

6 ATTACHMENTS F – CONTROL & MONITORING

The treatment/abatement systems for each emission point are in Table F.1(i) in Annex 1 of the Application Form. There are summary tables (Tables D.1.1, D.1.2 and D.1.3 in Attachment D) on the control and abatement of emissions from:

- supply and commercialisation of small molecule active pharmaceuticals
- supply and commercialisation of biopharmaceutical medicines
- support systems

6.1 Attachment F.1. Treatment, Abatement & Control Systems

This section will outline the changes that have taken place at the facility since the last application in 2005 (P0009-03) along with those proposed as part of the IE43 development. Changes include:

- Upgrade and modification of the thermal oxidisers
- Installation of an additional RTO unit
- Upgrading of the WWTP
- Changes to the surface water management system

6.1.1 Air

As described in the 2004 application, air abatement and control systems on-site consist of:

- Fume thermal oxidiser (RTO or Reeco unit)
- Scrubbers
- Carbon absorbers
- Filters (bag and HEPA filters) and Glove Bag Containment technology

Any changes or proposed changes to these systems are outlined below.

1. Installation of an additional RTO unit (Fume Thermal Oxidiser)

A second back up Regenerative Thermal Oxidiser Unit (Reeco 2 RTO) was installed in 2007 to increase fume abatement reliability to production buildings.

Each RTO unit (both manufactured by Reeco) consists of a central combustion chamber and three energy recovery chambers. These chambers contain ceramic heat exchange media (stoneware). During normal operation, the induced draught fan at the RTO maintains a negative pressure in each of the ducts so that residual contaminants following treatment and/or abatement at the buildings are collected and brought for destruction at the unit.

The solvent laden air enters the chamber via an inlet manifold. Inlet flow control valves direct the air into those chambers that are in inlet mode. The air passes through the stoneware beds (which have been pre-heated in a previous cycle) and is heated by the stoneware. It enters the combustion chamber at a temperature approaching the required combustion temperature of 850°C.

Two gas burners maintain a pre-set temperature in the RTO or alternatively if the incoming air contains sufficient concentration of solvents, the energy in the solvents provides the necessary heat to operate the unit and the burners automatically go onto pilot mode.

The clean air leaves the combustion chamber through the stoneware beds of the chambers. There the hot air gives up its heat to the stoneware and continues to a packed bed scrubber (scrubber 10) for acid gas removal. From here it goes to a reheat system for plume suppression.

A process flow diagram of the Reeco system is presented in Figure 6.1

The above description outlines the normal operation of the Reeco under current license conditions and assumes a presence of chlorinated solvent in the vapours being fed to the unit, thus requiring the operation of 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 over the coming years there is no longer a need to have Scrubber 10 in operation continuously when treating non chlorinated vapour streams.

No other source of acidic process vapour enters the Reeco as all such vapour streams are scrubbed at source to remove any acid gases present.

The operation of Scrubber 10 when not required leads to significant energy inefficiencies both in the electrical load required to operate the unit together with the significant energy input required to reheat the wet exhaust gases from the scrubber to prevent plume formation.

No adverse environmental effects are envisaged from operating the Reeco without the scrubber system as this has been successfully demonstrated during a period of agreed bypass of the scrubber system to allow for essential scrubber maintenance to be performed.

The proposal going forward is to continue to operate the Reeco RTO as a primary/secondary abatement system for all process off-gases and to route the RTO exhaust gases through Scrubber 10 only when treating chlorinated vapours in the RTO that have potential to create acid gas emission concentrations that would impact on emission limit values.

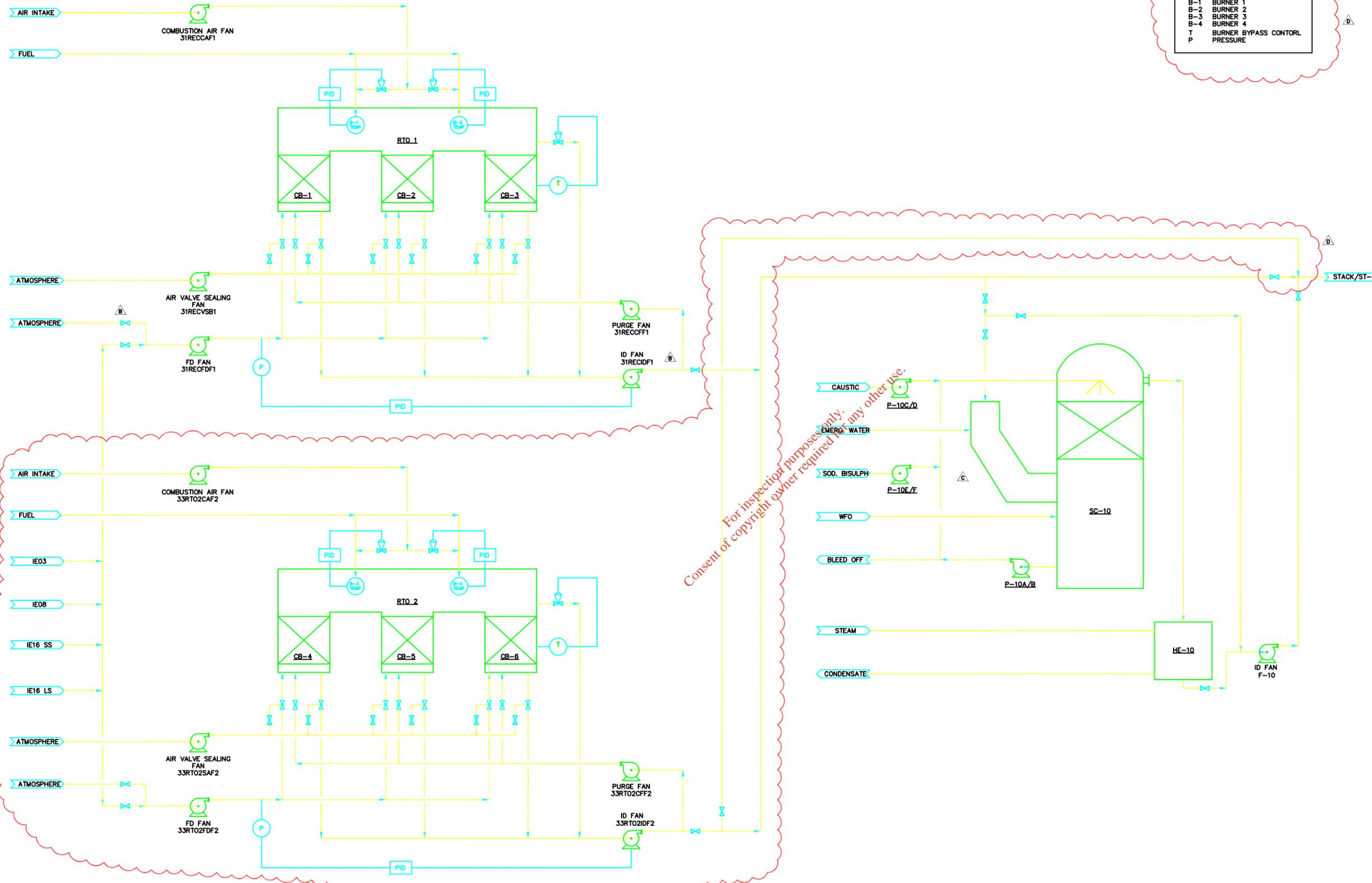
Procedures will be updated to reflect the proposed operating arrangement and monitoring of process off gases will be used to confirm chlorinated vapour levels.

Control System for Reeco

Continuous monitoring of volatile organic compounds, hydrogen chloride, nitrogen oxides and sulphur dioxide is carried out on the exhaust gases emanating from the regenerative thermal oxidiser prior to entering the stack. The sampling point location is such that RTO exhaust gases can continue to be monitored in situations where Scrubber 10 is either online or offline.

Periodic monitoring is carried out for individual organic substances, dioxins, hydrogen fluoride and hydrogen bromide.

The site continues to maintain a full compliance record to the limits for the RTO units.



PID CONTROLLER
 B-1 BURNER 1
 B-2 BURNER 2
 B-3 BURNER 3
 B-4 BURNER 4
 T BURNER BYPASS CONTROL
 P PRESSURE

STEP No.	PROCESS STAGE	PRODUCTION STEP
1	Set-Up	Check set up of Hydraulic pump & sump level
2	Set-Up	Connect Propane Gas to Pilot & Burner
3	Set-Up	Start I.D. Fan
4	Set-Up	Start F.D. Fan
5	Set-Up	Start Combustion Air Fan
6	Set-Up	Start Flush Fan
7	Set-Up	Start Seal Fan
8	Set-Up	Start Hydraulic Pump (1 or 2)
9	Set-Up	Start Valve Cycle System
10	Start-Up	Start both Burners from the DCS
11	Set-Up	Set Burner Target Temperature to 200°C (at a heat up rate of 2°C/min)
12	Start-Up	Maintain Temperature at 200°C for 5 Hours (Initial Cure)
13	Running	Set Burner Target Temperature to 500°C (at a heat up rate of 2°C/min)
14	Running	Maintain Temperature at 500°C for 12 Hours (12 Hour Cure)
15	Running	Set Burner Target Temperature to 850°C (at a heat up rate of 10°C/min)
16	Running	Start IE3, IE4, IE16SS, IE16LS & EC Ducts for service (ducts can be started once RECO Temperature >750°C)
17	Shutdown	Take IE3, IE4, IE16SS, IE16LS & EC Ducts offline
18	Shutdown	Inlet valve from the main duct to the Reeco will shut automatically
19	Shutdown	Fresh air valve from Atmosphere to Reeco will open automatically
20	Shutdown	FD & ID Fans will automatically go to Idle mode
21	Shutdown	Set unit target temp to 600°C
22	Shutdown	Burners B1 & B2 shutdown
23	Shutdown	Put FD & ID fan to manual with a setting of 100% output
24	Shutdown	Leave the valve cycle & hydraulic unit operating
25	Shutdown	Leave the unit operating with the above set up until internal temperature of the unit reaches ambient temperature (Approx 36 hours)
26	Shutdown	Once unit is cooled, it is required to stop the combustion air fan, the FD fan, the ID fan, the valve cycle & the hydraulic pump & seal fan
27	Shutdown	Close manual valves & disconnect propane gas from the pilot & burner

NOTES
 1. DELETED

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 Date: 19 Jun 2012
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EQUIPMENT DETAILS

TAG No.	CB-1/2/3	YSB-1	FDF-1	IDF-1	CAF-1	CAF-1	CB-4/5/6	SAF-2	FDF-2	IDF-2	CAF-2	CAF-2	HE-10	QUENCH	SCRUBBER TANK	SC-10	P-10A/B	P-10C/D	F-10	P-10E/F	
DESCRIPTION	Combustion Chambers	Air Valve Sealing Fan	Forced Draught Fan	Induced Draught Fan	Purge Fan	Combustion Air Fan	Combustion Chambers	Air Valve Sealing Fan	Forced Draught Fan	Induced Draught Fan	Purge Fan	Combustion Air Fan	Flue Gas Pre-Heater	Quench	Scrubber Tank	Scrubber Tank	Pump	Dosing Pump	Fan	DOSING PUMP	
MAKE	Reeco-Stream A/S	B.Bille	B.Bille	B.Bille	VEN	B.Bille	Reeco-Stream A/S	B.Bille	B.Bille	B.Bille	VEN	B.Bille	Thermotec	Christen & Loudon	Christen & Loudon	Christen & Loudon	Munch	SERA	EVG Lufttechnik	SERA	
MATERIAL	Int: Honeycomb Ceramic Structural Pore Size: 1/3 SS, 2/3 Heat.	ST.37 Hjaltru	Fan- MS Inside Coating with Leucostat	Nicrofer	Unknown	MS	Int: Honeycomb Ceramic Ext: 1/3 SS, 2/3 Heat.	ST.37 Hjaltru	Fan- MS Inside Coating with Leucostat	Nicrofer	Unknown	MS	316L SS	Alloy 59/GRP	GRP	GRP	PP	PP	316L SS	PP	
VOLUME													7.5m ³								
SIZE/CAPACITY													U=2.7m, H=1.48m Incl. 75mm	D= 1.2m	D=2.8m, H=3m	165.5m ³ /hr	140 l/hr			140 l/hr	
HEAD													To 10.4 Barg	-0.085 Barg	-0.085 Barg	-0.085 Barg	Op.Press.= 2.5 Barg	Op.Press.= 3 Barg		Op.Press.= 3 Barg	
DESIGN PRESSURE													To 10.4 Barg	-0.085 Barg	-0.085 Barg	-0.085 Barg	Op.Press.= 2.5 Barg	Op.Press.= 3 Barg		Op.Press.= 3 Barg	
DESIGN TEMP.													To 250°C	To 250/90°C	90°C	90°C	60°C	20°C			

SAVE NAME
02030446

CERTIFICATION

NO.	DATE	DESCRIPTION	BY	CHKD	APPV
02030446	19/06/2012	RTD-2 INCINERATOR ADDED	EP		
02030446	19/06/2012	SODIUM BISULPHATE DOSING ADDED	EP		
02030446	19/06/2012	CHANGES AS SHOWN	EP		
02030446	19/06/2012	TRANSFERRED FROM EL-001499	EP		

PROJECT NO.	N/A	AO
ELI LILLY S.A.-IRISH BRANCH DUNDERRAW, KINSHALE, CO. DUBLIN, IRELAND		
RECO FUME INCINERATOR PFD IE31 & IE33 AREA		
DATE	26/03/2002	
SCALE	N.T.S.	
PROJECT NO.	IE31-M06-06-000005	D

Carbon Absorbers

The site has licensed emission points for two carbon absorbers (A3-24 and A3-30) which were used to recover solvent vapours from a product that is no longer manufactured on site. These carbon absorbers have reached their end of life cycle and have been demolished. However as future processes may require such abatement/recovery technology plans for replacement of these units with associated emission points is outlined in Drawing No. 006.

A dedicated carbon absorber unit was also installed in 2007 as a backup to the Reeco RTO for capture of a specific chlorinated solvent vapour stream thus minimising potential environmental impact in the event of RTO failure. The operation of both units are interlinked such that the fume duct carrying the chlorinated solvent vapour is re-directed to the carbon absorber in the event of a Reeco shutdown or bypass. The fume duct is directed back to the Reeco as soon as the unit is back in service. The spent carbon from the beds is shipped offsite for incineration.

6.1.2 Wastewater

The main sources of wastewater effluent on site are:

- Process wastewater arising directly and indirectly (equipment cleaning, floor washing, abatement systems etc.) from manufacturing
- Utility wastewater (steam and hot water generation, purified water production and cooling systems)
- Sanitary/foul wastewater (canteen, washrooms and toilets and is similar in composition to normal domestic sewage)
- Contaminated surface water
- Incinerator quench water (thermal oxidiser)

Each of these sources is described in detail in Section 11.3.1.1 of the accompanying EIS as well as Attachment E.

The direct process wastewater (bio waste) from the proposed IE43 facility will be similar in nature to that arising from the existing licensed IE42 facility, consisting of growth media and chromatography elution materials which are highly biodegradable and akin to domestic effluent. As demonstrated in Section 11 of the accompanying EIS, the existing WWTP has sufficient organic and hydraulic treatment capacity available to accommodate IE43.

Wastewater Treatment Plants

There are currently two waste water treatment plants (WWTP) on-site namely:

- Biological WWTP
- Incineration process WWTP

As outlined in the 2004 IPPC licence application for the Dunderrow facility it was proposed to upgrade both of these plants. Works to the incineration process WWTP were completed in 2005 and included changes to the management of the hydraulic loads associated with the inorganic treatment system. This was achieved through the addition of an extra clarifier and sand filter which enhanced the solids removal capability of the plant.

Over the past 5 year period a significant investment has been made in upgrading the existing biological WWTP facility to increase the capability of the plant while also improving effluent quality and providing additional groundwater protection thorough secondary containment measures.

A summary of the works carried out include:

- Installation of mechanical mixing devices in the final effluent holding tank to aerate tank contents and promote oxidation of residual salts (e.g. sulphite to sulphate) thus reducing potential impact on the receiving waters.

- Lining of concrete effluent holding tanks with a high density polyethylene (HDPE) material to minimise risk of leakage to ground/groundwater.
- General piping refurbishment within the area and installation of additional hard surface area under pipe racks to prevent soil or groundwater contamination.
- The installation of a new sanitary waste tank and a new centrate waste tank with improved secondary containment for both tanks.
- Upgrade of the WWTP odour abatement device (Biofilter) and installation of new Monoshell media.

Upgrade of the WWTP sludge holding tanks including replacement of air sparge mixing with mechanical mixers and the replacement of the tank roofing system and associated venting arrangement to the Biofilter.

In all approximately €5 million has been spent on these upgrade works over the period.

In 2006 a Membrane Filtration Plant was installed to pre-treat a high volume process waste stream so as to render it suitable for biodegradation. An outline of the process is as follows;

The system contains a double pass nano filtration (NF) unit and associated storage vessels capable of processing up to 20m³/day of waste. The filtration process follows a series of filtration steps in which material to be removed from the waste stream is concentrated into a reduced volume which is forward processed for incineration. Permeate from the filtration step is then be routed to the wastewater treatment plant for further treatment.

The process has been quite successful and resulted in a significant diversion of material to biological treatment and away from the historical incineration route. However the associated manufacturing process has now ceased and the Membrane Filtration plant is currently out of service.

The Membrane Filtration Plant is being maintained for possible future use as a pre-treatment step or standalone treatment for hazardous waste streams to render them non-hazardous or suitable for bio-treatment. Any such development will be in line with BAT for the physio-chemical treatment of waste streams as outlined in the 2006 Waste Treatments Industries BREF document.

Details of proposed use will be notified to the Agency prior to re-commissioning of this unit.

