.I. No. 272 of 2009

The current ELVs meet the requirements of the Surface Waters Regulations.

The Pollution Reduction Programme (PRP) for priority (hazardous) substances supporting the environmental objective of *progressively reducing pollution by priority substances and ceasing and phasing out of emissions, discharges and losses of priority hazardous substances* has not been published. The RD requires the licensee to consider the PRP for their River Basin District (South West RBD) when published and implement any relevant measures.

The RD includes ELVs and monitoring requirements that have been specified as required by Chapter IV (special provisions for waste incineration plants and waste co-incineration plants) of the IED for SW2.

7.4 Storm Water

All site storm water (roadways, roofs and hardstanding areas not associated with production) is routed to the firewater retention pond from where it is discharged to Doon Creek via SW3. There are no silt traps or interceptors at the installation. The retention pond has a capacity of 6,110m³, lined with high density polyethylene and located at the south end of the site with on-line TOC and pH monitoring at both inlet and outlet.

The time required to fill the containment pond was reassessed in April 2012 to account for future development onsite including Building IE43. The capacity was considered adequate. In the event of a fire the site storm water shall be retained in the containment pond under the current licence (P0009-03). Following consultation with OEE, the RD requires the licensee to review the risk assessment and prepare a firewater management programme as the licensee must demonstrate how the pond/contaminated surface water will be managed in the event of a fire.

There is no treatment of this storm water in the pond other than perhaps some settlement of fine solids. There is a trigger limit set at 30mg/l for TOC and a pH range of 6-9. If these limits are exceeded, a valve closes automatically and an alarm is raised. The pond contents can also be returned to the biological WWTP for further treatment and subsequent discharge via emission point SW1 if required.

Monitoring results for SW3 in 2011 was submitted with the application and indicates average TOC of approximately 1.50mg/l and pH of 7.2. However, elevated levels of Ammonia (as N), 0.119mg/l and 0.197mg/l were recorded on the 09 December 2011 and 17 January 2012 respectively in SW3.

Cadmium levels of 0.2µg/l (0.0002mg/l) on two dates, 10/01/2012 and 17/01/2012 were also recorded. Cadmium is a priority hazardous substance with an EQS of 0.15µg/l under the Surface Water Regulations. The RD requires the licensee to monitor monthly SW3 for Ammonia (as N) and Cadmium.

The licensee has requested an increase in the pH range at SW3 from 6-9 to 6-10 in order to accommodate drift in summer months, particularly when algal growth occurs in the pond. No adjustment of storm water pH is carried out in the firewater retention pond. National BAT guidance for the sector suggests a pH range of 6 – 9 can be achieved. It is recommended that Lilly must meet the BAT pH requirements (6 – 9). It is not clear as to whether there are any potential inputs to the pond which may affect the pH of the storm water. In any case it is considered that proper maintenance (including the removal of algae) will ensure the accurate functioning of the retention pond. The RD requires that good housekeeping practices, to include removal of algae be considered under the Schedule of Environmental Objectives and Targets in the RD. If implemented, this part of the schedule will prevent additional contaminant loadings to the environment.

7.5 Emissions to ground or groundwater

No aspect of the activity gives rise to point or diffuse source of pollutant input to groundwater.

Historic contamination

Groundwater monitoring has been carried out biannually in accordance with the current licence (P0009-03) at a number of groundwater locations, with eight wells currently being monitored onsite.

There is known historical contamination at Well 18 (previously named RW-1), which occurred in 2003 near the IE8 production building. In response to the presence of the Methyl Tertiary Butyl Ether (MTBE) the licensee carried out the following mitigation measures;

- All production wells down gradient of the impacted zone were shutdown to minimise the potential for plume migration and/or expansion
- A comprehensive groundwater sampling and analysis programme was implemented to characterise the nature and extent of the impacted zone.

There have been detailed investigations on-site to determine the extent of the contamination, its location and remediation methodologies. The site has been undergoing soil and groundwater remediation works by contractors since 2004, which involved the drilling/installation of remedial Well 18, from which to pump and remove the MTBE impacted groundwater from the aquifer for discharge to the site WWTP. Residual levels of MTBE continue to be detected, albeit now at low levels below the Agency's Groundwater Interim Guideline Value⁸ of 30 µg/l. The monthly monitoring data in the AER for 2014 indicates a mean concentration reading of 9µg/l MTBE at Well 18.

MTBE is classified as a 'Non-Hazardous' substance in groundwater (EPA, 2010) and

⁸ EPA Guidance *Towards setting guideline values for the protection of groundwater in Ireland*, Interim Report.

a Groundwater Threshold Value for MTBE is not specified in the EC Environmental Objectives (Groundwater) Regulations 2010 (S.I. No. 9 of 2010).

The MTBE impacts in the groundwater are now considered largely remediated; however efforts are on-going and will continue until the Agency are satisfied that the area is decontaminated or does not require any further treatment, that the site is no longer posing a risk to groundwater off-site and contamination is not migrating. The OEE are satisfied with the remediation undertaken by the company. The existing licence requires groundwater monitoring of the site and this requirement is carried forward in the RD. The RD also requires that a review of the most recent hydrogeological assessment be carried out, having regard to the *Guidance on the Authorisation of Discharges to Groundwater* (EPA, 2011). These requirements aim to achieve the environmental objectives and standards set out in the Ground Water Regulations.

7.6 Baseline report

As part of the licence application Lilly submitted a baseline report as set out in Article 22 of the IED. This is required so as to allow for the making of a quantified comparison of the state of the soil and groundwater upon definite cessation of activities. The report identifies approximately 92 relevant hazardous substances (listed in Table A.4 Appendix 1 of the Baseline report) used or generated onsite.

All raw materials are stored in secure, contained warehouses. All bulk /waste solvent storage occurs in overground tanks located in bunded areas that drain to collection sumps that can be routed to either incineration or the biological WWTP as necessary. Storage facilities and tanker unloading areas are designed in accordance with BAT. The design and operation of the installation is such that contamination of groundwater is mitigated and the baseline status is uncontaminated by hazardous substances.

The site is located in the Doon river catchment. The geology of the site is of Lower Carboniferous age, and belongs to the Kinsale and the Courtmacsherry formations, both characterised mainly by calcareous mudstones or muddy limestone, calcareous siltstone and limestone. Soils underlying the site comprise reworked grey or grey brown clayey gravel clay with concrete constituents. The Geological Survey of Ireland (GSI) aquifer classification for the site and surrounds is (PI) Poor Aquifer – bedrock which is generally unproductive except for Local Zones. The GSI show that the main vulnerability rating under the site is 'High'. The combination of poor aquifer and high vulnerability gives a resource protection zone rating of PI/H. Groundwater movement beneath the site has been interpreted as being in a south westerly direction. Apart from the operation of the on-site groundwater remediation wells, there are no large groundwater abstractions located in the immediate vicinity of the installation.

The licensee considered that the baseline status of the site could be adequately characterised by reference to the results of biannual ambient groundwater monitoring carried out as a licence requirement since 1995. The licensee has monitored for major cations and anions, metals and VOC's since that time.

Historic contamination

As outlined in Section 7.5 Emissions to groundwater, there is groundwater and soil contamination issues as a result of historical practices that were carried out on-site.

Conclusion

It is considered that the Baseline Report identifies the state of the soil and groundwater contamination by relevant hazardous substances. The licensee has generally followed the *European Commission Guidance concerning baseline reports under Article 22(2) of the Directive 2010/75/EU on industrial emission*, which was adopted on 06 May 2014. Due to the requirements of groundwater and soil monitoring in the IED (Article 16), the RD requires groundwater and soil monitoring for relevant hazardous substances biannually and every five years respectively

7.7 Waste

All waste generated on-site is separated at source, recovered / recycled where possible and classified as hazardous or non-hazardous.

The incinerator handles hazardous liquid waste solvents generated from the processes. This waste may be routed for off-site treatment if the onsite incinerator has reached its capacity or is out of service. All hazardous solid waste is sent off site for incineration, this includes waste paint, laboratory waste, and hazardous incinerator slag. Aqueous process waste can be routed to the WWTP for treatment.

Any non-hazardous material suitable for recycling is placed in dedicated recycle bins while the non-recyclable fraction is placed in general waste bins. Food waste is collected separately and sent for composting as per the requirements of the Waste Management (Food Waste) Regulations 2009. Sludge, which arises from the WWTP, is dewatered on site prior to being shipped off-site to a drying facility. The dried sludge is then used as a support fuel in incinerators or cement kilns.

Biowaste includes any material that could potentially contain activated cells. Potentially contaminated solid waste will be inactivated in-house by heat treatment, prior to collection for disposal. This is a condition of Eli Lilly's GMO consent (Reg G0267-02).

In summary, 6,168 tonnes of hazardous waste was incinerated and 33 tonnes recycled in 2014. With regard to non-hazardous waste; 330 tonnes went to landfill and 2,348 tonnes was recycled.

7.8 Noise

The installation is located in a rural area, with planting around the boundary providing visual and noise screening from the site. The noise sensitive locations (NSL's) are the residential properties around the northern and western boundaries of the site of which there are 42 within 500m of the site boundary.

The main sources of internal noise at the installation are internal equipment such as boilers, compressors and refrigeration. All equipment is contained indoors and breakout noise is not expected and therefore minimal contribution to noise emissions. External noise sources comprise of air handling units, cooling towers with pumps and motors

Fehily Timoney was commissioned by the licensee to update the noise model for inclusion of additional noise sources namely the IE43 biotech manufacturing facility and the CHP plant. This report assessed the impact of predicted noise on the existing environment and determined compliance with the proposed licence limits based on the Agency's Noise Guidance Note NG4 (2012). Results show that there is no increase to the predicted noise levels with these additional noise sources in place. All predicted (worse case) results are within the limits specified in the guidance for all monitoring locations.

Condition 4 and *Schedule B:4 Noise Emissions* control the noise impact at NSL's; Schedule B.4 also specifies that there shall be no clearly audible tonal component in the noise emissions from the activity at any NSL.

8 Use of Resources

The total annual energy demand at the site amounted to in excess of 112GWhr in 2013, with approximately 40% of the energy demand accounted for by the consumption of electricity and remaining demand supplied by natural gas. The estimated quantities used in 2013 are given below.

Resource	Quantity
Electricity (MWh)	46,507
Light Fuel Oil (m3)	120
Natural gas (CMN)	5,974,454
Renewable energy generated on site (kWh)	18,000
Water usage on-site (m ³ /year) (includes groundwater, surface water and public supply)	365,452

A substantial proportion of the water used is supplied by ground water from a series of onsite boreholes. In 2013, 248,152 m³ of groundwater was used in the plant. It is envisaged that the IE43 process will require approximately 148,500m³/year, thereby increasing overall water consumption to 551,078m³/year. Water will be supplied by Cork County Council and onsite abstraction wells.