Figure 6.2 shows a schematic of the process flow of the biological WWTP. The main elements of the plant (as summarised in Section 11.5.2 – 11.5.6 of the accompanying EIS) are:

- Aqueous wastes **from small molecule manufacturing** are initially routed to a solvent decanter T-15, where solids and solvent residues are separated from the waste stream. These solvent/solid residues are routed tank T-208 for incineration. Thermally inactivated aqueous wastes streams from large molecule manufacturing (Biotech), containing residual cellular material, are introduced to the WWTP through T12. Excess utilities clean wastewater is introduced to the WWTP at Tank 37.
- **Equalisation, pH Correction and Emergency Dump Tank Capacity** - TK -14 is the balancing/pH correction system. This has a working volume of 1200 m³, which provides >5 days hydraulic balancing at present and will still provide >2 days balancing when the current expansion projects have been completed. This is a very conservative position as 24 hour balancing is more than adequate. Emergency dump tank capacity is also provided for off line diversion of unsuitable materials or excess loads. Incoming waste is pH corrected in T14 within the range of 6-5 - 8.5. This is further corrected in T12 to within a 6.5-7.5 range prior to addition to the aeration basin. Correction in both directions is undertaken by addition of 96% sulphuric acid or 25% caustic.
- **Aeration Tanks, Contact Tank and Pre-denitrification** - The forward feed system allows very fine control of both hydraulic and organic loading to the activated sludge system. This system comprises three interlinked tanks T-9, T-10 and T-11, which provide in excess of 2,200 m³ of available aeration capacity. The tank configuration is multi-purpose and can be used to provide classical aeration, contact tanks or pre-denitrification by selectively routing return activated sludge, forward feed and recycle flows to whichever configuration is required.
- **Off- Gas Management** - All off gases from the treatment plant are collected from the roofed tanks (balance tank, aeration tanks and sludge digestion tanks) and routed to the bio filter. The biofilter has a capacity of greater than 190,000 Nm³/day air flow, sufficient to service both the aeration basins and the sludge holding tanks. In the last five years, the biofilter underwent a major upgrade in which the existing wood bark beds were replaced by sea shell material.

- **Oxygenation** - Oxygenation is provided by subsurface jet aeration and ancillary blowers. At depth this system gives a high level of oxygen transfer efficiency. Dissolved oxygen is monitored in the relevant tankage. The system is serviced by 57 kW of installed blower capacity and 76 kW jet aeration pump capacity. This has a demonstrated oxygen transfer capacity of 136 kg O₂/hour at an efficiency of 1.02 kg O₂ transferred per kWh absorbed. This provides a very high level of mixing and agitation in addition to oxygen transfer. The efficiency would increase at higher organic loadings. The capacity, at the current efficiency, is conservatively estimated at 1,600 kg BOD/day or 3,263 kg COD/day and at a modest increase in efficiency would increase to 4,000 kg COD/day. This is considered sufficient to meet current and future site demands
- **Clarifiers** - Two 8m diameter clarifiers are available (T-124 and T- 125). With an effective surface area of 50 m², each of the clarifiers are capable of operating at an upward flow rate of 0.25m /hour giving a hydraulic capacity to the system of 25 m³/hour or 600 m³/day. The current and proposed hydraulic capacity uptake is only 50% and 90% peak respectively of the available capacity. Variable sludge return and sludge wastage is possible via the return activated sludge (RAS) pumps. A scum skimmer separately collects floatables and discharges them to the centrate (centrifuge supernatant) collection system and to the sludge management system.
- **Excess Sludge Management** - The excess activated sludge, is directed to and stored in two of the four tanks T-29, T-30, T-25, and T-24. Two tanks are usually devoted to sludge from the biological treatment plant and two to inorganics from the quench water treatment system. These provide aerated storage for up to 40 days depending on excess activated sludge generation rate and loadings. Any excess supernatant liquid can be decanted back to the biological treatment plant via the centrate sump. The sludge is dewatered to 15% solids in a centrifuge and the centrate returned to the biological treatment plant via the centrate sump. The dewatered sludge is discharged to a skip and transported offsite for drying prior to use as a support fuel for cement kiln/incineration activities.
- **Final Biological Treatment Plant Effluent Discharge** - The effluent from the clarifiers is discharged to T-37. This is the last chamber of the cooling pond set upstream of the entry to the wet well, T-36, for discharge via the pipeline and sea outfall to the seaward side of Sandycove in Kinsale Harbour. This chamber, T-36, provides a final pH safeguard with in situ measurement and correction. This chamber also receives the overflow from the quench system, which has been through the cooling ponds. The discharge is provided with flow measurement and flow proportional composite sampling prior to discharge.
- **Site sanitary waste** - This is collected in T-6, and pumped forward based on tank level control into the aeration basins T-10/T-11, where it is treated along with site aqueous waste. The domestic waste provides micronutrients not available in the pure process effluents.

With respect to the capacity of the biological WWTP, Section 11.5.2 of the EIS states:

"The current hydraulic load is approximately 270 m³/day containing 476 kg COD. The plant can conservatively cater for the anticipated expanded load of 460 m³/day containing up to 646 kg/COD/day when all current projects are commissioned. The existing items of plant can be configured to provide treatment for up to 600 m³/day containing up to 3,263 kg COD if required. Therefore, the current loads only utilise approximately 14.6% of total available biological capacity and this uptake will only increase to 77% hydraulic capacity and 19.8% organic capacity when the IE43 project is operating at peak capacity. In addition to the process effluents, a small but beneficial sanitary waste component is added from the sanitary sump directly to the aeration basins. This currently contributes approximately 75 m³/day containing 26 kg COD and is designed for twice that load and a maximum input of up to 24 m³/hour. The domestic waste provides micronutrients not available in the pure process effluents but which will now be enhanced by the addition of the IE43 effluent."

Incineration Process WWTP – quench water and scrubber blow down from the incineration process is routed through a separate treatment system before being combined with the biological WWTP effluent prior to discharge. The plant consists of two clarifiers (T49/50) operated in parallel and designed for a throughput of 1500 m³/day each. A pre clarifier polymer dosing system is in place to assist with suspended solids coagulation and flocculation. pH adjustment can also be carried out pre clarification. The effluent from the clarifiers is then routed to a three bed (T 64/65/66) polishing sand filter to achieve licence compliance for suspended solids concentration in this effluent stream.

Utility 'clean' wastewater and treated incinerator effluent is combined in the cooling ponds. A portion of this is then recycled back through the clarifiers and sand filters to act as make up water for the system. The remaining portion then discharges via further flow proportional sampling and continuous pH checking and back correction, if necessary, to the wet well T-36. In T-36 it is combined with the biological treatment plant final effluent and discharged to the ocean outfall off Sandy Cove in the outer Kinsale Harbour.

Control System

Process control for both treatment plants is achieved using the plant wide Fox I/A Distributed Control System. The plants are monitored and controlled by operations personnel on a 24-hour basis. Signal output for all critical parameters is relayed back to the control room and is visually displayed on the FOX I/A system. Audible alarms are also in place for all critical parameters that exceed set points.

The critical components covered by the FOX I/A are flow, pH, temperature, tank level, dissolved oxygen, aeration pump status, air blower status and sludge pump status. pH control at key locations across the WWTPs are fully automated so as to control within preset parameters. An additional control on the final effluent discharge pumps prevents discharge outside of licence limits for pH from the biological treatment plant. Variable speed air blowers also allow control of aeration tank dissolved oxygen values.

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6.1.3 Storm Water

The storm water run-off is essentially uncontaminated (comprising precipitation runoff from roadways, roofs and hard standing areas not associated with production). A small seasonal stream (Small Creek) which previously ran through the site and into the Containment Pond (T40) because of its potential to pick up contaminated run off has since been completely enclosed in pipe to remove this risk and now discharges to Doon Creek at the site perimeter.

Contaminated run-off

The potential for contamination to occur from a spill in a bunded area is low as all water collected within a bunded area is sent to the WWTP via an active collection system and treated prior to discharge.

The containment pond (T-40) is designed to retain potentially contaminated fire water or storm water which is collected in the storm water drainage system across the site. The pond has a capacity of 6,110 m³ and is lined with high-density polyethylene.

The proposal included in the 2004 IPPC application has since been implemented and run off from the site is now collected via two separate systems, one collecting run off from the West side of the site and the other from the East side. These two zones are controlled by valving arrangements in inlet Chambers A and B as shown in Figure 6.3.

In the event of a fire or a spillage to the surface water drainage system, the relevant site surface water shall be retained in the containment pond. The site surface water drainage system consists of two separate systems, the West Site (IE3/IE8/IE16) and the East Site (IE30/IE42/IE43) controlled by valving arrangements in Chambers A and B. The surface water drainage system for the East Side of the site has been extended to include storm water run-off from the IE43 development.

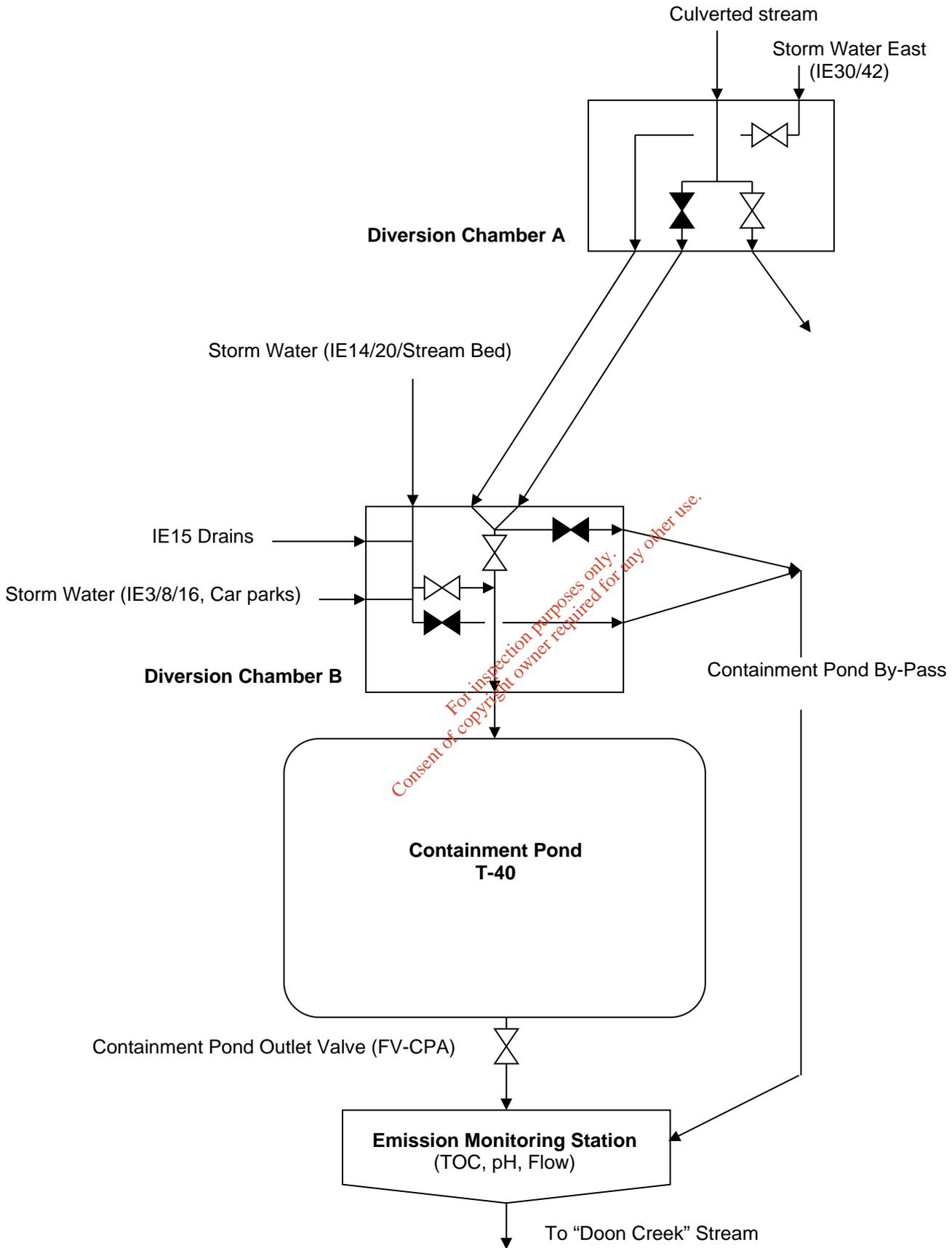
In the event of a firewater event on one side of the site it is possible to divert the storm water flow from the other side of the site around the containment pond to ensure that maximum fire water capacity is available to contain the surface water run-off. All storm water discharges, whether routed through the containment pond or bypassing the pond are monitored for pH and TOC. Contaminated storm water collected in the containment pond can be pumped back to the waste water treatment plant for further treatment.

Under normal conditions the site storm water flows through the pond and discharges through the open outlet valve provided that pH and TOC values are within programmed limit values. The limit values set are 30 mg/l TOC with a pH range of 6 - 9. If the monitored values exceed the limit the outlet valve closes automatically and an alarm is raised.

While normal storm water pH values fall well within limit values, a pH drift due to natural environmental conditions can occur during summer months in the containment pond, particularly when algal growth occurs in the pond. This can result in a rise in pH to 9-10 in the pond, particularly during dry periods where flows become stagnant.

To accommodate this natural pH drift it is proposed to adjust the pH trigger limits to 6-10 pH units for pond discharge under this licence review application.

Figure 6.3: Details of the On-Site Surface Water Management System



Control System

Located at the southern end of the containment pond T-40 is an emission monitoring station that provides continuous monitoring of the surface water discharge from the site. The parameters monitored are TOC and pH. The monitoring data is relayed back to the Fox DCS and displayed on the Operator Interface Panel (OIP) in the Environmental Control Room (IE7).

If a TOC concentration of greater than 20 mg/l is registered a siren and a "High TOC" alarm light will be activated in the Control Room. The WWTP Operator will acknowledge this alarm and contact Technical Support/SSL to investigate the cause of the high TOC occurrence. The red alarm light will remain active if the TOC is greater than 20 mg/l.

If the TOC discharge continues to rise to greater than 30mg/l the outlet valve of the containment pond will close. The siren will activate and the WWTP Operator shall again acknowledge this alarm. An alarm will also be received by security when the containment pond outlet valve closes.

Similarly, if the pH of the discharge stream exceeds the current programmed range of 6 - 9 pH units (proposed range of 6-10 pH units), then the automatic valve at the outlet from the containment pond receives a signal to close. The siren will again activate in the Control Room and the WWTP Operator shall acknowledge this alarm and contact Technical Support/SSL to investigate the cause.

If there is a malfunction of any of the monitoring instruments the containment pond outlet valve will also receive a signal to close and an alarm will again be activated in the Control Room.

The containment pond outlet valve can also be closed from key remote locations around the site (IE7 Control Room, IE10 Security Centre, IE15 Drum Store, IE20 Solvent Tank Farm and at the valve itself. These shut-off valves can be activated immediately in the event of an uncontained spill.

In the event of an incident on one side of the site and the by-pass of storm water runoff from the other side of the site the TOC and pH of the stream that is by-passed around the pond continues to be monitored. If the pH or TOC of this by-pass stream go out of range (pH not between 6-9 pH units, TOC >30mg/l), the valving arrangement will be diverted back to its normal position of inlet valve to pond open with pond by-pass being closed off.

6.1.4 Firewater Retention Capacity

The fire / storm water containment pond has a capacity of 6,110 m³. Since the pond was installed at the site in 1987, the time period required for the pond to reach full capacity during various worst case firefighting and rainfall scenarios (0.5 year to 100 year return periods) has been reassessed in line with the Agency guidance note on Firewater Retention Facilities.

These reassessments have been undertaken as;

- (1) the developed area at the site has increased,
- (2) as the drainage strategy has been altered (as per the 2004 license review application), and
- (3) as the credible worst case fire water volume has changed.

The time required to fill the pond was last reassessed in April 2012 to account for both the future IE43 development and a significantly reduced credible worst case fire water volume as calculated by Factory Mutual (the site's loss prevention insurer). This reduced worst-case fire water volume reflects the declining fire risk at the site and the continuing designation of the site as 'Highly Protected' by the insurer.

The output from this most recent assessment is outlined in Table 6.1 below. This demonstrates that there is a significant improvement (i.e. increase) in the time period required for the pond to reach full capacity in comparison to previous assessments for the highest risk west side of the site (and as previously communicated to the Agency). (Note: Although the drained impermeable area on the east side of the site is larger than the west side, the worst case credible firewater volume that could arise from the west side of the site is significantly greater, due to the inherently safer nature of the type of operations undertaken on the east side of the site i.e. biotech manufacturing etc.).

In pipe attenuation has been included as part of the additional surface water drainage facilities required for the IE43 development, which reduces the rate at which surface water is routed to the containment pond.

Despite this, the additional drained impermeable area added as part of the IE43 development significantly reduces the time taken for the pond to reach full capacity under the various worst case firefighting and rainfall scenarios for the lower risk east side of the site. However, this reduced time for the east side of the site is not less than the time required for the pond to reach full capacity during the various worst case scenarios for the higher risk west side of the site and therefore the overall risk for the site as a whole (east and west) will not increase as a result of the addition of the IE43 facility. The current retention pond capacity for the site is therefore considered adequate for this future development.

Table 6.1: Fire Water Retention Pond Calculations 2012

Situation	Im-permeable Area	Volume Req. Under EPA Guidance Note*	Max Firewater Volume	Max. Pond Volume	Time to fill existing Firewater Retention (Includes fire flow and Stormwater run-off)							
	(hectares)	(cu m)	(West – 2321 cu m) (East – 692 cu m)	(cu m)	½ Year RP	1 Year RP	2 Year RP	5 Year RP	10 Year RP	20 Year RP	50 Year RP	100 Year RP
Existing Site (West)	8.58	6,092	2,321	8,413	>48	35	26	12	8.5	6	4	2.5
Existing Site (East) – IE30, IE42, etc.	9.01	6,397	692	7,089	>48	>48	>48	35	22	14	8.5	55
Future Site – Fully Developed East Site (Flows from IE43 attenuated)	11.57	8,215	692	8,907	>48	41	32	15.5	10	7	4	3

6.1.5 Thermal Oxidisers Upgrade

In 2004, there were two solid/liquid waste thermal oxidisers on site which were used to treat solvent and solid waste generated by production processes. These were the:

- John Zink unit
- Thermall unit

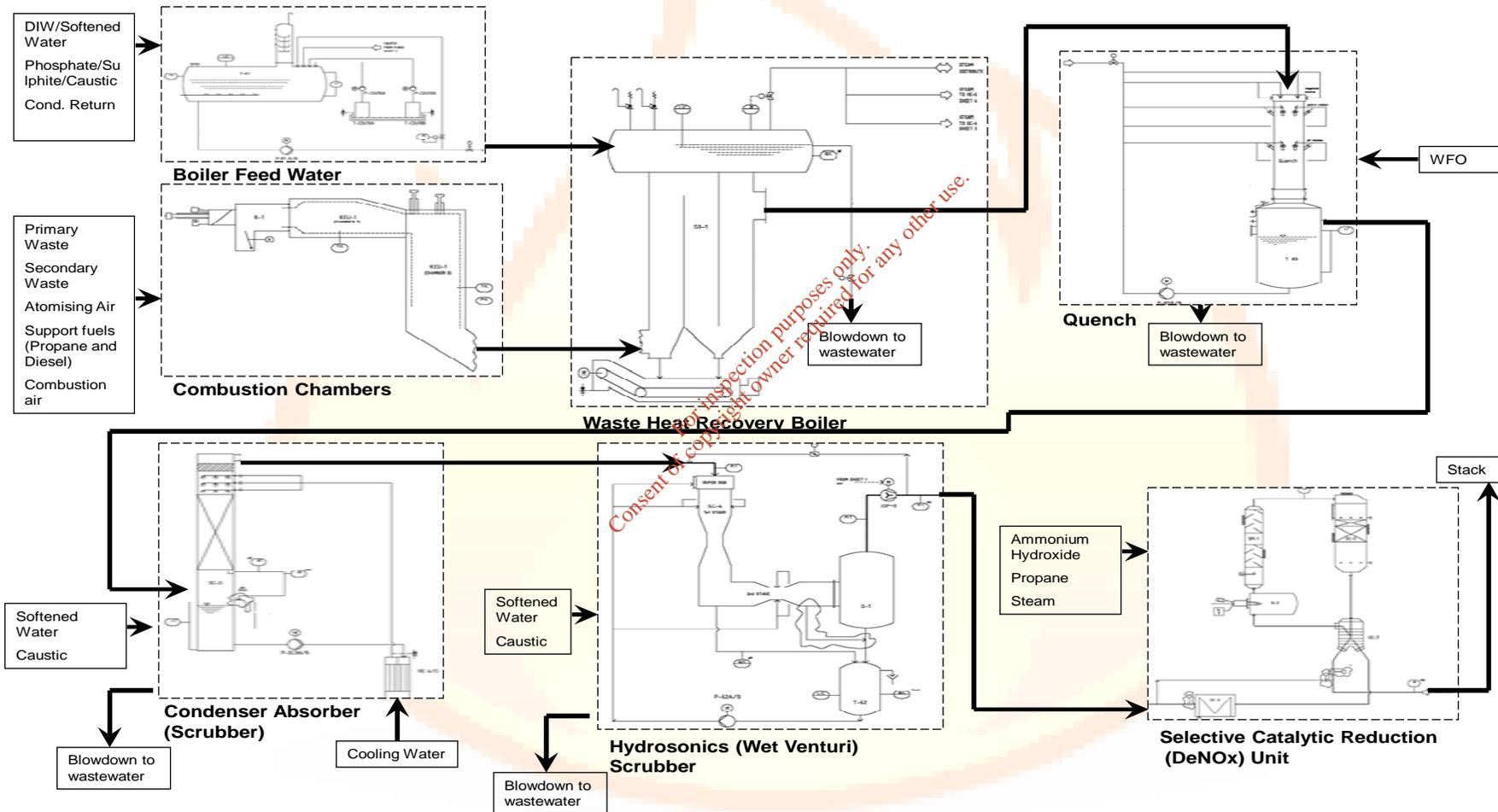
The Thermall unit was shut down at the end of 2010 with the entire unit being demolished in 2014. It is proposed however, to retain the licence emission point for future developments.

In 2006, the John Zink (KEU) incinerator was upgraded to include (refer to Figure 6.4):

- Replacing the burner chamber with a larger chamber that meets the 2 second residence time and burning temperature requirements while at least maintaining the current site waste throughput capacity.
- Re-design of the burner chamber and addition of a de-NO_x unit to meet legislative requirements relating to NO_x emissions.
- The installation of a heat recovery boiler for steam generation.

Figure 6.4: Process flow diagram of the upgraded John Zinc Incinerator

KEU Incinerator Process Overview



The upgraded John Zink (KEU) is used as the primary means of disposing of solvent waste of varying calorific value. Solvent waste is segregated into high calorific material (Primary Waste) and low calorific material (Secondary Waste). The unit is designed such that destruction of the high calorific material provides additional heat for the destruction of the low calorific material. This unit, when fully operational, recovers and reuses approximately 3 tonnes per hour of high pressure steam from the heat recovery boiler. A portion of this steam is used to run the incineration plant itself. The remainder of the steam is supplied to the site steam supply.

The John Zink (KEU) has the capacity to treat approximately 6.5 million KGs of Primary Liquid Waste and approximately 9.7 million KGs of Secondary Liquid Waste annually based on a design intention to continuously operate the unit for up to 24 hours per day and 335 days per year. All solid hazardous waste is currently shipped offsite for treatment at approved licensed facilities.

The John Zink gas cleaning equipment consists of a two-stage process comprising a condenser/absorber for acid gas removal and a hydrosonic scrubber for particulate and droplet removal. The cooled and cleaned gases are combined with the RTO discharge. The heat from the fume thermal oxidiser raises the temperature of the wet gas leaving the scrubbers, preventing a visible steam plume being formed at the stack discharge.

The design and operation of the KEU is in line with BAT as outlined in the 2006 Waste Incineration BREF document.

While the current license conditions relate to the incineration of waste with >1% halogenated content at 1,100°C the profile of solvent waste being generated on site at present is changing such that the halogenated content of solvent waste could be < 1% for extended periods of time, depending on production schedules. It is therefore proposed to operate the KEU on a dual temperature strategy going forward, in line with BAT as outlined in section 4.2.19 of the 2006 Waste Incineration BREF document.

Proposed operating conditions are as follows:

Parameter	Specification
Minimum combustion temperature during gas residence time	<ul style="list-style-type: none"> at least 850 °C, or at least 1100 °C for hazardous wastes with greater than 1 % halogenated organic substances (as Cl)

To ensure compliance to the above production schedules will be reviewed for the potential to generate halogenated solvent waste streams and all hazardous waste for incineration will be analysed for halogenated solvent content.

Control System for the Solid/Liquid Thermal Oxidisers

Continuous monitoring of carbon monoxide, total organic carbon, hydrogen chloride, particulate, nitrogen oxides and sulphur dioxide levels is carried out on the exhaust gases and recorded in the Talas (CEMS). The monitoring is undertaken prior to the gases entering the combined stack. The unit is also monitored periodically, as required by the current licence for hydrogen fluoride, hydrogen bromide, dioxins/furans and heavy metals. The TALAS is configured such that the exceedance of any pre-programmed stack emission value immediately causes the shut off of the waste feed to the John Zink (KEU) incinerator while the auxiliary natural gas burner maintains the unit temperature.

The monitoring of other critical operational controls such as temperature, air flow etc. is carried out by the Foxboro I/A Distributed Control System (DCS). Again hardwired or software interlocks can be used to control unit operations ensuring that pre-programmed parameters are maintained.

Refer to section 4.1.3 of this document for further details of these process control systems.

6.2 Attachment F.2 Emissions Monitoring & Sampling Points

All sampling and monitoring points for the site are identified on Drawing 008 Sheets 1 to 6 in Attachment F.2 supporting information overleaf.

Table F.1(i) includes abatement/treatment control information for point source emissions and Table F.2.(i) includes information of emissions monitoring and sampling points.

Table F.2(ii) describes the ambient environment monitoring and sampling points. Tables F.1 and F.2 are in Annex 1 of the Application Form.

6.3 F.3 Tabular Data on Monitoring and Sampling Points

Monitoring and sampling point data has been tabulated in the excel format required by the EPA for each emission point and is included on the CD-Rom submitted to the EPA.

The table is located in folder 'Attachment F.3.' on the CD-Rom.

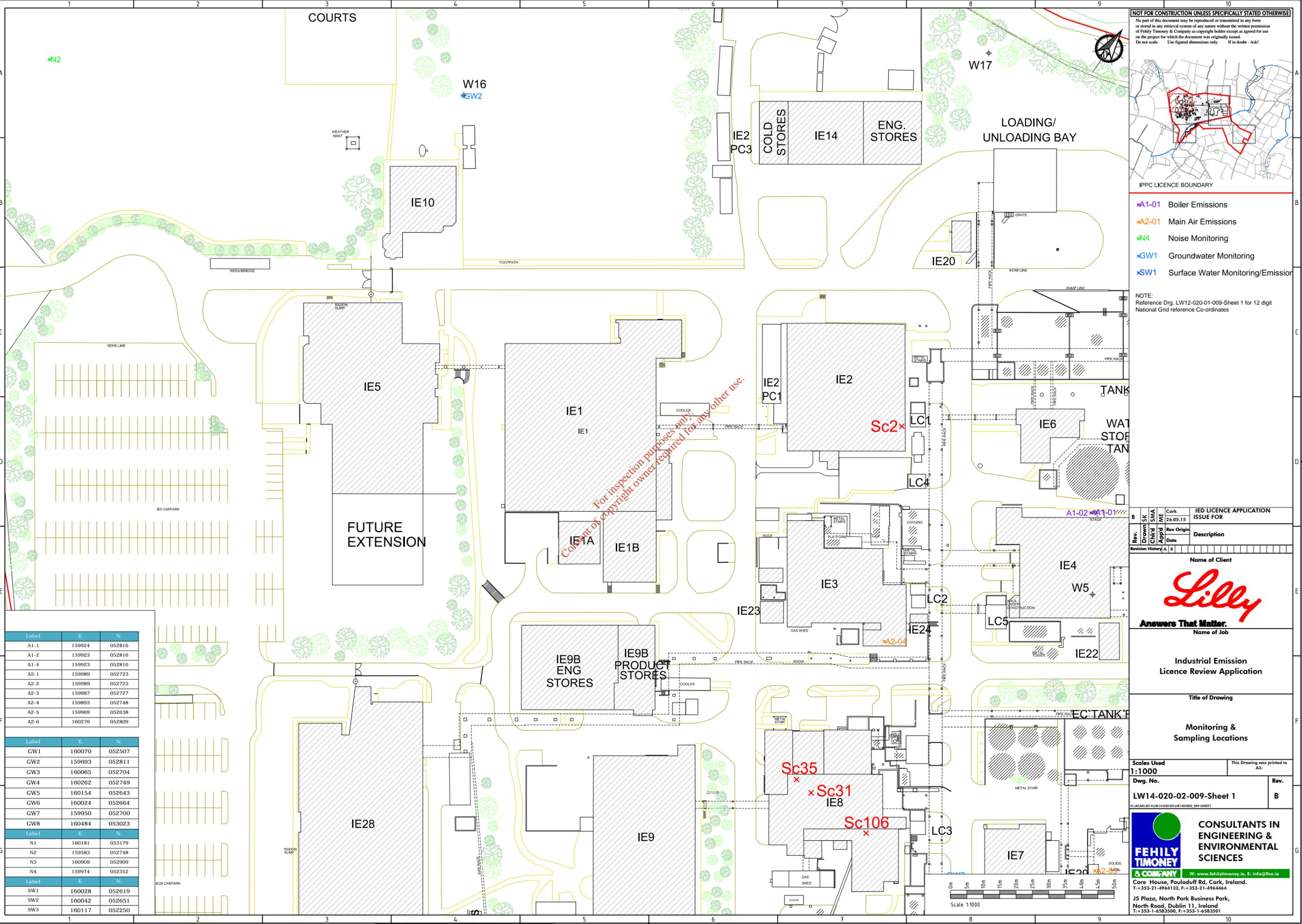
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Attachment F.2 Supporting Information

Monitoring and Sampling Locations Drawing – Drawing 009 Sheets 1 to 6

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IPPCC LICENCE BOUNDARY

- ✕A1-01 Boiler Emissions
- ✕A2-01 Main Air Emissions
- ✕N4 Noise Monitoring
- ✕GW1 Groundwater Monitoring
- ✕SW1 Surface Water Monitoring/Emission