There are a large number of chemicals used annually on the site as part of process operations, some of which include;

- 250 tonnes Ethylene Dichloride (H350 – may cause cancer),
- 100 tonnes Dimethylformamide (H360D – May damage the unborn child),
- 40 tonnes Raloxifene Hydrochloride (H360 – may damage fertility or the unborn child, H351 – suspected of causing cancer),
- 1 tonne Pemetrexed Disodium Heptahydrate (H341 – suspected of causing cancer genetic defects, H360).

Chapter V of the IED applies to the activity at the installation and Article 58 of the IED requires the substances or mixtures which carry the hazard statements, H340, H350, H350i, H360D or H360F be completely ceased or replaced where possible. The application of Chapter V and BAT for this sector in this regard and the associated conditions are included in the RD.

9 Greenhouse gas emissions and Climate Change impact

The installation has acquired a Green House Gas (GHG) Permit (no. IE-GHG023-10352-4) from the Agency in accordance with the European Communities (Greenhouse Gas Emissions Trading) Regulations, 2004, as amended (S.I. No. 437 of 2004 and amendments). The category of activity under the GHG Regulations is 'combustion installations with a rated thermal input exceeding 20 MW (except hazardous or municipal waste installations).' The permit does not control emissions of gases other than carbon dioxide. Regulation 23 requires that the Agency shall not have regard to ELVs, BAT, or require a licence review, with respect to greenhouse gases unless it is necessary to ensure no significant local pollution. CO₂ will be the

only such greenhouse gas emitted from the installation in significant quantities. With regard to reducing the climate impact of the installation, the RD requires an energy efficiency audit and an assessment of resource use efficiency. The EMP objectives and targets include use of cleaner production.

10 Measures to prevent accidents and limit their consequences

The application details a range of measures that will be employed to prevent accidents and limit consequences. These include:

- Equipment design features
- Bunding and containment
- Storage and transport infrastructure and practices
- Training and procedural control
- Inspections
- Contingency plans and emergency response procedures.

Condition 9 of the RD requires procedures to be put in place to prevent accidents with a possible impact on the environment and to respond to emergencies so as to minimise impact on the environment.

11 Compliance with E.U. Directives

11.1 Industrial Emissions Directive (IED) (75/10/EU)

The IED requires that the competent authority take account of the general principles set out in Article 11 when determining the conditions of the licence. The installation falls within the scope of Annex I of Council Directive 2010/75/EU concerning industrial emissions. The RD as drafted takes account of all of the relevant requirements of Article 11 and is consistent with the requirements of the IED.

11.2 Habitats Directive (92/43/EC) & Birds Directive (79/409/EEC)

The installation is located in a rural setting, surrounded by land in pasture and tillage. Dunderrow village is located north west of the site on the R605, which is the regional road from Kinsale to Inishannon. There are no designated sites within 3km of the outfall or within 8km of the installation boundary.

Table 9 List of European Sites assessed, their associated qualifying interests and conservation objectives.

	European Site (site code)	Distance/ Direction from installation	Qualifying interests (* denotes a priority habitat)	Conservation objectives
1	Sovereign Islands SPA (site code: 004124)	3.8km west of the outfall (10km south west of the installation boundary)	Species: Cormorant <i>Phalacrocorax carbo</i>	As per NPWS (2015) Conservation objectives for Sovereign Islands SPA [004124]. Generic Version 4.0. Department of Arts, Heritage and the Gaeltacht (dated 13/02/2015).

2.	Old Head of Kinsale SPA (site code: 004021)	6.9km east of the outfall (12km south of the installation)	Species: Kittiwake <i>Rissa tridactyla</i> , Guillemot <i>Uria aalge</i> .	As per NPWS (2015) Conservation objectives for Old Head of Kinsale SPA [004021] Generic Version 4.0. Department of Arts, Heritage and the Gaeltacht (dated 13/02/2015).
3.	Courtmacsherry Bay SPA (site code: 004219)	12km outhwest of the installation	Species: Great Northern Diver <i>Gavia immer</i> , Shelduck <i>Tadorna tadorna</i> , Wigeon <i>Anas penelope</i> , Red-breasted Merganser <i>Mergus serrator</i> , Golden Plover <i>Pluvialis apricaria</i> , Lapwing <i>Vanellus vanellus</i> , Dunlin <i>Calidris alpina</i> , Black-tailed Godwit <i>Limosa limosa</i> , Bar-tailed Godwit <i>Limosa lapponica</i> , Curlew <i>Numenius arquata</i> , Black-headed Gull <i>Chroicocephalus ridibundus</i> , Common Gull <i>Larus canus</i> Habitats: Wetlands	As per NPWS (2014) Conservation objectives for Courtmacsherry Bay SPA [004219] Generic Version 1.0. Department of Arts, Heritage and the Gaeltacht (dated 03/09/2014).
4.	Courtmacsherry Estuary SAC (site code: 001230)	8.6km west of the installation	Habitats: Estuaries, Mudflats and sandflats not covered by seawater at low tide, Annual vegetation of drift lines, Perennial vegetation of stony banks, Salicornia and other annuals colonising mud and sand, Atlantic salt meadows <i>Glauco-Puccinellietalia maritima</i> , Mediterranean salt meadows <i>Juncetalia maritimi</i> , Embryonic shifting dunes, Shifting dunes along the shoreline with <i>Ammophila arenaria</i> (white dunes), Fixed coastal dunes with herbaceous vegetation (grey dunes)	As per NPWS (2014) Conservation objectives for Courtmacsherry Estuary SAC [001230] Generic Version 1.0. Department of Arts, Heritage and the Gaeltacht (dated 09/07/2014).