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GW2	159693	052811
GW3	160065	052704
GW4	160262	052749
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GW6	160024	052664
GW7	159950	052700
GW8	160484	053023
N1	160181	053179
N2	159583	052748
N3	160909	052909
N4	159974	052352
SW1	160028	052619
SW2	160042	052651
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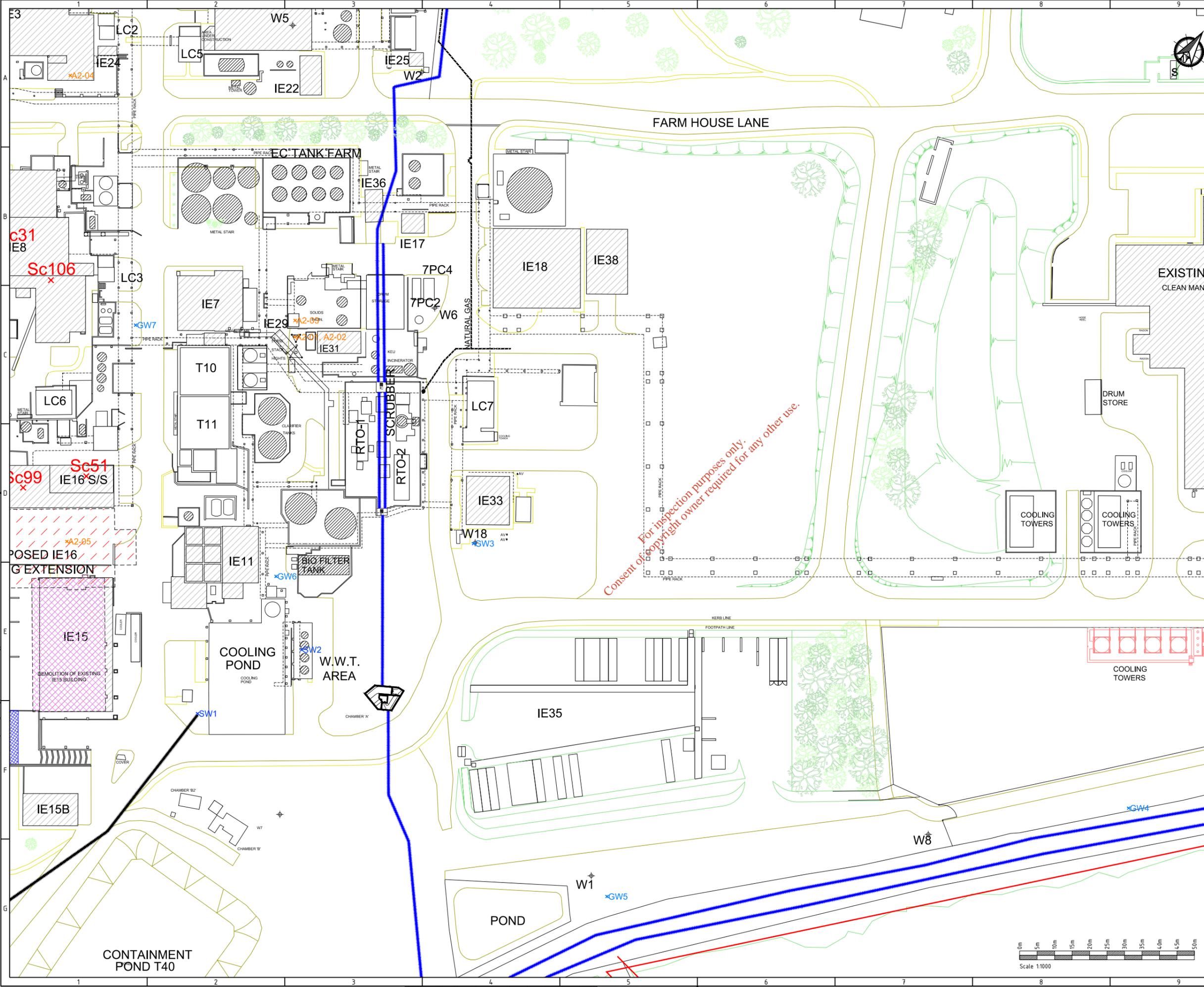
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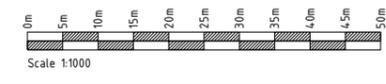
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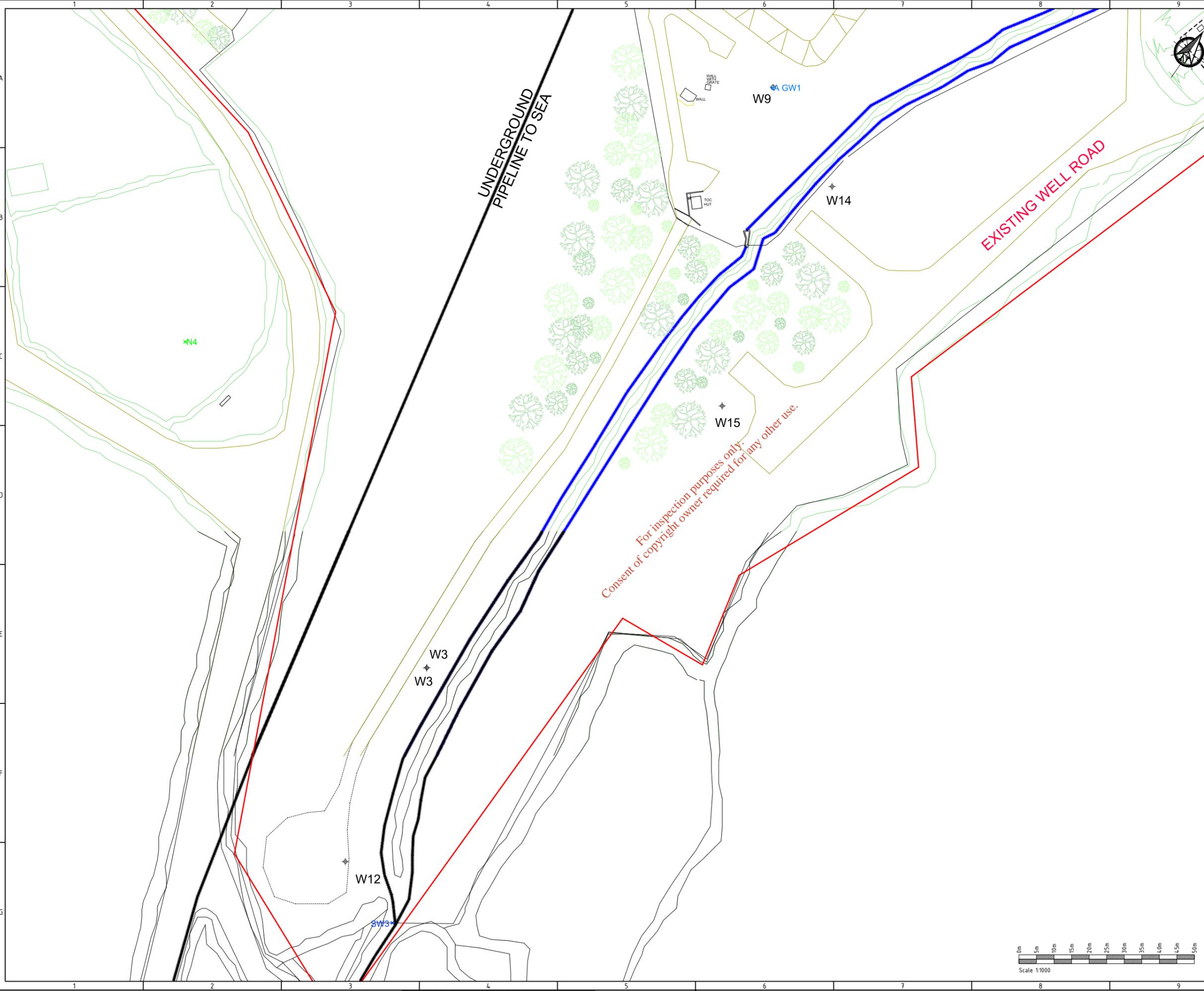
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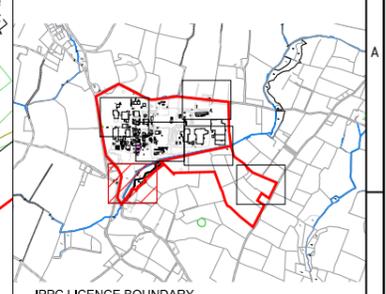
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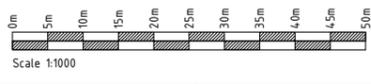
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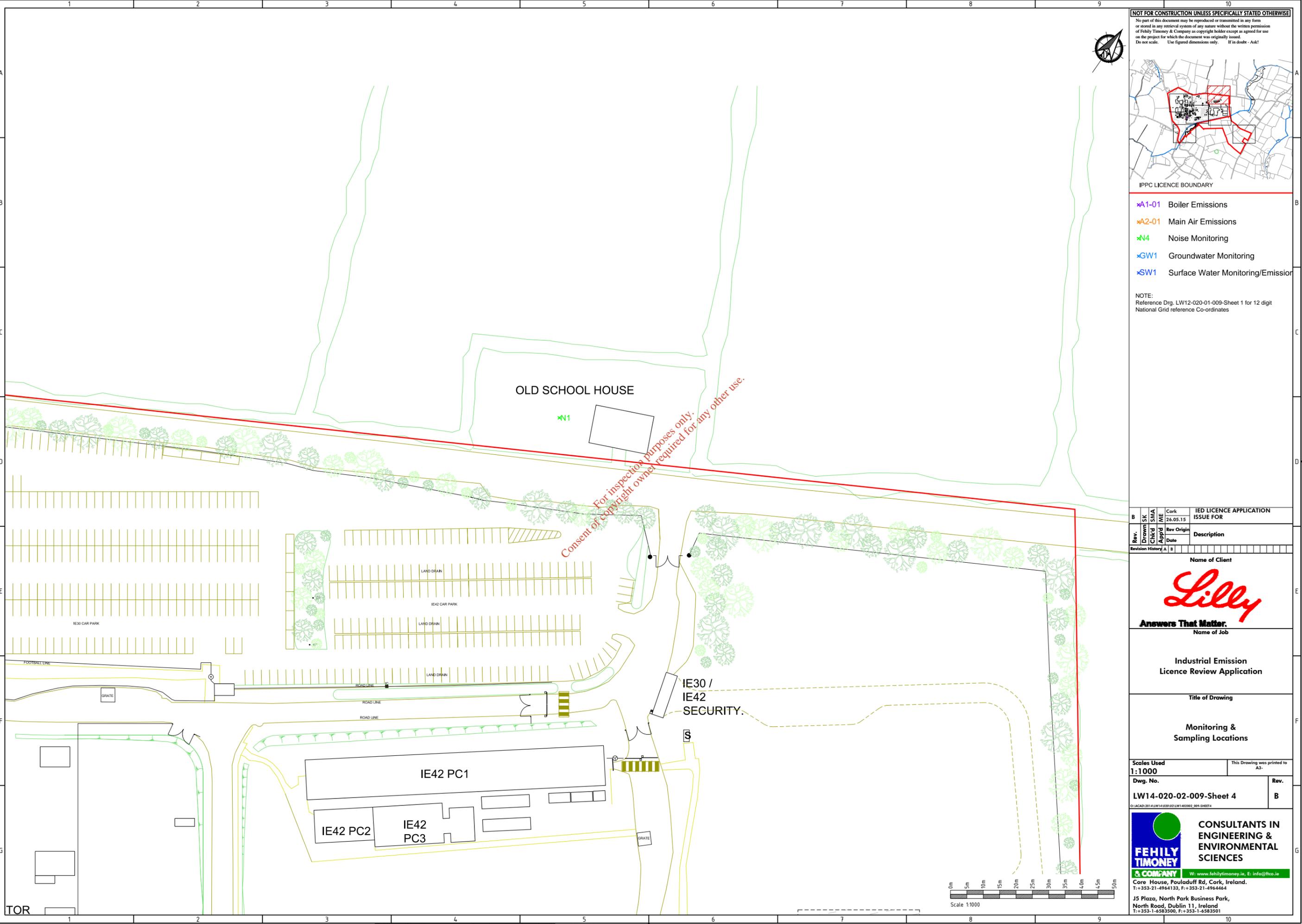
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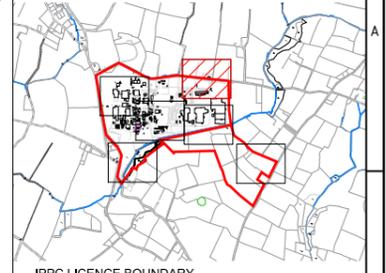
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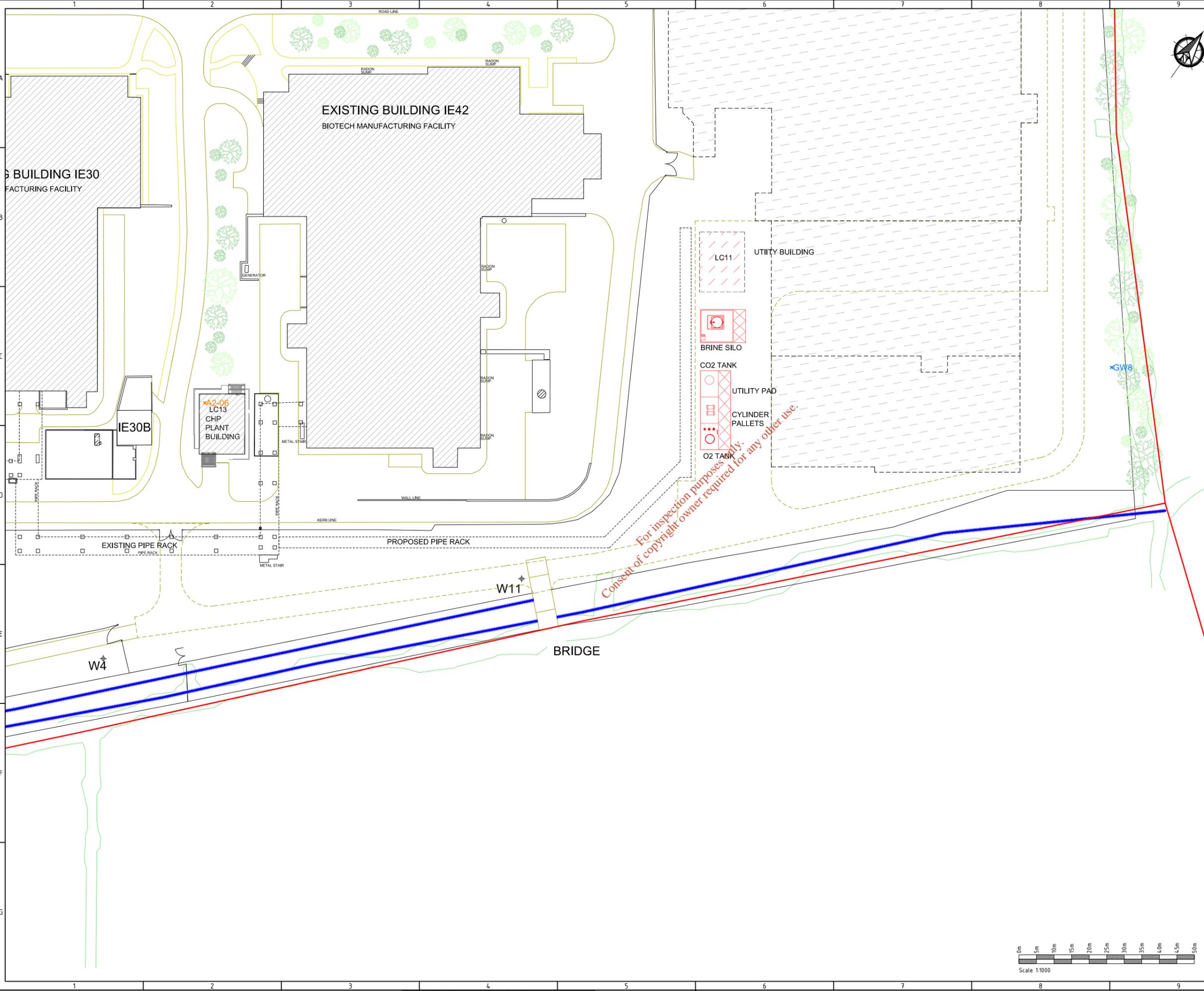
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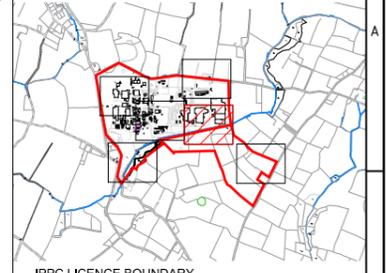
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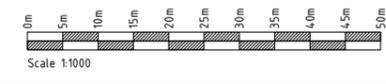


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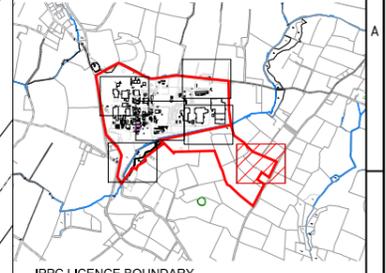
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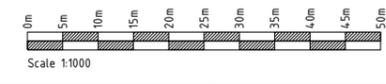
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7 ATTACHMENT G – RESOURCE USE AND ENERGY EFFICIENCY

7.1 G.1 - Raw Materials, Intermediates and Products

Details of the raw materials, intermediates and products used on-site are detailed in Tables G.1 (i) and G.1 (ii) of the application form.

Details on the water usage onsite during 2013 is also provided in Table 7.1.

Table 7.1: Water Usage on-Site 2013

Water use	Previous year m ³ /yr	Current year m ³ /yr
Groundwater	260,966	248,152
Surface water	0	0
Public supply	94,738	117,300
Total	355,704	365,452

Eli Lilly and Company's Global Product Stewardship Strategy which is outlined in Attachment I.8.e and I.8.f describes the environmental considerations of raw materials, intermediates and products use at the facility.

7.2 G.2 – Energy Efficiency

Description of the Energy Used in or Generated by the Activity

Details of energy resources used on site are presented in Table 7.2.

Table 7.2: Energy Usage on-Site 2013

Energy usage on site		
Energy Use	Previous year MWh	Current year MWh
Total	119,812	112,584
Electricity	47,724	46,507
Fossil Fuels:		
Heavy Fuel Oil (m ³)	0	0
Light Fuel Oil (m ³)	24	120
Natural gas (m ³)	6,280,965	5,974,454
Coal/Solid fuel	0	0
Renewable energy generated on site	18	18

The vast bulk of the energy consumed at the site is now supplied in two main forms namely:

1. Natural gas supplied via a low pressure gas pipeline to site.
2. Electricity from the national grid.

The total annual energy demand at the site amounted to in excess of 112 GWhr in 2013, with approximately 40% of the energy demand accounted for by the consumption of electricity and remaining energy demand primarily supplied by natural gas as outlined in Figure 7.1 below. The IE43 building will increase the area of serviced floor space at the site by in excess of 40%. Serviced floor space is the main factor driving energy consumption at the site and as consequence the total energy demand is expected to increase in line with the floor space increase. However, improved energy efficiency standards and various energy reduction initiatives are hoped to offset a significant proportion of the increased energy demand.

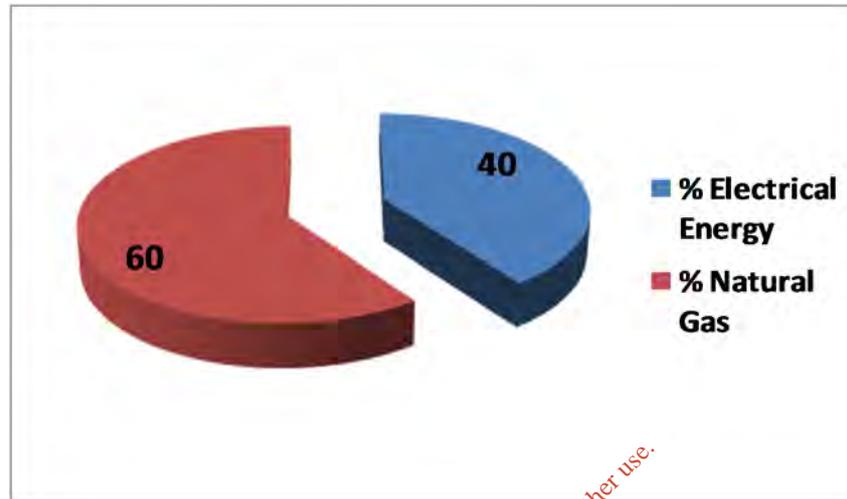


Figure 7.1: Approximate Demand Breakdown of Energy Supplied to the Site

The main energy using aspects at the site are listed below:

- Heating, Ventilation and Air Conditioning (HVAC) Systems
- Steam Production (primarily for HVAC and process heating applications)
- Waste Treatment Systems
- Cooling Towers
- Refrigeration
- Compressed Air Systems
- Nitrogen Generation

Natural Gas is primarily consumed in the first three energy using aspects listed above whilst a significant quantity of electrical energy is consumed across all the energy using aspects.

Small quantities of diesel are available for use in the site firewater pumps, the site emergency electrical generators and in a limited range of site transport vehicles. Diesel is also available as the back-up fuel alternative to natural gas but this fuel is only used in exceptional circumstances. The increased usage of diesel in 2013 is related to such circumstances when it was used to fuel a temporary boiler while existing boilers were out of service for maintenance. The normal consumption of diesel is limited to short weekly tests of the site emergency electrical generators, short weekly tests of the site firewater pumps and in a small number of site transport vehicles. There is also potential for the use of diesel in the site emergency generators during electrical power outages to the facility but such events are relatively rare.

Renewable energy is generated at the site through the use of solar water heating panels for two of the site buildings (IE7 and IE9). This does offset some natural gas consumption at the site steam boilers but the quantity of renewable energy generated by these solar water heating panels is relatively insignificant.

Therefore, because the use of diesel at the site is quite limited and as the generation of renewable energy is relatively insignificant, energy consumption at site can be considered to be largely restricted to the two main forms outlined above i.e. natural gas and electrical energy from the national grid.

Prior to the installation of the natural gas supply to the site in 2011, significant volumes of Heavy Fuel Oil (HFO), diesel and propane were used at the site. The introduction of natural gas to the facility was part of the site's overall programme to improve the sustainability and reduce the environmental footprint of the site operations, whilst also delivering significant energy efficiency, economic and reliability benefits.

Measures Taken to Ensure that Energy is used Efficiently, Energy Assessments & Auditing at the Site

Site Energy Management Team - This team is led by a Utilities Engineer and core membership of the team also includes a Plant Electrical Engineer, a Maintenance Planner, a Six Sigma Black-belt, the Team Leader for Environmental Control & Utilities and an Environmental Specialist with additional participation by representatives from different areas across the site as required.

Measures implemented to ensure efficient use of energy at the site are coordinated through this team and the team leader member of this team is accountable to a member of the site leadership team who has ultimate responsibility for efficient energy use at the site. The activities of the Site Energy Management Team are governed by a charter. The overall approach to site energy management is outlined in Figure 7.2, with further context provided in the proceeding sections.

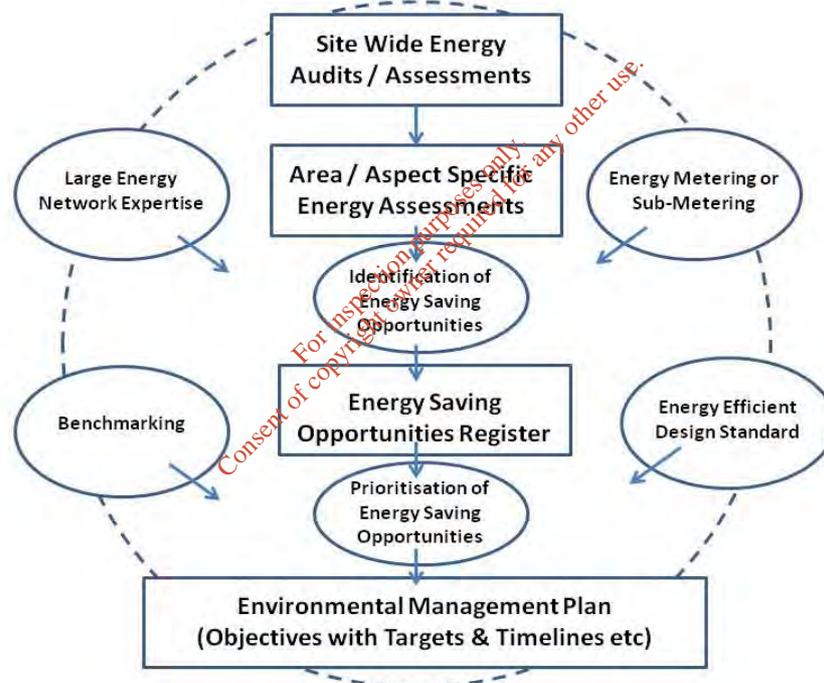


Figure 7.2: Outline of the Overall Site Approach to Energy Management

Energy Auditing and energy assessments - Three major site-wide energy assessments and audits were completed at the site from 2002 to 2009:

- A site -wide audit was completed in November 2002 by an external energy consulting firm.
- In October 2006, one energy management and one energy procurement specialist working at a corporate level within the company undertook a detailed audit of site energy use and management at the site.
- In 2009, an external energy management specialist was employed to undertake a detailed 'Energy Aspects' review for the site, within the context of the energy management standard BS EN16001.

All three site-wide energy assessments and audits were completed in a manner that is consistent with the requirements of the EPA Guidance document on Energy Audits.

Energy Aspect Specific Assessments/Area Focused Energy Assessments – Since 2006. A number of building focused and/or energy aspect specific assessments have been completed annually. Based on the findings of the site-wide audit, the most significant energy using aspects or the buildings with the largest energy demand are prioritised for the more focused assessments. Comprehensive energy metering and sub metering is in place at the site has been used as an important source to support these energy assessments and audits.

The site is also a member of the Large Industry Energy Network (LIEN) group, facilitated by the Sustainable Energy Authority of Ireland (SEAI). Membership of this group has been particularly useful when the site has undertaken energy aspect or building focused assessments as an industry energy expert from the SEAI has been made available to assist the site with many of these assessments.

Membership of this group has also provided the opportunity to benchmark the site energy systems and energy management practices against the site's industry peers for best practice.

Energy Saving Opportunities Register and Environmental Management Programme - The primary purpose of the energy assessments outlined above is to identify and assess energy saving opportunities across the site. Once identified, these energy saving opportunities are added to the 'Site Energy Saving Opportunities Register' for further consideration. The energy saving opportunities are prioritised on the basis of the assessment of various criteria including the:

- Extent of the potential energy savings,
- Costs & resources required to implement the energy saving opportunity and
- Ease of implementation.

If based on the assessment it is decided that the energy saving opportunities should be implemented, the opportunity will be then added as an objective with associated targets on the site 'Environmental Management Programme', which is updated annually and progress against the programme reviewed at set intervals.

Energy Performance Indicators - Energy Performance Indicators (EPIs) for some of the main energy aspects of the site have also been used to assess the site energy management performance as required. The energy metering and sub-metering in place at the site has been an important tool in the success of the EPIs when used.

The main EPI for the site that is used to monitor site energy management performance on an ongoing base is 'Energy Intensity' defined as the overall site energy consumption relative to the area of serviced floor space and this EPI has been used to set the overall site targets for energy management performance. The site is required by its parent company at a corporate level to achieve and maintain a specified 'Energy Intensity' target over a defined timeframe. This requires the ongoing monitoring and reporting of site energy management performance to the parent company. In addition, specific initiatives required to achieve or maintain the specified Energy Intensity reduction target are included as required in a 'Roadmap' submitted to the parent company.

Therefore, the identification and implementation of energy saving opportunities with ongoing detailed monitoring of energy consumption and the assessment of performance relative to defined targets are seen as the central elements of the site's strategy to ensure energy is used efficiently in site operations on an ongoing basis. A list of many of the energy saving opportunities implemented at the site in recent years is outlined below in Table 7.3, with the estimated or realised energy savings also detailed.

Energy Efficient Design - Another important measure that helps ensure that energy is used efficiently at the site, relates to 'Energy Efficient Design'. The company at a corporate level has issued its own comprehensive 'Energy Minimisation' engineering standard (EDS-01020) to all sites globally within the company.

The purpose of this standard is to express the minimum requirements for energy efficiency considerations in the engineering design of facilities, systems, and equipment at Eli Lilly and Company. The standard is based on and references a selection of industry standards and guidance documents. In effect this means that when any new facilities, systems or equipment are being designed for installation at any of the company's sites, the design must be undertaken with reference to these standards. This requirement has been especially important in recent years as the site has invested heavily in new equipment and facilities including the new IE43 development. Again, Table 7.3 below provides an outline of many the energy savings realised at the site in recent years and the implementation of many of these would have been governed by the 'Energy Minimisation' standard.

Table 7.3: Outline of Main Energy Saving Opportunities Implemented at the Site (2008 to 2014)

Energy Saving Initiative	Year Completed	Estimated Annual Savings (KWh)
New Nitrogen (PSA) Plant Technology	2008	~2.8 Million KWh
Installation of Waste Treatment Heat Recovery	2008	~6.5 Million KWh
Cooling Tower Consolidation Project	2009	~0.85 Million KWh
Compressed Air Leaks Survey & Repairs	2009	0.30 Million KWh
Air Compressor Upgrades	2009	~0.35 Million KWh
Chiller Plant Upgrades	2010	~0.50 Million KWh
IE28 'Out of Hours' HVAC Shutdown	2010	~0.40 Million KWh
IE7 and IE9 Solar Water Heating Projects	2010/2011	~0.01 Million KWh
Installation of Economisers on all Steam Boilers following Natural Gas Introduction	2011	~3.9 Million KWh
IE30 HVAC Set Points redesign and Air Change Setback	2011	~5.1 Million KWh
IE28 Lab Fume Hood Optimization Project	2011	~0.44 Million KWh
RTO 1 vs. RTO 2 Operational Strategy	2013	~0.91 Million KWh
Reduced reheat of RTO / Sc-10 Emissions	2014	~3 Million KWh
IE28 AHU-2/3 Heat Recovery Unit Optimization	2014	~1.2 Million KWh
Miscellaneous Lighting control improvements	2014	~0.4 Million KWh

8 ATTACHMENT H – MATERIALS HANDLING

8.1 Attachment H.1 – Raw Materials, Intermediates, Products Handling

Details of the raw materials, intermediates and products used on-site are detailed in Tables G.1 (i) and G.1 (ii) of Annex 1 in the application form.

The following activities which are relevant to this attachment are described elsewhere in the Attachments document. Please refer to the sections as referenced below.

Waste streams generated by the main activities on site:

- Small molecule active pharmaceuticals supply and commercialisation (Attachment D.1, Section 4.1.1 (1) see waste handling heading)
- Biopharmaceutical Medicines supply and commercialisation (Attachment D.1, Section 4.1.1 (2) see waste handling heading)

Storage and transfer of materials:

- Bulk storage and tanker unloading (Attachment D.1, Section 4.1.6)
- Waste Solvent Storage (Attachment D.1, Section 4.1.6)

8.2 Attachment H.2. – Waste Prevention

Eli Lilly and Company's Global Product Stewardship Strategy which is outlined in Attachment I.8.e and I.8.f describes the environmental considerations of raw materials, intermediates and products use at the facility. The strategy has methods in place for waste prevention, waste minimisation, minimisation of raw materials and environmental considerations of processes on site.

8.3 Attachment H.3. –Recovery and Disposal of Wastes Generated on Site

Waste Generation

The quantities of each type of waste generated on site in 2013 is contained in Tables H.3.(i). In summary just over 8,900 tonnes of waste were handled on site in 2013. Just under half of all waste generated was treated on site.

Of the total waste generated, 59% was incinerated, of which 46% was incinerated on-site with the remainder exported. 38% of waste was sent for recovery in Ireland of which it is likely that all of it was subsequently sent for recycling. 2.6 % of waste was landfilled in Ireland. A small proportion, > 1% was used for energy recovery in Ireland.

Details of waste handled on site are included in Table H.3.(i) of Annex 1 of the Application Form.

8.4 Attachment H.4. – Waste Hierarchy

The waste hierarchy as set out in Section 21(A) of the Waste Management Acts 1996-2013 is as follows:

- Prevention
- Preparation for re-use
- Recycling
- Other recovery (including energy recovery)
- Disposal

The nature of the wastes generated by the manufacturing of pharmaceuticals means that specific forms of waste treatment are required. The majority of waste generated (59%) was hazardous. 59% of waste was sent for incineration of which the majority was hazardous. This is the most appropriate treatment method for these waste categories. Energy is recovered from all material routed for incineration. 38% of materials were recovered and sent for recycling. Only 2.5% of waste was disposed of to landfill, which occupies the lowest position on the waste hierarchy. The site has made a concerted effort over the past number of years to redirect as much non-hazardous waste as possible away from landfill by improving segregation at source so that such waste streams become suitable for recycle or can be used as a fuel source in waste to energy plants.

Environmental decisions are driven by the Global Product Stewardship Strategy which was mentioned above and is outlined in Attachment I.8.e and I.8.f.

Solvent Recovery/Re-use

Where possible "clean" solvent waste streams are segregated at source in the process and are routed for recovery. Recovery can take place either in the on-site solvent recovery facility or alternatively material can be shipped off-site to an approved recovery facility. Material recovered on site is re-used in the process while material shipped off-site for recovery is primarily for alternative use. Any such material being shipped off-site is transported as a hazardous waste under the appropriate certification by the site waste management contractor. The re-use of the recovered material is confined to chemical industry sources that have no association with food production so as to ensure such material cannot enter the food chain.

Mixed solvent waste streams with high energy content that cannot be recovered are either used for on-site stream generation in the waste heat boiler of the John Zink-KEU incinerator or alternatively can be shipped offsite to approved and licensed facilities for use in energy recovery or as a support fuel in industries such as cement manufacturing.

Waste Handling Arrangements

Refer to Attachment C, Section 3.1.4 Waste Control Systems.

A number of different types of wastes are generated onsite. Wastes are primarily solid or liquid wastes (solvent/aqueous). Any gaseous waste streams generated onsite are treated in onsite abatement systems. Wastes generated onsite can either be hazardous or non-hazardous. Some waste streams are recovered, recycled, treated or disposed of onsite and other wastes are recovered, recycled, treated or disposed offsite. Off-site treatment or disposal of waste only occurs where there is no on-site capacity to treat it.

Wastes are classified as hazardous or non-hazardous. Hazardous liquid wastes (solvent based) are recovered where possible onsite or if not are incinerated onsite. This waste may be routed for off-site treatment if the onsite incinerator has reached its capacity or if the incinerator is out of service.

Waste oils and oil filters are stored in a designated waste oil holding tank/designated bin onsite and are removed offsite by an approved waste contractor.

All hazardous solid waste is sent offsite for incineration. Hazardous solid waste generated onsite includes:

- Empty unclean raw material packaging
- Fibre/Plastic drums and liners containing used PPE, wipes, packaging etc.
- Waste paint
- Florescent tubes/batteries
- WEEE
- Rejected solid material
- General laboratory waste
- Discarded lab chemicals and product samples
- Catalyst material
- Hazardous incinerator brick/slag

All this waste is segregated and stored in appropriate containers in dedicated locations prior to being removed offsite for incineration.

Non-hazardous waste generated onsite includes:

- General municipal solid waste – compacted prior to transport offsite – sent to a Materials Recovery Facility (MRF) for further segregation of recyclable and disposable fractions.
- Commercial and industrial material – plastics, mixed dry recyclables – baled/compacted prior to transport offsite – again sent to a MRF for further segregation of recyclable and disposable fractions.
- Mixed packaging – baled/compacted prior to transport offsite – sent for offsite recovery/disposal
- Food waste – sent for composting offsite
- Waste wood material– sent for offsite recovery
- Waste metal material– sent for offsite recovery/disposal
- Construction and demolition waste - sent for off-site recovery
- WWTP sludge's – sent to a sludge drying facility
- Non-hazardous incinerator brick – sent offsite for disposal
- Waste cooking oil - sent for off-site recovery
- Glass - sent for off-site recovery
- Confidential paper - sent for offsite for shredding and re-use

All these wastes are managed by a dedicated waste contractor onsite who collects, segregates and transports off-site as appropriate.

Wastes arising from the biotechnology facility can be broken down into cell contact/non-cell contact wastes which include:

- Cell contacted solids
- Cell containing liquid
- Non-cell contacted solids
- Non- cell containing liquid
- General waste

Waste that contains or has been in direct contact with cell material will be inactivated by chemical/heat treatment onsite or sent directly to bio-waste containers for offsite disposal. All bio-waste transported offsite is incinerated irrespective of how it has been treated or inactivated onsite. All cellular material handled in the Biotech facility is currently classified as Class 1GMM material.

Non cell-contacted solid waste is placed in clear waste liners provided within each area and is taken off-site for incineration. Non-cell contacted liquid waste from the cell culture and purification processes will be emptied to the aqueous waste system via aqueous waste floor drains and will be treated in the onsite waste water treatment plant.

A baler has been installed on-site to maximise the quantity per load of selected solid waste streams that are being shipped off site for treatment. These waste streams include PPE, wipes, packaging from chemical manufacturing processes and consumables from the GMM manufacturing process. Baling of these waste streams provides significant environmental benefits to the site both in terms of the reduction in outer packaging volumes and also the reduction in carbon footprint associated with reduced transport movements. The baler is located in the IE18 hazardous waste drum store.

General waste such as warehouse packaging waste or plastic containers is segregated and recycled as appropriate.

Only approved waste contractors who have appropriate waste permits and licences are hired to transport, recover or dispose of Eli Lilly waste offsite. A database has been set up to log all waste movements offsite.

8.5 Attachment H.5. –Waste Recycling and Recovery

As can be seen in Table H.3.(i) of Annex 1, fractions of waste are kept segregated on site, stored separately on site and moved off-site for recovery and recycling as separate fractions.

By segregating waste fractions on site and sending them off-site for appropriate treatment, the site is contributing to national recovery and recycling targets as set out in the following:

- Packaging Directive 94/62/EC as amended
- Batteries Directive 2006/66/EC
- Waste Framework Directive 2008/98/EC - recovery and recycling of C&D
- Landfill Directive 1999/31/EC - the segregation of food waste from the municipal waste stream

Food waste generated on site is collected separately and routed to a composting facility as per the requirements of the Waste Management (Food Waste) Regulations 2009.

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9 ATTACHMENT I – EXISTING ENVIRONMENT & IMPACT OF THE ACTIVITY

9.1 Attachment I.1 – Assessment of Atmospheric Emissions

9.1.1 Introduction

This section assesses the cumulative impacts, if any, of emissions from the main emissions points onsite, on the surrounding environment, including:

Table 9.1: Main Atmospheric Emission Points

Main Emission Point	Current label	Proposed Label
Boilers	4-1	A1-1
Proposed additional boiler	N/A	A1-2
Reeco (RTO)	7-1 (a)	A2-1
John Zink (KEU) Thermal oxidiser	7-1 (b)	A2-2
Thermal thermal oxidiser	7-1 (c)	A2-3
Proposed Carbon absorber IE3	A3-24	A2-4
Proposed Carbon absorber IE16	A3-30	A2-5
Proposed CHP unit	N/A	A2-06

This assessment evaluates the impact on ambient air quality of limit value emissions, as outlined in Schedule B of the facilities licence (P0009-03) and technical amendments, from the main atmospheric emission point sources. The Eli Lilly facility now operates the onsite boilers on natural gas. It is proposed to increase heat and electricity supply capability onsite by developing a Combined Heat and Power (CHP) plant which will also operate on natural gas. An additional gas fired boiler may also be required in the medium term to meet projected steam demand. These proposed emission sources are also included in the assessment.

This assessment was carried out using the air prediction model AERMOD to calculate maximum ground level concentrations of emissions from the main atmospheric point sources, at and beyond the site boundary. The modelling assessment has been undertaken in accordance with the Environmental Protection Agency Office of Environmental Enforcement (OEE), *Air Dispersion Modelling from Industrial Installations Guidance Note (AG4)*, 2010.

9.1.2 Model Selection

AERMOD is an advanced air model which increases the reliability and accuracy of the predictions and allows the calculation of emission concentration percentiles for comparison to ambient air quality regulations.

It is considered that AERMOD is appropriate for the assessment of impacts of pollutant emissions from this facility, as in the region of the site, there is no complex terrain features which would significantly alter meteorological conditions. Also, due to the low source stack heights in this assessment, pollutant concentrations over long distances are not considered significant and therefore the prediction of pollutant concentrations by AERMOD within 10 km of sources is sufficient. In addition, the Eli Lilly facility is not located in close proximity to a coastline and therefore, the impacts of coastal fumigation do not need to be modelled in this assessment.

9.1.3 Model Input Data

This section outlines the input parameters for the AERMOD model.

Physical Parameters for Emission Points

The main atmospheric emissions were modelled as point sources. Table 9.2 sets out the physical characteristics of these emission points.

Table 9.2: Physical Parameters for Emission Points

Source	Release Height (m)	Stack Diameter (m)	Ambient Flow Rate (m/s) *	Average Exhaust Temperature (°C)
Boilers	20	0.9	30.5	240
Proposed CHP Engine	20	0.7	21.77	177
Proposed Additional Boiler	20	0.6	32.1	120
Combined John Zink (KEU) /Reeco (RTO)	23.8	0.7	26.3	103
Thermal thermal oxidiser	25	1.1	5.9	100
Proposed Carbon absorber IE3	20	0.5	1.3	30
Proposed Carbon absorber IE16	23	0.5	3.6	30

* Flow rate is based on the maximum flow rate outlined in schedule B of the Licence (P0009-03) uncorrected for operating temperature, pressure, moisture and oxygen.

The maximum ELVs stipulated in the facilities licence (Schedule B and technical amendments) were modelled in this assessment for each main existing atmospheric emission point sources. For the proposed carbon absorbers, the maximum ELV of 20 (mg C/ Nm³) for organic solvents in waste gases from the Industrial Emissions Directive (IED) (2010/75/EU), was used.