In consideration of the documents submitted with the licence application, and having considered the processes and emissions associated with the activity (as outlined throughout this Inspector's report), a screening for Appropriate Assessment was undertaken to assess, in view of best scientific knowledge and the conservation objectives of the site, if the activities individually or in combination with other plans or projects are likely to have a significant effect on any European Site. In this context, particular attention was paid to the European site(s) specified in Table 9 above.

The activities are not directly connected with or necessary to the management of any European Site and the Agency considered, for the reasons set out below, that it can be excluded, on the basis of objective information, that the activities, individually or in combination with other plans or projects, will have a significant effect on any

European Site and accordingly determined that an Appropriate Assessment of the activities was not required.

This determination is based on the following reasons:

- The installation is not located within any European site
- Air dispersion modelling conducted demonstrates that emissions from the activities will not cause breaches of relevant air quality standards or guidelines beyond the site boundary and will have a negligible impact on any SAC/SPA. Schedule B specifies limit values for emissions to air which will not adversely affect protected species and habitats.
- It has been determined that the two onsite WWTP's have the capacity to sufficiently treat the effluent discharges from the activity, which ultimately discharges via SW1 to an outfall in Kinsale Harbour, which hydrologically is approximately 3.8km west of the Sovereign Islands SPA (site code: 004124). The RD requires the licensee to meet emission limit values set in Schedule B to ensure discharges will not negatively impact water quality and ensure the continued protection of water dependent species.
- Table 5: Receiving waters of this report shows that the trophic status of Kinsale Harbour is unpolluted (2014). Based on this the predicted impact on the SPA is negligible.
- With respect to water quality, the process effluent was assessed in terms of BAT for the sector; Surface waters regulations, Groundwater Regulations and Chapter IV & V of the IED. This will contribute to the protection of this waterbody.
- There is no direct emission to groundwater
- There are specific precautionary infrastructural and procedural measures in place at the installation to prevent significant impacts occurring due to chemical spills or fire.
- As the nearest SPA is 3.8km and the nearest SAC is 8.6km from the installation, it is considered that noise will not impact on the noise sensitive qualifying interests.

The Agency is satisfied that no reasonable doubt remains as to the absence of adverse effects on the integrity of those European sites specified in Table 9 above.

11.3 Seveso Directive (2012/18/EU)

The applicant made an assessment of the status of the installation in relation to the Seveso III Directive which has been implemented in Ireland via the Chemicals Act (Control of Major Accident Hazards involving Dangerous Substances) Regulations, SI 209/ 2015. The assessment concludes that under the regulations, the site has been classified as an upper-tier establishment and is subject to the requirements of SI 209/2015. This is due to the quantities of materials stored on site that are considered toxic and/or a danger to the environment. The installation 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 Health and Safety Authority (HSA) is the competent authority responsible for administration and enforcement of these regulations. One of the general principals governing the basic obligations of the operator of an installation which falls under the IED (Article 11) is that the necessary measures are taken to prevent accidents and limit their consequences. Condition 9 of the RD puts requirements in place in this regard.

11.4 Air Quality Directives (2008/50/EC and 2004/107/EC)

The CAFÉ Directive has been transposed as the Air Quality Standards Regulations 2011 (S.I 180/2011). As outlined above, dispersion modelling of emissions to air was undertaken for the application, which indicated that emissions from the installation will not cause any breaches of relevant Air Quality Standards, as specified in SI 180/2011.

11.5 Environmental Liability Directive (2004/35/CE)

The Environmental Liabilities Directive has been transposed into national legislation by *European Communities (Environmental Liability) Regulations 2008* (SI 547/2008). An Environmental Liabilities Risk Assessment (ELRA) and a Decommissioning Management Plan (DMP) have been completed by the licensee to the satisfaction of the Agency. The financial provision is under assessment by the OEE.

The RD includes conditions and schedules, which require the licensee to control operation of the activities and meet the specified emission limit values. Condition 10 requires the licensee to maintain a fully detailed and costed plan for decommissioning or closure of the site or part thereof and the decommissioning management plan (DMP) to be reviewed annually. Condition 12 of the RD as drafted, satisfies all the requirements of the Environmental Liabilities Directive in particular those requirements outlined in Article 3(1) and Annex III of 2004/35/EC.

11.6 Water Framework Directive [2000/60/EC], European Communities Environmental Objectives (Surface Water) Regulations, S.I. No. 272 of 2009, European Communities Environmental Objectives (Ground Water) Regulations, S.I. No. 9 of 2010

The RD, as drafted, specifies ELVs and requirements that aim to achieve the environmental objectives and standards set out in this Directive, as well as those set out in the implementing national regulations. Condition and limits in schedules, are included in the RD for the protection of surface and groundwater.

11.7 S.I. 148 of 2013 on Waste Incineration and Waste Co-Incineration

Chapter IV of the IED and the European Union (Waste Incineration and Waste Co-Incineration Plants) Regulations 2013 (S.I. 148 of 2013) have replaced the Incineration of Waste Directive 2000/76/EC, the Air Pollution Act, 1987 (municipal Waste Incineration) Regulations, 1993 (S.I. No. 347 of 1993); and (from 07 January 2014), the European Communities (Incineration of Waste) Regulations 2003 (S.I 275 of 2003) respectively.

Although ELVs associated with the Waste Incineration Directive already apply to incineration activities at the installation, new licence conditions in addition to those identified in consideration of BAT have been included in the RD. These are associated with abnormal operating conditions (refer to condition 3.17), wastewater from incineration activities (condition 4.5) and is in accordance with S.I. 148 of 2013 on Waste Incineration Plants and Waste Co-Incineration Plants.