For proposed boilers, the ELVs from the sites existing licence for the existing boilers onsite was used. Emission limit values for combustion plants outlined in the IED, apply to combustion plant with a thermal input of equal to or greater than 50 MW. The three existing boilers onsite have a combined rated thermal input of 21.6 MW (7.2 MW each) emitted through a common stack therefore the ELVs in the IED do not apply to this plant.

Although the proposed boiler will emit through a separate stack the combined rated thermal input of all four boilers will remain less than 50 MW and therefore the IED ELV will not apply.

For the proposed CHP engine, typical emission levels as supplied by the manufacturer were used. Again, the total rated thermal input for this proposed plant will be less than the 50 MW threshold in the IED and therefore the ELV's stipulated in this Directive will not apply.

This is a conservative modelling exercise as typical emissions are significantly lower than the ELV's modelled.

Emissions from the Reeco RTO and the John Zink thermal oxidiser are combined and released through the one emission point. The emissions from the RTO and John Zink are combined using a weighted average calculation and based on the volume flows from each system.

With regards to the combined ELVs for metals, it was assumed conservatively that the individual concentrations of each metal released contributed to the total ELV and the predicted ambient concentrations were compared to individual ambient limit values for each particular metal. In reality, levels of metals recorded on-site are significantly lower than the ELV.

Table 9.3 illustrates the emission data that was inputted into the model for these point sources.

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Table 9.3: Emissions Data from Main Atmospheric Emissions On-site

Parameter	Boiler		Thermal Incinerator		KEU		Proposed Carbon Absorber IE16		Proposed Carbon Absorber IE3		Proposed CHP Plant		Proposed New Boiler	
	Emission Limit Value	Mass Emission	Emission Limit Value	Mass Emission	Emission Limit Value	Mass Emission	Emission Limit Value	Mass Emission	Emission Limit Value	Mass Emission	Emission Limit Value	Mass Emission	Emission Limit Value	Mass Emission
	mg/Nm ³	mg/s	mg/Nm ³	mg/s	mg/Nm ³	mg/s	mg/Nm ³	mg/s	mg/Nm ³	mg/s	mg/Nm ³	mg/s	mg/Nm ³	mg/s
Oxides of Nitrogen (expressed as NO ₂)	250	3,175	400	1367	400	1887					500	932	250	1527
Dust/Particulates			30	102.5	30	141.5								
Total Organic Carbon (TOC)			20	68	20	94	20	60.8	20	22.2				
Hydrogen chloride (HCL)			60	205	60	283								
Hydrogen Fluoride (HF)			4	13.7	4	19								
Hydrogen bromide (HBr)			5	17.1	5	23.6								
Sulphur Dioxide (SO ₂)			200	683.3	200	943.6								
The sum of Cadmium (as Cd) and thallium Mercury (as Hg) and its compounds			0.05	0.2	0.05	0.24								
The sum of antimony (as Sb), arsenic (as As), lead (as Pb), chromium (as Cr), cobalt (as Co), copper (as Cu), manganese (as Mn), nickel (as Ni), and vanadium (as V)			0.5	1.7	0.5	2.35								
Dioxins/furans (TEQ)			0.0000001	0.00000034	0.0000001	0.0000005								
Carbon monoxide (CO)			150	0.5	150	707.7								
Operating conditions i.e. temperature, moisture and oxygen	0°C, 3% O ₂ , 0% H ₂ O	240°C, 6% O ₂ , 6% H ₂ O	0°C, 11% O ₂ , 0% H ₂ O	100.7°C, 13% O ₂ , 6% H ₂ O	0°C, 11% O ₂ , 0% H ₂ O	100.7°C, 13% O ₂ , 6% H ₂ O	0°C, 20% O ₂ , 0% H ₂ O	30°C, 20% O ₂ , 5% H ₂ O	0°C, 20% O ₂ , 0% H ₂ O	30°C, 20% O ₂ , 5% H ₂ O	0°C, 5% O ₂ , 0% H ₂ O	177 °C, 10% O ₂ , 0% H ₂ O	0 °C, 3% O ₂ , 0% H ₂ O	120 °C, 3% O ₂ , 0% H ₂ O

Receptors

A receptor is a location at which the model will calculate maximum ground level concentrations. The height of the receptor is set at 1.5 m which represents the breathing level of humans.

The model was set up to assess the impact of emissions on the area surrounding the facility using a variable density receptor grid. Two variable polar grids were used. The first grid is 4 km in diameter centred on the facility with a grid resolution of 200 m. The second grid had a resolution of 500 m and expanded from the 4 km grid to 10 km to assess impacts on the surrounding environment. Receptors were also placed on the boundary of the facility to determine the impact of emissions on the surrounding environment at and beyond the boundary of the facility.

Building Downwash

The Good Engineering Practice (GEP) stack height is the minimum height required by a stack in order to avoid structural or building wake-effect induced downwash. Downwash brings pollutants closer to ground level at a shorter downwind distance giving the worst-case scenario for a particular site.

Relevant building dimensions were inputted into the model and the model software Building Profile Input Parameters (BPIP) was run to calculate the potential for building downwash on each emission source in each of the 36 wind direction sectors (10° width/sector). This model also calculates GEP heights where the effect of building downwash is eliminated. This data is then used in AERMOD to calculate plume downwash (i.e. adjusted plume centreline due to building wake affects).

Meteorological Data

Five years of meteorological data (2004 - 2008) from the synoptic station at Cork Airport was assessed in the modelling analysis. Cork Airport is located c. 20 km north-east of the site. The estimated annual mean windspeed at the site is approximately 6 m/s from the Met Eireann website. The annual wind speed at Cork airport is 5.7 m/s therefore the ratio of these windspeeds is 1.05 which is within the recommended ratio outlined in AG4 (0.9-1.1).

Two meteorological files are inputted into the model, a surface file and an upper air file. For surface meteorological conditions, hourly averages of surface data such as wind direction, wind speed, ambient air temperature, cloud cover and cloud height is used. Upper air conditions incorporated into the upper air file include atmospheric stability and mixing heights. The mixing height is the depth through which atmospheric pollutants are typically mixed by dispersion. The model selects upper air conditions that represents worst-case scenario.

To assess the worst case met data year, each individual met data year was modelled and examined to ascertain which year resulted in the highest predicted process contribution. The worst case met data was deemed to be the year 2008 and this met data was used in the modelling assessment, to determine the short term, long term and percentile concentration results in this report.

The wind rose for 2008 at Cork Airport is provided in Figure 9.1. The prevailing wind direction at Cork Airport is predominantly south westerly and the dominant wind speed is between 3.09 and 5.14 m/s. Missing hours (0.55%) and calm hours (1.24%) from the 2008 wind meteorological dataset combine to a total of 1.79% of hourly data. These unavailable hours will not significantly alter the modelling results.

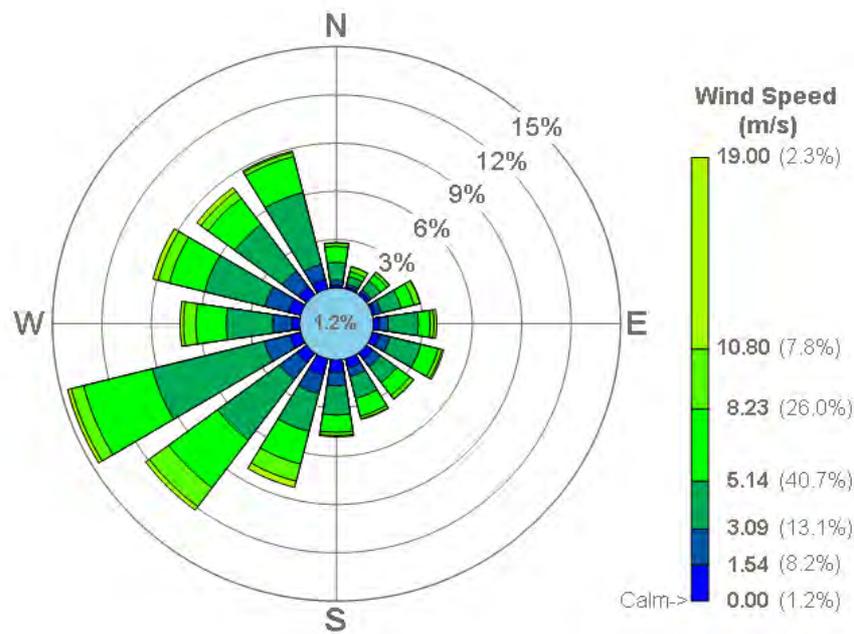


Figure 9.1: Windrose for Cork Airport 2008

Outputs

Calculations are made using a complex series of equations and assumptions. The model estimates the concentration value for each source and receptor combination for each hour of meteorological data.

The model was run to determine the maximum 1-hour, 24-hour and annual ground level concentrations of the relevant pollutant emissions. The 8-hour carbon monoxide (CO) concentration was also determined. Relevant percentiles were calculated in order to compare to relevant ambient air quality guidelines.

These maximum predicted ground level concentrations were then evaluated against the relevant ambient air quality guidelines. The modelled facility contribution was also added to maximum average EPA monitored rural background pollutant concentrations, where available, and compared to the relevant ambient air quality guidelines, in accordance with the *Environmental Protection Agency Office of Environmental Enforcement (OEE) Air Dispersion Modelling from Industrial Installations Guidance Note (AG4), 2010*.

Results from the model are discussed in Section 9.1.6.

9.1.4 Relevant Standards

In accordance with the Environmental Protection Agency Office of Environmental Enforcement (OEE), *Air Dispersion Modelling from Industrial Installations Guidance Note (AG4), 2010* the ambient air quality standards relevant to Ireland are the EU Ambient Air Quality Directives 2008/50/EC and 2004/107/EC. These Directives have been transposed into Irish Law by the Irish ambient air quality standard, S.I. No. 180 of 2011 – Air Quality Standards Regulations, 2011 and S.I. No. 58 of 2009 – Arsenic, Cadmium, Mercury, Nickel and Polycyclic Aromatic Hydrocarbons in Ambient Air Regulations 2009.

The EPA guidance states that in the absence of EU ambient air quality limit values for some pollutants, statutory standards from other EU countries should be examined for limit values for comparison purposes.

Statutory standards from other EU countries examined included:

- The Danish C-values (as 99%ile) outlined in the *Danish EPA's Environmental Guidelines No. 1, 2002 Guidelines for Air Emission Regulation Limitation of air pollution from installations* (EPA, Danish, 2002)
- The Health and Safety Authority: 2011 Code of Practice for Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001 (S.I No. 619 of 2001) (HSA, 2011)
- *Appendix F of the UK Environment Agency "IPPC Horizontal Guidance Note H1 - Environmental Risk Assessment for Permits"* (Environment Agency, 2010) short term hourly Environmental Assessment Levels (EAL) and long term annual EAL are available. EALs for some pollutants not listed in the 2010 version was taken from the 2003 version of this document (*Appendix D of the UK Environment Agency "IPPC H1 - IPPC Environmental Assessment for BAT"* (Environment Agency, 2003).

With regards to guidelines available for dioxin and furans, the WHO Air quality Guidelines for Europe (2000) states that air concentrations of 0.3 pg/m³ or higher of polychlorinated dibenzodioxins (PCDDs) and dibenzofurans (PCDFs) are indications of local emission sources that need to be identified and controlled.

The most toxic dioxin is 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD). There is a US Protective Action Criteria (PAC) for TCDD. These PAC criteria may be used to evaluate the severity of the event, to identify potential outcomes, and to decide what protective actions should be taken. PACs have three common benchmark values for each chemical (i.e., PAC-1, -2, and -3). Each successive benchmark is associated with an increasingly severe effect that involves a higher level of exposure. In this assessment, PAC -1 limit value is used as it conservative and represents mild and transient health effects. The PAC-1 for TCDD is 30 pg/m³.

9.1.5 Existing Environment

To estimate the background pollutant concentration in the area of the site, a desktop study was undertaken to establish the existing air quality in the area of the site. European air quality legislation requires that each member state be defined in terms of Zones and Agglomerations for Air Quality with Ireland divided into four zones. Dublin Conurbation is one zone – Zone A and Cork Conurbation is defined as Zone B. Zone C consists of 24 towns (i.e. Athlone, Bray, Celbridge) and cities (including, Galway, Limerick, Waterford) with a population of greater than 15,000 while Zone D.

The EPA operates a number of fixed and mobile air monitoring stations. As the site is located in a rural Zone D location – 2008, 2009 and 2010 EPA air quality data monitored in rural areas, with air quality Zone D, was reviewed and summarised in Tables 4.1 and 4.2. An average of the maximum rural location monitoring results can be used as a conservative representation of the air quality in proximity to Eli Lilly facility. These values are then added to the modelled facility contribution and compared to the relevant ambient air quality guidelines.

Eli Lilly conducted continuous background NO₂ monitoring in the vicinity of the Dunderrow site during 2006 and 2007. The average concentrations recorded ranged from 4.9 µg/m³ – 6.2 µg/m³. These figures were taken as a more representative background level than that recorded at the EPA monitoring stations and therefore was used to calculate the overall concentration.

Table 9.4: Summary of EPA Monitoring Results 2008 -2010 (Units: ug/m³)

Pollutant	Parameter	2008								2009					2010					Avg	
		Cork Harbour	Kilkitt, Co. Monaghan	Glashboy, Co. Cork	Castlebar	Carnsore Point, Co. Wexford	Shannon Estuary	Letterkenny	Mace-head	Kilkitt, Co. Monaghan	Shannon Estuary	Glashboy, Co. Cork	Castlebar Co. Mayo	Macehead	Kilkitt, Co. Monaghan	Shannon Estuary	Glashboy, Co. Cork	Castlebar Co. Mayo	Longford		Macehead
NO _x	Hourly Max	212	107	266						53		319	310		189		568	705			303
	Annual Mean	15	4	13						3		15	13		4		14	17			11
NO ₂	99.8 %ile Hourly	60	35	61						23		69	67		25		65				51
	Hourly Max	63	80	75						50		87	87		32		101	129			78
	Annual Mean	10	3	9						11		8			3		10	10			7
CO	8 Hourly Max	900																			900
	Annual Mean	400																			400
SO ₂	99.7 %ile Hourly	17	15							11	17				11	11					16
	Hourly Max	33	42							16	27				14	20					29
	24 -HR Max	12	14							12	11				10	11					13
	Annual Mean	4	4							4	4				2	3					4
PM ₁₀	90.4 %ile Daily		21		25	49				14			23		19			27	40		27
	24 -HR Max		57		73	146				55			64		42			108	105		81
	Annual Mean		10		16	30				8			13		10			15	21		15
Lead	Annual Mean								0		0.0005			0.0078							0.003
Arsenic	Annual Mean								0.0003		0.0005			0.0027							0.001
Cadmium	Annual Mean								0.00006		0.00005			0.0008							0.0003
Nickel	Annual Mean								0.0013		0.008			0.0054							0.0050
Mercury	Annual Mean								0.002					0.00145						0.00145	0.002

Source: Air Quality in Ireland 2008, 2009 and 2010

9.1.6 Results

The predicted results and relevant limit values are summarised in Table 9.5.

Table 9.5: Summary of Modelling Results ($\mu\text{g}/\text{m}^3$ (unless otherwise stated))

Parameter	Period	With CHP Plant & New Boiler	Air Quality Standards Regulations 2009 & 2011	Danish C-Value Limit	2011 HSA Chemical Agent Regs 2001		2010 Horizontal Guidance Note H1 - Annex (f)	
		Predicted Maximum Ground Level Concentration			Short Term (1-hour) EAL (15-min STEL/10)	Long Term Annual EAL (annual) (8-hr exposure limit (OEL)/100)	Short Term (1-hour) EAL	Long Term Annual EAL (annual)
Nox as NO ₂	1-HR - 99.8%	169	200					
	Annual	8	40					
Particulates	24-HR - 90.4%	0.86	50					
	Annual	0.24	40					
TOC	1-HR	14						
	1-HR - 99%	6		150 *				
	24-HR	4						
	Annual	0.6						
HCL	1-HR	22			1500		750	
	1-HR - 99%	9		50				
	24-HR	6						
	Annual	0.5				80		20 **
HF	1-HR	2			250		160	
	1-HR - 99%	0.6		2				
	24-HR	0.5						
	Annual	0.04				15		16
HBr	1-HR	2			660		700	
	1-HR - 99%	0.8						
	24-HR	0.6						
	Annual	0.04						
SO ₂	1-HR - 99.7%	37	350					
	24-HR - 99.2%	16	125					

Parameter	Period	With CHP Plant & New Boiler	Air Quality Standards Regulations 2009 & 2011	Danish C- Value Limit	2011 HSA Chemical Agent Regs 2001		2010 Horizontal Guidance Note H1 - Annex (f)	
		Predicted Maximum Ground Level Concentration			Short Term (1- hour) EAL (15- min STEL/10)	Long Term Annual EAL (annual) (8-hr exposure limit (OEL)/100)	Short Term (1-hour) EAL	Long Term Annual EAL (annual)
	Annual	2	-					
CO	8-HR	24	10,000					
Cadmium (as Cd)	1-HR	0.02						
	1-HR - 99%	0.008		0.01				
	24-HR	0.005						
	Annual	0.0005	0.0050			0.1		0.005
Thallium (as Tl)	1-HR	0.02					30 **	
	1-HR - 99%	0.008		0.3				
	24-HR	0.005						
	Annual	0.0005				1		1 **
Mercury (as Hg)	1-HR	0.02					7.5	
	1-HR - 99%	0.008		1				
	24-HR	0.005						
	Annual	0.0005				0.2		0.25
Antimony (as Sb)	1-HR	0.2					150	
	1-HR - 99%	0.07						
	24-HR	0.04						
	Annual	0.004				5		5
Arsenic (as As)	1-HR	0.17						
	1-HR - 99%	0.067		0.01				
	24-HR	0.04						
	Annual	0.004	0.0060			0.1		0.003
Lead (as Pb)	1-HR	0.2						
	1-HR - 99%	0.067		0.4				
	24-HR	0.04						
	Annual	0.004	0.0500			1.5		
Chromium (as Cr)	1-HR	0.2					150	
	1-HR - 99%	0.067		1				
	24-HR	0.04						
	Annual	0.004				20		5

Parameter	Period	With CHP Plant & New Boiler	Air Quality Standards Regulations 2009 & 2011	Danish C- Value Limit	2011 HSA Chemical Agent Regs 2001		2010 Horizontal Guidance Note H1 - Annex (f)	
		Predicted Maximum Ground Level Concentration			Short Term (1- hour) EAL (15- min STEL/10)	Long Term Annual EAL (annual) (8-hr exposure limit (OEL)/100)	Short Term (1-hour) EAL	Long Term Annual EAL (annual)
Cr)	24-HR	0.04						
	Annual	0.004				20		5
Cobalt (as Co)	1-HR	0.2					6	
	1-HR - 99%	0.067		0.5				
	24-HR	0.04						
	Annual	0.004				1		0.2
Copper (as Cu)	1-HR	0.2			200		200	
	1-HR - 99%	0.067		10				
	24-HR	0.04						
	Annual	0.004				10		10
Manganese (as Mn)	1-HR	0.2					1500	
	1-HR - 99%	0.067		80				
	24-HR	0.04						
	Annual	0.004				2		150
Nickel (as Ni)	1-HR	0.2						
	1-HR - 99%	0.067		0.1				
	24-HR	0.04						
	Annual	0.004	0.0200			5		0.02
Vanadium (as V)	1-HR	0.2					1	
	1-HR - 99%	0.067		0.3				
	24-HR	0.04						
	Annual	0.004						5
Dioxins/Furans (pg/m ³)	1-HR	0.01						
	1-HR - 99%	0.014						
	24-HR	0.011						
	Annual	0.0008						

* Organic solvents mixture

**Data from 2003 Environmental Agency IPPC Horizontal Guidance Note

Table 9.6 below combines the modelled facility process contribution to the average EPA monitored rural background concentrations (as summarised in Section 9.1.5). These results are compared with the limits set out in S.I. No. 180 of 2011, S.I. No. 58 of 2009 and relevant European limit values.

Table 9.6: Summary of Modelling Process Contribution and EPA Monitored Background Concentrations

Parameter	Period	Predicted Maximum Ground Level Concentration (ug/m ³)	Maximum Average Background Concentrations (ug/m ³)	Modelled Ground level Concentration + Background Concentrations (ug/m ³)	Air Quality Standards Regulations 2011 (SI 180 of 2011) (ug/m ³)	2011 HSA Chemical Agent Regs 2001	2010 Horizontal Guidance Note H1 - Annex (f)
						Long Term Annual EAL (annual) (8-hr exposure limit (OEL)/100) (mg/m ³)	Long Term Annual EAL (annual) (mg/m ³)
Nox as NO ₂ ¹	1-HR - 99.8%	169	6*	175	200		
	Annual	8	7	15	40		
Particulates	24-HR - 90.4%	0.9	27	28	50		
	Annual	0.2	15	16	40		
SO ₂	1-HR - 99.7%	37	16	53	350		
	24-HR - 99.2%	16	29	45	125		
CO	8-HR	24	900	924	10,000		
Cadmium (as Cd)	Annual	0.0005	0.0003	0.0008	0.0050	0.1	0.005
Mercury (as Hg)	Annual	0.0005	0.002	0.003		0.2	0.25
Arsenic (as As)	Annual	0.004	0.001	0.005	0.0060	0.1	0.003
Lead (as Pb)	Annual	0.004	0.003	0.007	0.0500	1.5	
Nickel (as Ni)	Annual	0.004	0.0050	0.0090	0.0200	5	0.02

1 NO₂ from John Zink, Thermall, Existing Boilers, Proposed CHP Engine

*Average background concentration recorded in the vicinity of Eli Lilly site during 24 month period

9.1.7 Discussion of Results

The results of the modelling assessment indicate that maximum ELV's stipulated in the facilities licence from the existing main atmospheric emission point's on-site and the ELVs for the proposed emission points are in compliance with the statutory limits set out in the relevant Irish air quality regulations and the most stringent European standards, at and beyond the site boundary of the facility. The modelling assessment represents a worst case scenario as the concentrations of emissions on-site are significantly lower than this.

Predicted levels for dioxin and furans are significantly below the WHO Air Quality Guidelines concentrations of 0.3 pg/m³ and within the PAC-1 for TCDD of 30 pg/m³.

Modelled facility process contributions added to average EPA monitored rural background concentrations, where available, are also in compliance with the relevant Irish air quality regulations and European limit values.

As previously mentioned, this is a conservative modelling exercise as typical emissions are significantly lower than the permitted ELV's. In particular it was assumed for the purposes of the modelling exercise that individual concentrations of each metal compound released at the site contributed to the total ELV and the predicted ambient concentrations were compared to individual ambient limit values for each particular metal. In reality, levels of metals recorded on-site are significantly lower than the ELV.

Consequently, although the predicted 1 hour 99%ile predicted arsenic concentration is elevated over the Danish C-value 99%ile ambient limit this is not the case during operations. Typical arsenic levels from the John Zink (KEU) Thermal Oxidiser and the Reeco are significantly lower at 0.000009 mg/m³ which give an ambient 99%ile concentration of 0.0002 ug/m³. This is well within the 99%ile Danish C-value ambient limit, at and beyond the site boundary.

In conclusion, the cumulative impact of emissions, from the main atmospheric emissions points' onsite, will not adversely impact the ambient air quality of surrounding environment.

9.2 Attachment I.2 – Assessment of Impacts of Surface Water Discharges on Receiving Waters

An assessment has been undertaken to determine the impact of surface water discharges from the site. There are two surface water discharges from the site namely:

- Treated wastewater effluent discharge to coastal waters
- Storm water run-off to Doon Creek

The impacts of both these discharges are discussed individually below.

9.2.1 Impacts of Treated Wastewater Effluent Discharge to Coastal Waters

Introduction

Currently, treated waste water emissions from the Eli Lilly site are discharged via a 9 km purpose built pipeline of approximately 25 cm in diameter. It is discharged from a multiport subtidal diffuser to coastal water east of Sandy Cove Island, outside Kinsale Harbour and south of Money Point, designated as the end of the Bandon Estuary by the EPA.

As part of this waste licence review, the Marine Ecosystem Research Laboratory of the Ryan Institute in the National University of Ireland, Galway, were commissioned to undertake a near field surface water discharge dispersion assessment of the Eli Lilly outfall, Kinsale, Co. Cork. A summary of the assessment undertaken by Marine Ecosystem Research Laboratory is provided below.

The assessment was undertaken to investigate if the receiving surface water body would be compliant with EC Environmental Objectives (Surface Waters) Regulations (S.I. No. 272/2009) if the treated wastewater emissions were discharged at the potential worst case limits permitted under the current Licence (P0009-03).

Summary of Modelling Methodology

Two modelling approaches were used:

1. Simple dispersion / dilution model developed by the Scottish Environmental Protection Agency (SEPA). This model was published as guidance by the Irish EPA in 2011
2. A three-dimensional Updated Merge (UM3) model from the United States Environmental Protection Agency (USEPA).

The Eli Lilly diffuser was modelled using the following characteristics:

- Number of ports = 12
- Port diameter = 0.03176 metre (m) (1.25 inches)
- Port spacing = 4.116 m (13.5 feet)
- Port orientation = vertical (90°)
- Port distance above bottom = 1 m
- Diffuser orientation = perpendicular to ambient flow
- Distance from shore = 975.6 m (3200 feet)
- Effluent Temperature = 15°C
- Effluent Salinity = 0
- Maximum flow rate from Emission Point SW1 (6.1) = 3,000 m³/day, from Emission Point SW2 (W2) = 1500 m³/day

Effluent concentration was simulated at the maximum emission limits and maximum volume discharge for each substance, as outlined in Schedule B.2. of the current licence (P0009-03) for the site. Total Nitrogen emissions were modelled as being 100% DIN for the purposes of assessing potential exceedance of the EQS. Total Phosphorous emissions were modelled as being 100% Molybdate Reactive Phosphorous (MRP). This was for two reasons: the only data available for the water body are MRP concentrations, and MRP is a potential nutrient in transitional, but not coastal waters.

Ambient currents were measured with an acoustic Doppler current profiler (ADCP). The average current speed and direction were used to model dispersion (17.5 cm/s, 178° West). Water depth was set to the level of the lowest astronomical tide (LAT), 12m for testing compliance with Surface Waters Regulations. The water column was considered to be not stratified for modelling purposes.

Where an EQS has been established, the calculated concentrations at 100m from the diffuser were assessed to determine if it had exceeded the EQS. The percentage change from the background level was calculated. The emission concentration level necessary to exceed the EQS (Exceedance Concentration) was determined by numerical simulation. The ratio of the current emission limit to the Exceedance Concentration was expressed as a percentage.

The EQS chosen was the most conservative option in each case. Generally, the Annual Average (AA) EQS was used. The EQS for waters already achieving Good ES was used as the EPA has classified ES in Kinsale Harbour as Good (McGarrigle et al 2010 (**Appendix 2**)). Toluene and xylene both have an AA EQS of 10 µg/l, but the AA-EQS of benzene (8 µg/l) was used for the combined emission of all three substances.

Existing Environment

Time series monitoring data from the EPA monitoring program stations near to the diffuser were used to calculate the background concentrations in the existing environment for Total Nitrogen, Total Phosphorous (taken as being equivalent to Molybdate Reactive Phosphate; (MRP)), Ammonia and Dissolved Inorganic Nitrogen (DIN).

Similar existing environment monitoring data was also available from the NUIG monitoring program (O'Brien 2000; Kennedy 2005, 2006, 2007, 2012 (**Appendix 2**)). This monitoring data is outlined in Tables 9.7 and 9.8.

The median value from this monitoring data was used as the background concentration in the estuary. In the case of DIN and MRP, the median winter concentration was used. For other parameters the following were used as background concentrations:

- Chemical Oxygen Demand (COD) was estimated at 1 mg/l as this is a low level, likely to reflect the ambient levels in coastal waters of Good ES.
- For metals, the background level was estimated to be 10% of the Environmental Quality Standard (EQS) from S.I. No. 272 of 2009, or 1 $\mu\text{g l}^{-1}$, whichever was the larger.
- Concentration for the combined BTEX parameter of benzene, toluene and xylene was estimated as 1 $\mu\text{g/l}$.
- Concentrations of dioxins and furans were estimated at low levels that approximate the limits of detection in seawater

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Table 9.7: Summary of EPA Water Monitoring data of the Lower Bandon Estuary and Kinsale Harbour 2007-2009

Lower Bandon Estuary														TSAS criteria	Threshold	Value	Eutrophic
	Summary Stats	Salinity	Temp (°C)	pH	Secchi (m)	DO sat. (%)	DO (mg/l)	BOD (mg/l)	TON (mg/l)	NH ₃ (mg/l)	DIN (mg/l)	MRP (µg/l)	Chl. a (µg/l)				
Winter	MINIMUM	0.07	4.57	7.2	0.6	66.4	8.4	< 1	0.16	0.02	0.166	17	< 0.5	Winter DIN	1.682	2.054	Fail
	MEDIAN	13.85	8.36	7.9	1.3	92.2	9.8	< 1	1.89	0.06	2.054	28	1.2	Winter MRP	60	28	Pass
	MAXIMUM	35.19	9.82	8.1	2.0	98.5	12.2	1.0	4.96	0.65	4.997	42	7.1	DIN-	0.889	0.537	Pass
	No. of samples	42	48	48	30	48	42	11	48	48	48	48	47	MRP-	51	11	Pass
															Chloro. Median	12.8	5.4
Summer	MINIMUM	0.29	12.33	7.4	0.5	73.6	6.3	< 1	0.01	0.02	0.015	10	< 0.5	Chloro 90 percentile	25.6	35.6	Fail
	MEDIAN	25.27	15.71	8.1	1.3	98.0	8.3	2.2	0.48	0.03	0.537	11	5.4	Opportunistic algae	0.6		
	MAXIMUM	35.15	19.70	8.7	4.6	199.9	16.5	8.8	3.10	0.42	3.529	118	92.3	DO%sat 5 percentile	74	78.3	Pass
	No. of samples	130	131	135	48	130	130	56	135	135	135	135	135	DO%sat 95 percentile	126	158.0	Fail
														BOD	4	6.3	Fail

Kinsale Harbour														TSAS criteria	Threshold	Value	Unpolluted
	Summary Stats	Salinity	Temp (°C)	pH	Secchi (m)	DO sat. (%)	DO (mg/l)	BOD (mg/l)	TON (mg/l)	NH ₃ (mg/l)	DIN (mg/l)	MRP (µg/l)	Chl. a (µg/l)				
Winter	MINIMUM	18.54	6.34	7.9	2.0	93.2	8.5		0.16	0.02	0.167	18	< 0.5	Winter DIN	0.314	0.200	Pass
	MEDIAN	34.96	9.51	7.9	2.0	97.8	9.0		0.18	0.02	0.200	21	0.9	Winter MRP	41	21	Pass
	MAXIMUM	35.19	9.83	8.1	2.0	106.3	10.4		1.07	0.19	1.264	37	4.1	DIN-	0.314	0.050	Pass
	No. of samples	8	8	8	1	8	8		8	8	8	8	8	MRP-	41	5	Pass
															Chloro. Median	10.3	1.3
Summer	MINIMUM	27.74	12.13	7.8	3.5	87.1	7.5	< 1	0.01	0.02	0.015	< 5	< 0.5	Chloro 90 percentile	20.6	3.1	Pass
	MEDIAN	34.29	14.50	8.1	5.0	102.0	8.5	1.6	0.03	0.03	0.050	5	1.3	Opportunistic algae	0.6		
	MAXIMUM	35.20	17.45	8.3	5.8	113.3	9.4	3.5	6.00	0.82	6.040	14	4.6	DO%sat 5 percentile	79	91.5	Pass
	No. of samples	30	30	30	8	29	28	12	30	30	30	30	30	DO%sat 95 percentile	121	112.9	Pass
														BOD	4	3.1	Pass

Source: McGarrigle et al, 2010 (Appendix 5)

Table 9.8: Summary of Water Monitoring Data of the Lower Bandon Estuary and Kinsale Harbour 2005-2012

Inner Harbour / Lower Bandon Estuary

Winter	Summary	Salinity	TON (mg/l)	NH ₃ (mg/l)	DIN (mg/l)	MRP (µg/l)	SPM	TSAS criteria	Threshold	Value		
Winter	MINIMUM	12.34	-	0.01	0.31	8.73	17.53	Winter DIN	1.16	1.07	Pass	
	MEDIAN	21.18	-	0.04	1.07	95.12	26.98	Winter MRP	55.36	95.12	Fail	
	MAXIMUM	30.33	-	0.08	1.66	390.98	65.20	DIN-	0.65	0.09	Pass	
	No. of samples	54.00	-	54.00	54.00	54.00	52.00	MRP-	47.08	23.65	Pass	
Summer	MINIMUM	19.42	-	0.01	0.03	9.70	16.93	Chloro. Median				
	MEDIAN	28.63	-	0.05	0.09	23.65	23.55	Chloro 90 percentile				
	MAXIMUM	32.36	-	0.07	0.79	48.35	32.29	Opportunistic algae				
	No. of samples		68.00	-	68.00	68.00	68.00	68.00	DO%sat 5 percentile			
									DO%sat 95 percentile			
								BOD				

Middle Harbour

		Salinity	TON (mg/l)	NH ₃ (mg/l)	DIN (mg/l)	MRP (µg/l)	SPM	TSAS criteria	Threshold	Value		
Winter	MINIMUM	26.44	-	0.02	0.19	10.47	18.40	Winter DIN	0.35	0.54	Pass	
	MEDIAN	33.06	-	0.04	0.54	22.55	25.75	Winter MRP	42.15	22.55	Pass	
	MAXIMUM	35.04	-	0.08	1.27	60.89	50.18	DIN-	0.27	0.09	Pass	
	No. of samples	54.00	-	54.00	54.00	54.00	52.00	MRP-	40.94	23.65	Pass	
Summer	MINIMUM	3.73	-	0.02	0.03	9.70	17.13	Chloro. Median				
	MEDIAN	34.16	-	0.04	0.09	23.65	22.46	Chloro 90 percentile				
	MAXIMUM	35.08	-	0.07	0.36	48.35	32.85	Opportunistic algae				
	No. of samples		68.00	-	68.00	68.00	68.00	68.00	DO%sat 5 percentile			
									DO%sat 95 percentile			
								BOD				

Table 9.8 Cont Summary of Water Monitoring Data of the Lower Bandon Estuary and Kinsale Harbour 2005-2012

Outer Harbour

		Salinity	TON (mg/l)	NH ₃ (mg/l)	DIN (mg/l)	MRP (µg/l)	SPM	TSAS criteria	Threshold	Value	
Winter	MINIMUM	32.21	-	0.02	0.18	10.72	19.93	Winter DIN	0.35	0.24	Pass
	MEDIAN	34.95	-	0.03	0.24	23.68	24.61	Winter MRP	40.06	23.68	Pass
	MAXIMUM	35.45	-	0.07	0.39	55.80	45.61	DIN-	0.27	0.08	Pass
	No. of samples	54.00	-	54.00	54.00	54.00	52.00	MRP-	40.15	29.88	Pass
Summer	MINIMUM	33.72	-	0.01	0.02	9.57	19.37	Chloro. Median			
	MEDIAN	34.86	-	0.04	0.08	29.88	23.63	Chloro 90 percentile			
	MAXIMUM	35.49	-	0.07	0.22	57.17	31.59	Opportunistic algae			
	No. of samples	68.00	-	68.00	68.00	68.00	68.00	DO%sat 5 percentile			
								DO%sat 95 percentile			
								BOD			

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Model Results

The results of this modelling assessment are outlined in Table 9.9 below.