In accordance with Article 45(2) of the IED, a permit granted to a waste incineration plant using hazardous waste shall include a list of quantities of the different categories of hazardous wastes which may be treated, the minimum and maximum mass flows of those hazardous wastes, their lowest and maximum calorific values and their maximum content of pollutants, e.g. PCB, PCP, Chlorine, Fluorine, sulphur, heavy metals and other polluting substances. These requirements have been specified in Schedule A.2 of the RD.

12 Fit & Proper Person Assessment

The Fit & Proper Person test requires three elements of examination:

Technical Ability

The licensee has provided details of the qualifications, technical knowledge and experience of key personnel. The licence application also includes information on the on-site management structure. It is considered that the licensee has demonstrated the technical knowledge required.

Legal Standing

Neither the licensee nor any relevant person has relevant convictions under the Environmental Protection Agency Act 1992, as amended, the Waste Management Act 1996, as amended, the Local Government (Water Pollution) Acts 1997 and 1990, the Air Pollution Act 1987 and the Air Pollution Act 1987 (Environmental Specifications for Petrol and Diesel Fuels)(Amendment) Regulations 2004.

Financial Standing

In May 2015, under the current licence (P0009-03), the licensee commissioned a revised ELRA for the installation. Environmental liabilities can be subdivided into known and unknown liabilities. The required financial provision for the worst case scenario, unknown environmental liability based on the risk with the highest consequence rating, was deemed to be €2,977,238. Lilly's global property insurance policy provides coverage for contamination and pollutant clean up in the amount of \$2m for environmental liabilities that result from covered risks such as flooding, fire etc.

Lilly global property insurance policy provides significant coverage for unknown liabilities in addition the site also relies on 'parental company guarantee' to cover unknown liabilities at the site.

In any event, a revised ELRA was agreed by the OEE on the 12 January 2016 to a value of €4,875,066. The DMP was agreed on the 14 February 2014 to the value of €25,000,000. The financial provision has yet to be agreed and is required under the RD.

It is my view, on the basis of the information supplied in the review application, and on consultation with OEE, that the licensee meets the required technical and financial requirements and can be deemed a Fit & Proper Person for the purpose of this review application.

13 Environmental Impact Assessment (EIA) Directive (85/337/EEC, as amended)

The following section identifies, describes and assesses the likely significant direct and indirect effects of the proposed activity on the environment, as respects the matters that come within the functions of the Agency, for each of the following factors: human beings, flora, fauna, soil, water, air, climate, the landscape, material assets and cultural heritage.

The main mitigation measures proposed to address the range of predicted significant impacts arising from the activity have also been outlined. The cumulative impacts with other developments in the vicinity of the activity have also been considered, as regards the impacts of emissions from the activities. This section must be read in conjunction with the analysis carried out in all sections of this report.

13(a) Human Beings

Likely significant effect	Description of effect	Assessment addressed in section:
Noise nuisance	Potential noise activity at NSLs from manufacturing process.	13(a)(i)
Air Pollution	Air quality impacts on human health as a result of operations e.g. boilers, thermal oxidiser.	13(a)(ii), 13 (e)
Environmental impacts from incidents/abnormal operation	Potential for direct and indirect impacts on human health from fire/explosion or spillage from onsite solvent usage/storage and any incident leading to from air, water, ground/groundwater contamination. The potential exists for the exceedance of ELVs for emissions to air from the thermal oxidiser/incineration.	13(a)(iii)

Assessment of Effects on Human Beings

13(a)(i) Noise Nuisance

As discussed in section 7.8 above, the main sources of noise emissions from the installation are associated with process buildings extraction fans, cooling towers, pumps and motors. Other noise sources include boilers, incinerators and thermal oxidisers. There have been no noise complaints in the past three years (at the time of writing this report). The results from the most recent annual noise survey indicate the operation of the plant will not result in a breach of the licence limits.

Mitigation Measures

The following mitigation measures will further reduce the likelihood of a negative impact on human beings from noise:

- Regular and effective maintenance of machinery
- Site equipment to be located away from NSLs where feasible
- Condition 4 and Schedule B4: Noise Emissions controls the noise impact at NSL's
- Condition 6.15 of the RD includes a requirement for an annual noise survey.

Conclusion

I am satisfied that there will not be significant effects on human beings and other noise sensitive receptors from the operation of the activity.

Accordingly, if the activity is carried out in accordance with the RD and the conditions attached, the operation of the activity will not cause environmental pollution. The conditions of the RD and the mitigation measures proposed will significantly reduce the likelihood of accidental emissions occurring and limit the environmental consequences of an accidental emission should one occur.

13 (a)(ii) Air Pollution

Section 7.1 described main emissions to air arising from the operation of the RTO, incinerators, boilers and CHP plant. This included planned /future air emission points from an incinerator, carbon absorbers and a boiler. The modelling carried out as part of the review application was conservative and indicated that the installation, if operated in accordance with the conditions of the licence, is not expected to cause breaches of relevant air quality standards.

Mitigation Measures

- Significant abatement on all main emission to air including incineration and a regenerative thermal oxidiser, HEPA filters.
- Condition 5 of the RD specifies that no emissions from the installation, including odours, shall result in impairment or an interference with amenities or the environment beyond the installation boundary.

Conclusion

I am satisfied that there will not be significant effects on air, from the operation of the activity. I am also satisfied that there will be no subsequent indirect effects on human beings, flora and fauna.

Accordingly, if the activity is carried out in accordance with the RD and the conditions attached, the operation of the activity will not cause environmental pollution and the risk of accidental emissions occurring is low. The conditions of the RD and the mitigation measures proposed are appropriate to minimise the risk of accidental emissions occurring and adequately limit the environmental consequences of an accidental emission should one occur.

13(a)(iii) Environmental impacts from incidents/abnormal operation

The aspect of the licensed activity with the most potential for incident/accident is considered to arise from the use/storage of solvents and dangerous substances on site. Generally speaking, in any chemical manufacturing process there is potential for accidental spillages, leaks and fires with subsequent potential for impact on air, soil, ground/groundwater and personnel. Information received in the review application, possible major accidents were identified and control/mitigation measures in place to prevent same were described. Also process and incinerator scrubber effluent which discharges via the onsite WWTP into Kinsale Harbour has the potential to convey liquids from accidental spillages/leaks.

Mitigation Measures

- Process discharges must comply with licence conditions before discharge to Kinsale Harbour
- All storage tanks are designed with appropriate safety systems for the material to be stored, are located above ground in bunded areas and are subject to regular integrity testing.
- All firewater run-off is collected in a containment pond for retention before suitable disposal. Likelihood of groundwater contamination is much reduced; as all contaminated firewater/storm water is directed to the pond which is HDPA lined rendering it impermeable.
- Most operations are highly automated which give greater consistency of operation and reduces potential for error.
- Condition 6.7 requires all abatement systems to be calibrated and maintained.
- Condition 6.13 applies trigger levels for TOC and pH on the outlet to the containment pond. Such that storm water exceeding these levels will be diverted for retention and suitable disposal.

There is a potential for a short term automated by-pass of the primary air emissions abatement equipment. A specific response procedure is in place that details the required steps to be completed. This is considered an abnormal operation. It is discussed further in Section 7.1 above and controlled by Condition 3 of the RD.

Conclusion

I am satisfied that there will not be significant effects on human beings, receiving waters, air or soil, due to accidents or incidents from the operation of the activity. Accordingly, if the activity is carried out in accordance with the RD and the conditions attached, the operation of the activity will not cause environmental pollution and the risk of accidental emissions occurring is low. The conditions of the RD and the mitigation measures proposed will significantly reduce the likelihood of accidental emissions occurring and adequately limit the environmental consequences of an accidental emission should one occur.

13(b) Flora & fauna

Likely significant effect	Description of effect	Effect assessed in section:
Water pollution damaging aquatic habitats or directly impacting aquatic flora/fauna	Water quality impacting flora/fauna and their habitats from operation of the activity e.g. contamination of surface water systems, leakage of stored chemicals or breaches of licensed ELVs for discharges to water.	13(b)(i)

Assessment of Effects on Flora and Fauna

13(b)(i) Water pollution damaging aquatic habitats or directly impacting aquatic flora/fauna.

There are no Natura 2000 sites with hydrological links to the discharge (see appropriate assessment screening in this report).

As discussed in section 7.3, there is no direct emissions to water; rather indirect emissions to water which arise from the process discharge (as well as scrubber blow down), which is treated at the onsite WWTP's before being discharged to Kinsale Harbour via SW1. This section of the report also goes into considerable detail in the assessment of the proposed discharges impact on the receiving water. On foot of this assessment, limits were specified which aim to ensure that the installations discharges would not result in the breaching the relevant DIN EQS for Kinsale harbour. The appropriate assessment in Section 11 above concludes that significant impacts from the activities are unlikely.

There is potential for groundwater to be polluted from fires and accidental spillages on site. However, in addition to the surface water/groundwater protecting infrastructure described above, the RD specifies various conditions to significantly reduce the likelihood of any such spillage.

Mitigation Measures

The following mitigation measures will further reduce the likelihood of a negative impact on flora and fauna from water pollution:

- ELVs for process discharges (schedule B) have been set with regard to the EQS for the receiving waters, as well as the BAT guidance note for the sector and relevant legislation on emissions.
- Compliance with IE licence conditions regarding appropriate waste and chemical storage, bunding, firewater retention, accident prevention and emergency response.

Conclusion

I am satisfied that there will not be significant effects on water from the operation of the activity. I am also satisfied that there will be no subsequent indirect effects on human beings or flora and fauna.

Accordingly, if the activity is carried out in accordance with the RD and the conditions attached, the operation of the activity will not cause environmental pollution and the risk of accidental emissions occurring is low. The conditions of the RD and the mitigation measures proposed will significantly reduce the likelihood of accidental emissions occurring and adequately limit the environmental consequences of an accidental emission should one occur.

13(c) Soil/Groundwater

Likely significant effect	Description of effect	Effect assessed in section:
Contamination of soils or groundwater	Contamination from accidental spillages e.g. tank/bund failure.	13(c)(i)

Assessment of Effects on Soil/Groundwater

13(c)(i) Contamination of soils or groundwater

The possibility exists of leakage or accidental spillages for example of stored chemicals due to failed containment systems.

Mitigation Measures

The following mitigation measures will further reduce the likelihood of an impact on soils and /or groundwater from spillages or failed containment:

- Compliance with Industrial emissions licence conditions including those governing bunding and containment,
- Containment of surface water drainage,
- Accident prevention and emergency response.

In addition Condition 10 includes the requirement, where appropriate, to remove contaminated soil/subsoil for disposal or recovery following termination or planned cessation or licensable activities. Schedule C.6 of the RD specifies groundwater and soil monitoring requirements.

Conclusion

Based on the above assessment and the mitigation measures in place, I am satisfied that there will not be significant negative effects on soil or groundwater from leakage or failed containment. Accordingly, the operation of the activity in accordance with the RD will not cause environmental pollution, while any accidental emission is not likely to have a significant effect on the environment.

13(d) Water

Likely significant effect	Description of effect	Effect assessed in section:
Surface water contamination	Possible contamination of the receiving water body (Kinsale Harbour) by breaching emission limits values for discharges to water (one process emission point SW1). Possible contamination of surface water by failed bunds, spillage of stored chemicals.	13(c)(i), 13(b)(i), 13(d)(i)

Assessment of Effects on Water

13(d)(i) Surface Water Contamination

There is a single process emission point to Kinsale Harbour from the installation (SW1). In the unlikely event of major spillages, failure of the WWTP system, process control, monitoring and containment there is a possibility of contamination of the receiving waterbody.

Mitigation Measures

As per 13(c)(i) and 13(b)(i)

- Both WWTP's are monitored and controlled by operations personnel on a 24-hour basis and audible alarms are in place for all critical parameters.
- Absorbent material to control spillages,
- Fire-water risk management programme,
- In the event of a fire, storm water runoff can be isolated using a shut off valve installed on the outlet of the containment pond.

Conclusion

Based on the above assessment and the mitigation measures in place, I am satisfied that there will not be significant negative effects on surface water from leakage or failed containment. Accordingly, the operation of the activity in accordance with the RD will not cause environmental pollution, while any accidental emission is not likely to have a significant effect on the environment.

13(e) Air

Likely significant effect	Description of effect	Effect assessed in section:
Reduction in air quality	Possible breaches of air quality standards.	13(e)(i)

Assessment of Effects on Air

13(e)(i) Reduction in Air Quality

The possibility exists of breaches of air quality standards from licensed emission points including two incinerators, a thermal oxidiser, CHP plant and four boilers. Minor emissions onsite are associated with exhaust fans and vent points on various

production buildings. Air dispersion modelling was done on the scenario of all major emission points operating continuously at the current licence limits. The installation, if operated in accordance with the conditions of the licence, is not expected to cause breaches of the relevant air quality standards.

Mitigation Measures

- Significant abatement on all main emissions to air, including a thermal oxidiser, incinerator, carbon adsorption and HEPA filters.
- The incinerator operates to Chapter IV standards to ensure the almost complete destruction of any dioxins/furans formed in the thermal treatment process.
- Abatement of NOx emissions from the incinerator and thermal oxidiser is provided by selective catalytic reduction (SCR). SCR is a means of converting NOx into nitrogen and water.
- ELVs have been set below those modelled by the licensee; regard was had to Chapter IV & V of the IED, BAT guidance note for the sector and relevant legislation on emissions.
- Condition 5 of the RD specifies that no emissions from the installation, including odours, shall result in an impairment of, or an interference with amenities of the environment beyond the installation boundary.
- The notification of incidents, isolation of the sources of emission which lead to an incident and the identification and execution of measures to minimise the emissions/malfunction which lead to incidents (condition 9 and 11).

Conclusion

Based on the above assessment and the mitigation measures in place, I am satisfied that there will not be significant negative effects on air quality from breaches of ELVs for emissions to air or breaches of air quality standards.

Accordingly, if the activity is carried out in accordance with the RD and the conditions attached, the operation of the activity will not cause environmental pollution. The conditions of the RD and the mitigation measures proposed will significantly reduce the likelihood of accidental emissions occurring and limit the environmental consequences of an accidental emission should one occur.

13(f) Climate

Likely significant effect	Description of effect	Effect assessed in section:
Release of climate altering substances	From fuel combustion	13(f)(i)

Assessment of Effects on Climate

13(f)(i) Release of Climate Altering Substances from the use of fuels

The operation of the boilers, CHP plant and combustion processes at the installation will contribute to the release of climate altering substances into the environment. As discussed in Section 8 (resources) above, the installation uses natural gas to fuel four boilers (one on standby) onsite to generate heat and steam.

Mitigation Measures

The mitigation measures discussed below will reduce the likelihood of an impact on air quality:

- The RD requires energy efficiency and resource use efficiency to be addressed as part of the Resource Use and Energy Programme (Condition 7).
- Energy audits are carried out annually at the installation; with recommendation incorporated into the EMS.
- The incinerator has a waste to energy boiler installed which recovers heat generated from the incineration of waste liquids and in doing so reduces dependency on natural gas.
- The use of solar panels onsite reduces the licensee's reliance on other energy sources.

Conclusion

I am satisfied that based on the above assessment, the nature of the activity and the mitigation measures in place, that the likelihood of a significant effect on climate occurring from the release of climate altering substances is negligible.

Accordingly, if the activity is carried out in accordance with the RD and the conditions attached, the operation of the activity will not cause environmental pollution and the risk of accidental emissions occurring is low. The conditions of the RD and the mitigation measures proposed are appropriate to minimise the risk of accidental emissions occurring and adequately limit the environmental consequences of an accidental emission should one occur.

13(g) Landscape, Material Assets & Cultural Heritage

Likely significant effect	Description of effect	Effect assessed in section:
Archaeology and architecture	Distance or damage of archaeology and architecture from activity at the installation	13(g)(i)
Landscape and visual impact	The addition of new structures to the site such as the IE43 building is likely to have a long term visual impact on the landscape. However the operation of the activity is unlikely to negatively impact on the landscape of the area.	13(g)(ii)
Use of natural resources and generation of wastes	Water, natural gas and electricity will be used in the operation of the activity. Quantities of other waste will also be produced as part of the licensable activity, such as WWTP sludge.	13(g)(iii)

Assessment of Effects on landscape, material assets and cultural heritage,

13(g)(i) Disturbance of archaeology and architecture

The EIS noted that there were four⁹ features of archaeological interest within the installation boundary and there are two¹⁰ other sites adjacent to the site. Extensive investigations have taken place on the site over the past eleven years and the EIS states that there are no features of architectural interest within the site boundary.

It is unlikely that emissions from the operation of the activity will impact on any such features.

Mitigation Measures

- 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 NPWS.

Conclusion

I am satisfied that there will not be significant effects on archaeology and architecture from the operation of the activity based on the nature of the activity and the mitigation measures in place. Accordingly, if the activity is carried out in accordance with the RD and the conditions attached, the operation of the activity will not cause environmental pollution and the risk of accidental emissions occurring is low.

13(g)(ii) Landscape and Visual Impact

The installation is located at Dunderrow, near Kinsale, Co Cork. The character of the landscape is agriculture in nature with rolling, east-west oriented, and valley/ridge topography. The Bandon River lies 1.5km to the southwest. The levels of landscape and visual impact of the installation on the surrounding landscape has been light. This has been achieved through the utilisation of dark colours which help to incorporate the buildings into the landscape and the provision of a mature evergreen screen around the perimeter of the site. The location of the IE43 building is a significant addition to the overall complex however these buildings will be nestled into the lower ground and behind existing buildings onsite. The operation of the activity is unlikely to impact on the landscape of the area.

Mitigation Measures

- Additional planting to provide an effective screen for much of the installation and reduce visual impact of the buildings.
- Local natural colour tones will be utilised to incorporate buildings into the environment.

Conclusion

I am satisfied that there will not be significant effects on landscape from the operation of the activity. Accordingly, if the activity is carried out in accordance with the RD and the conditions attached, the operation of the activity will not cause environmental pollution and the risk of accidental emissions occurring is low. The conditions of the RD and the mitigation measures proposed are appropriate to minimise the risks of accidental emission should one occur.

⁹ Bullaun stone (CO111-034), fulacht fiadh (CO111-035), souterrain (CO111-085), ringfort (CO111-089)

¹⁰ Graveyard (CO111-033), fulacht fiadh (CO111-090).

13(g)(iii) Use of natural resources and generation of wastes

Section 8 above outlines the resources and other materials (including hazardous substances) used by the activity. The RD includes conditions dealing with energy efficiency, the use of resources and the management of waste at the installation.

Mitigation Measures

Mitigation measures with regard to consumption of natural resources are discussed in Section 13(f)(i) above. The RD includes detailed requirements with regard to the management of waste including record keeping requirements, limitation on acceptable wastes for incineration (Schedule A) and the use of resources (Condition 7).

Conclusion

I am satisfied that based on the above assessment, the nature of the activity and the mitigation measures in place, that the likelihood of a significant negative impact on the landscape, material assets and cultural heritage from the consumption of natural resources is negligible.

Accordingly, if the activity is carried out in accordance with the RD and the conditions attached, the operation of the activity will not cause environmental pollution and the risk of accidental emissions occurring is low. The conditions of the RD and the mitigation measures proposed are appropriate to minimise the risks of accidental emission should one occur.

13(h) Interaction of effects

I have considered the interaction between the factors referred to in Tables 14(a) to 14(g) above and the interaction of the likely effects identified. The interaction between factors as a results of the operation of the installation are summarised below:

	Human Beings	Flora and Fauna	Soil	Water	Air	Climate	Landscape, Material Assets and Cultural Heritage
Human Beings			✓	✓	✓	✓	✓
Flora and Fauna			✓	✓	✓	✓	
Soil				✓			
Water	✓	✓	✓				
Air	✓	✓				✓	
Climate					✓		

Landscape, Material Assets and Cultural Heritage	✓		✓	✓			
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Based on the assessment in parts 13(a) to 13(g) above, and the mitigation measures proposed (including the relevant conditions in the licence), I do not consider that the interactions identified are likely to cause or exacerbate any potentially significant environmental effects of the activity.

Reasoned Conclusion on Environmental Impact Assessment

Having regard to the impacts (and interactions) identified, described and assessed above, I consider that the mitigation measures proposed will enable the activity to operate without causing environmental pollution. I also consider that the potential impacts on the environment identified above, even if they occur, are unlikely to damage the environment, and the risk of them occurring is not unacceptable.

14 Recommended Determination (RD)

In preparing this report and the RD I have consulted with Agency technical and sectoral advisor Sean O'Donoghue on aspects associated with emissions to air.

I consulted with the OEE Inspector, Martin O'Reilly, regarding enforcement issues relating to the current licence (Reg. No. P0009-03). The most recent OEE licence enforcement site visit was carried out on 10 April 2015 (ref: SV00142) and there was no non-compliances recorded during the site visit. There are no significant enforcement issues with this site. I consulted with the Office of Environmental Assessment (OEA) in relation to discharges to coastal waters and with ELP Inspector Bernie Murray in relation to GMO.

The RD specifies the necessary measures to provide that the installation shall be operated in accordance with the requirements of Section 83(5) of the EPA Act 1992 as amended, and having regard to the AA screening and EIA. The RD gives effect to the requirements of the Environmental Protection Agency Acts 1992 as amended and has regard to the submission made.

15 Charges

The annual charge include in the recommended determination is the 2016 annual enforcement charge of **€33,223**, which reflects the anticipated enforcement effort required and the cost of monitoring.

16 Recommendation

Having regard to the EIA, AA screening and the requirements of section 83(5) of the EPA Acts as amended, I recommend that a Proposed Determination is issued subject to the conditions and for the reasons as drafted in the RD.

Signed



Orla Harrington

Procedural Note

In the event that no objections are received to the Proposed Determination of the application, a licence will be granted in accordance with Section 87(4) of the Environmental Protection Agency Acts 1992 as amended as soon as may be after the expiration of the appropriate period.

Appendix 1 revised site boundary.



Appendix 2 location of outfall