Table 9.9: Summary of Model results for contaminant concentrations 100m from Eli Lilly diffuser, Kinsale, Co. Cork

	SEPA model		UM model (LAT)		Compliance		C_100m (UM)	Change relative to background	Exceedence concentration	Emission Limit as % of	
	D	C_effluent	C_background	C_100m	C_100m	EQS					SW Regs
6.1	mg/l	mg/l	mg/l	mg/l	mg/l	mg/l			mg/l		
BOD	8572.8	600	3.100	3.170	3.280	n/a		6%			
COD	8572.8	1500	1.000	1.175	1.530	n/a		53%			
Total N	8572.8	100	0.326	0.338	0.357	n/a		15%			
Total P / MRP*	8572.8	100	0.021	0.033	0.060	n/a		183%			
DIN*	8572.8	100	0.200	0.212	0.232	0.350	pass	66%	16%	410	24.4%
NH4-N	8572.8	50	0.030	0.0358	0.0477	n/a		59%			
Tin	8572.8	100	0.001	0.0127	0.0410	n/a		4000%			
Copper	8572.8	0.5	0.001	0.0011	0.0012	0.0050	pass	23%	16%	10.5	4.8%
Zinc	8572.8	0.6	0.004	0.0041	0.0042	0.0400	pass	10%	4%	185	0.3%
Benzene, Xylene and Toluene	8572.8	0.1	0.001	0.0010	0.0010	0.0080	pass	13%	2%	17.9	0.6%
W.2		µg/l	µg/l	µg/l	µg/l	µg/l				µg/l	
Copper and its compounds	17145.6	500	1	1	1.1	5.0	pass	21%	7%	10,500	4.8%
Zinc and its compounds	17145.6	1500	4	4.1	4.2	40	pass	5%	5%	185,000	0.8%
Dioxins, Furans	17145.6	0.30	0.01	0.01	0.01	n/a		0.40%			

In this study, none of the emissions exceeded the relevant EQS at a distance of 100m from the diffuser. Most of the emissions were predicted to produce concentrations at 100m that are an order of magnitude below the relevant EQS when being discharged at the emission limits. The dispersive nature of the diffuser location appears to dilute the emissions very effectively.

The results predicted increases over background levels for:

- Total Nitrogen increased by 15% relative to the background levels. Total Nitrogen has no associated EQS
- Modelled DIN concentrations increased by 16% and the maximum emission limits were 24.4% of the Exceedance Concentration
- Ammonia levels were increased by 59% relative to the background level. Ammonia has no associated EQS
- Tin increased by 4000% from the nominal background level of 1 µg/l. Inorganic tin is generally not toxic to vertebrates, invertebrates or macroalgae. There is no EQS for tin in coastal waters
- Dioxins and Furans increased only marginally in the model simulation
- Molybdate Reactive Phosphate concentrations were modelled using the conservative assumption that all Total-Phosphorous emissions would be in the form of MRP. Total-P / MRP increased by 189% on background levels. There is no EQS associated with Total-P or MRP in coastal waters.

Conclusion

The results of this modelling study indicate that the wastewater discharges up to and including maximum loads permitted by the current licence will not adversely impact the Ecological Status or breach of Environmental Quality Standards in the receiving water body in accordance with the EC Environmental Objectives (Surface Waters) Regulations (*S.I. No. 272/2009*).

A copy of the Marine Ecosystem Research Laboratory, Ryan Institute, National University of Ireland, Galway, report is included in **Appendix 2** of this application.

Based on the above conclusions, it should be possible to maintain current emission limit values (ELV) for all parameters listed in Schedule B.2 of the current licence. The maintenance of the Total phosphorus and Total Nitrogen/Ammonia limit values are of particular concern as the site manufacturing processes expand to include Biotech manufacturing. The development of this type of manufacturing process will lead to a significant increase in the use of aqueous based cleaning products and buffers which have a high phosphorus content.

Currently a fivefold increase in the use of these cleaning products and buffers is envisaged with the full development of the IE42 and IE43 facilities. This will ultimately impact on the phosphorus concentration of the aqueous waste streams for treatment in the WWTP and may lead to increased concentration level in the final effluent discharge.

Nitrogen/Ammonia concentrations through the WWTP can also be impacted by certain discharges from the Biotech process therefore it is important to retain current ELV's for these compounds so as to enable the system to absorb these fluctuations. This is considered the best environmental option in treating these waste streams given that the modelled ELV's do not impact on the quality of the receiving water and compliance to the requirements of the Surface Water Regulations is being maintained.

Another factor that will influence final effluent concentration values is the requirement of the current licence to minimise water demand and to reduce the overall volume of effluent discharge.

A feasibility study is currently being undertaken on site to assess the possibility of converting the Membrane Filtration Plant for use in the treatment of grey utilities water to a standard sufficient for re-use in site utilities. If this project is successful it will result in a significant reduction in the overall quantity of effluent discharge. As a consequence of this however the actual concentration of residual compounds present in the effluent discharge will increase while the actual mass loading will remain unchanged. It is important that this be recognised in any future licence conditions applied to such discharges.

Note: Refer to **Appendix 2** for further details on the references cited in this section.

9.2.2 Impacts of Storm Water Run-off to Doon Creek

Introduction

Currently, surface water from the Eli Lilly plant discharges to the Doon (Creek) River which in turn outfalls to a transitional waterbody (Bandon River) prior to outfalling to a coastal water body (Kinsale Harbour).

Impacts of this storm water run-off from the Eli Lilly plant was assessed to ensure the receiving surface water body is compliant with EC Environmental Objectives (Surface Waters) Regulations (S.I. No. 272/2009).

Methodology

A programme of surface water monitoring was undertaken during 2011 and 2012 at two locations, both upstream and downstream of the storm water discharge (SW3) from the Eli Lilly facility. DC-U2 is located upstream of the SW3 discharge on Doon Creek and DC-D3 is located downstream of SW3 discharge on Doon Creek. Grab samples were taken from these locations on six occasions and the samples were sent to a laboratory for analysis.

Existing Environment

The results of the monitoring programme are shown on Tables 9.10 and 9.11.

These tables also include a column relating to the allowable water quality limit for each of the parameters analysed. Where available, 'Good Status' limits from the *EC Environmental Objectives (Surface Waters) Regulations (S.I. No. 272/2009)*, henceforth called the surface water regulations 2009, were applied due to the nature of the transitional and coastal water bodies. The Doon Creek is not monitored as part of the Water Framework Directive (WFD), however, it outfalls to the Bandon River and Kinsale Harbour which have moderate status with the aim to achieve good status. The water of the Doon Creek was classified as "soft" for the majority of the results, as the hardness was recorded as less than 100 mg/l CaCO₃. The limits in the surface water regulations 2009 relating to soft water were therefore applied to the waterbody where applicable. The annual average environmental quality standard (AA-EQS) outlined in the surface water regulations 2009 was used as the guideline limit as this standard is more conservative.

For parameters not outlined in surface water regulations 2009, such as electrical conductivity, total organic carbon (TOC), nitrite and nitrate, the most conservative limit referenced in the *EPA Parameters of Water Quality 2001* was applied. It should be noted that some of these limits are not directly applicable to the Doon Creek waterbody but can be used as a guideline limit. No limits were identified for total nitrogen (as N), total phosphorous (as P) and tin.

Upstream of the Eli Lilly facility discharge, at DC-U2, it was observed that the majority of parameters were in compliance with the inland surface water AA-EQS limit values, with the exception of ammonia, copper and cadmium. With respect to ammonia, one result during monitoring period 03/01/12 was greater than the mean limit; however, it was less than the 95%ile limit. During the monitoring period on the 10/01/12, recorded copper and cadmium levels were greater than the limit however, for all other cadmium and copper samples, the results were below the limit of detection of the laboratory.

Downstream of the Eli Lilly facility discharge, at DC-D3, it was observed that the majority of parameters were in compliance with the inland surface water AA-EQS limit values, with the exception of ammonia, orthophosphate, copper and cadmium. With respect to ammonia, one result during monitoring period 03/01/12 was greater than the mean limit; however, it was less than the 95%ile limit. During the monitoring period on the 10/01/12, recorded copper and cadmium levels were greater than the limit however, for all other cadmium and copper samples, the results were below the limit of detection of the laboratory.

With regards to orthophosphate, one result from the first monitoring period in 09/12/11 was greater than the mean and 95%ile limits however, for all other samples, the results were below the inland surface water limit values.

Table 9.10: Monitoring results from DC-U2 (Doon Creek Upstream of SW3 discharge)

Parameter	Results (mg/l)						Allowable Limit
	Date 09/12/11	Date 13/12/11	Date 20/12/11	Date 03/01/12	Date 10/01/12	Date 17/01/12	
pH	7.38	7.05	7.18	7.20	7.48	7.35	Soft water 4.5 < pH < 9.0 *
Temperature	9.4	9.1	14.8	12.2	12.8	15.4	Not greater than a 1.5°C rise in ambient temperature outside the mixing zone *
Electrical conductivity (µS/cm)	250	270	260	276	260	262	1000 µS/cm (measured at 20oC) **
Dissolved oxygen (% Sat)	102.4	102.1	98.3	100.4	100.8	103.5	80% sat < 95%ile < 120% sat *
TOC	1.65	2.34	1.53	2.47	1.34	2.26	No abnormal change**
Biochemical oxygen demand	<1.0	<1.0		<1.0	<1.0	<1.0	Good status ≤1.5 (mean) or ≤ 2.6 (95%ile) *
Ammonia (as N)	0.011	0.043	0.050	0.093	0.013	0.058	Good status ≤0.065 (mean) or ≤0.140(95%ile) *
Total Nitrogen (as N)	5.4	6.2	5.5	6.2	5.4	4.9	-
Nitrite (as N)	<0.013	<0.013	<0.013	<0.013	0.013	<0.013	0.50 mg/l (0.10mg/l for ex water treatment works) **
Nitrate (as N)	5.51	6.47	5.01	<0.12	5.35	4.08	50 mg/l **
Total Phosphorous (as P)	0.01	0.02	0.01	0.03	0.01	0.03	-
OrthoPhosphate (as P)	0.013	0.019	<0.009	<0.009	<0.009	<0.009	Good status ≤0.035 (mean) or ≤ 0.075 (95%ile) *
Hardness	88.0	93.3	87.2	95.8	82.5	92.5	Soft Water - Water hardness ≤100 mg/l CaCO ₃ *
Toluene	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	0.01mg/l *
Ethylene Dichloride	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	0.01mg/l *
Fluoride	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.5mg/l *

Parameter	Results (mg/l)						Allowable Limit
	Date 09/12/11	Date 13/12/11	Date 20/12/11	Date 03/01/12	Date 10/01/12	Date 17/01/12	
Arsenic	<0.0002	<0.0002	0.0004	<0.0002	<0.0002	0.0003	0.025mg/l *
Cadmium	<0.0001	<0.0001	<0.0001	<0.0001	0.0001	<0.0001	0.00009mg/l *
Chromium	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	III:0.0034mg/l VI:0.0047mg/l *
Mercury	<0.00002	<0.00002	<0.00002	0.00002	<0.00002	<0.00002	0.00005mg/l *
Copper	<0.003	<0.003	<0.003	<0.003	0.008	<0.003	0.005 mg/l *
Nickel	0.001	0.0012	0.0010	0.0013	0.0012	0.0011	0.02mg/l *
Zinc	0.0039	0.0045	0.0022	0.0054	0.0030	0.0050	0.5mg/l *
Tin	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	-
Lead	<0.0003	<0.0003	0.0004	<0.0003	0.0003	<0.0003	0.0072mg/l *

* EC Environmental Objectives (Surface Waters) Regulations (S.I. No. 272/2009)

** EPA Parameters of Water Quality 2001

Table 9.11: Monitoring results from DC- D3 (Doon Creek Downstream of SW3 discharge)

Parameter	Results (mg/l)						Allowable Limit
	Date 09/12/11	Date 13/12/11	Date 20/12/11	Date 03/01/12	Date 10/01/12	Date 17/01/12	
pH	7.36	7.12	7.29	7.33	7.46	7.33	Soft water 4.5 < pH < 9.0 *
Temperature (C)	9.6	9.4	14.6	12.2	13.8	15.3	Not greater than a 1.5°C rise in ambient temperature outside the mixing zone *
Electrical conductivity(µS/cm)	258	276	288	289	279	276	1000 µS/cm (measured at 20oC) **
Dissolved oxygen (% Sat)	102.8	102.2	95.9	99.1	101.4	104.6	80% sat < 95%ile <120% sat *
TOC	1.73	2.39	1.55	2.59	1.32	2.11	No abnormal change**

Parameter	Results (mg/l)						Allowable Limit
	Date 09/12/11	Date 13/12/11	Date 20/12/11	Date 03/01/12	Date 10/01/12	Date 17/01/12	
Biochemical oxygen demand	<1.0	<1.0		<1.0	<1.0	<1.0	Good status ≤ 1.5 (mean) or ≤ 2.6 (95%ile) *
Ammonia (as N)	0.059	0.036	0.053	0.068	0.014	0.034	Good status ≤ 0.065 (mean) or ≤ 0.140 (95%ile) *
Total Nitrogen (as N)	<1.0	5.4	5.2	6.2	5.1	4.4	-
Nitrite (as N)	<0.013	<0.013	<0.013	<0.013	<0.013	<0.013	0.50 mg/l (0.10mg/l for ex water treatment works) **
Nitrate (as N)	0.93	5.32	4.71	<0.12	4.63	3.81	50 mg/l **
Total Phosphorous (as P)	0.09	0.03	0.02	0.03	0.01	0.02	-
OrthoPhosphate (as P)	0.079	0.018	0.014	<0.009	<0.009	<0.009	Good status ≤ 0.035 (mean) or ≤ 0.075 (95%ile) *
Hardness	82.4	97.0	90.6	104.7	90.7	92.5	Soft Water - Water hardness ≤ 100 mg/l CaCO ₃ *
Toluene	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	<0.0005	0.01mg/l *
Ethylene Dichloride (1,2 Dichloroethane)	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	<0.0001	0.01mg/l *
Fluoride	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.5mg/l *
Arsenic	0.0003	<0.0002	0.0003	<0.0002	0.0002	<0.0002	0.025mg/l *
Cadmium	<0.0001	<0.0001	<0.0001	<0.0001	0.0002	<0.0001	0.00009mg/l *
Chromium	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	III:0.0034mg/l VI:0.0047mg/l *
Mercury	<0.00002	<0.00002	<0.00002	0.00003	<0.00002	<0.00002	0.00005mg/l *
Copper	0.003	0.003	<0.003	<0.003	0.006	<0.003	0.005 mg/l *
Nickel	0.0006	0.0011	0.001	0.0013	0.001	0.0011	0.02mg/l *
Zinc	0.0576	0.0079	0.0037	0.0053	0.0034	0.0050	0.5mg/l *
Tin	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	-
Lead	<0.0003	<0.0003	<0.0003	<0.0003	<0.0003	<0.0003	0.0072mg/l *

* EC Environmental Objectives (Surface Waters) Regulations (S.I. No. 272/2009)

** EPA Parameters of Water Quality 2001

It was observed that although 'Good Status' limits were applied to Biochemical Oxygen Demand (BOD) results, all results obtained were also in accordance with 'High Status' limits.

It should also be noted that the results provided for both upstream and downstream discharge points DC-U2 and DC-D3 do not differentiate Chromium, into Chromium III or Chromium VI, as per the surface water regulations 2009. The results however, for both monitoring discharge points are in accordance with both limit requirements.

Impact assessment

With the exception of elevated level of orthophosphate during the first monitoring period, the elevated levels of ammonia, copper and cadmium during the respective monitoring periods are elevated both upstream and downstream of the facility discharge at SW3. It should be noted that elevated concentrations predominantly decrease from the upstream to downstream locations.

With regards to orthophosphate, while one elevated level was recorded downstream during the first monitoring period, all other recorded levels were well within the allowable limit value. Therefore, it can be concluded that the discharge from the Eli Lilly facility at SW3 is not impacting the surface water quality of Doon Creek.

Conclusion

From the monitoring assessment undertaken both upstream and downstream from the storm water discharge (SW3) from the Eli Lilly facility, it was observed that the majority of monitored parameters were in compliance with the inland surface water AA-EQS limit values stated in EC Environmental Objectives (Surface Waters) Regulations (S.I. No. 272/2009).

While some elevated levels above the inland surface water AA-EQS limit values were recorded during the assessment, these elevated levels occurred during a one-off monitoring period and all other recorded levels were well within the allowable limit value. These elevated levels also occurred both upstream and downstream of the facility discharge which concludes that the discharge from the Eli Lilly facility at SW3 is not impacting the surface water quality of Doon Creek.

9.3 I.3 - Assessment of Impact on Receiving Sewer

There are no discharges to sewer from the site therefore there is no requirement for Attachment I.3.

9.4 Attachment I.4 - Assessment of Impact of Ground/Groundwater Emissions

There are no direct emissions to groundwater from the site. A baseline report has been prepared for the site and is included in **Appendix 3**.

9.5 Attachment I.5 - Ground and/or Groundwater Contamination

Details of a groundwater contamination incident with MTBE which occurred at the site in 2003 are outlined in Attachment D.2. The residual impacts from this incident are localised to a confined area of the site aquifer and are now considered largely remediated. Detailed information related to this incident has been previously reported in formal correspondences to the Agency and during Agency visits to the site. In addition, yearly remediation updates have been included in the Annual Environmental Reports submitted to the Agency since the incident occurred and during Agency visits to the site. A summary of the impact of the incident, the mitigation measures that were undertaken in response to the incident and the current status of the residual groundwater impacts is provided below.

Impact of MTBE in Groundwater and Compliance with the EC Environmental Objectives (Groundwater) Regulations 2010 (S.I. No. 9 of 2010):

The following points should be considered when assessing the impact and significance of the level of MTBE in groundwater;

- The zone of residual MTBE impacts is confined to a localised area of the site aquifer with limited migration potential and no offsite impacts.
- MTBE is classified as a 'Non-Hazardous' substance in groundwater (EPA, 2010).
- A Groundwater Threshold Value for MTBE is not specified in the EC Environmental Objectives (Groundwater) Regulations 2010 (S.I. No. 9 of 2010) and therefore the presence of the compound in groundwater does not impact compliance with these regulations.
- The Agency has assigned an Interim Groundwater Guideline Value (IGV) of 30µg/l to MTBE (EPA, 2003).
- The MTBE concentration at the impacted area of the site aquifer is now being sustained in a downward trend below the Agency IGV of 30µg/l.

Mitigation Measures Undertaken in Response to the Presence of MTBE in Groundwater:

The following is an outline of the various mitigation measures that were implemented at the site in response to the detection of MTBE in the impacted area of the site aquifer. This includes measures that were implemented immediately after detecting the presence of the MTBE in the aquifer and in the intervening period since then in order to remediate the impacted area. The measures implemented are detailed in various reports, which are retained onsite.

- All production groundwater wells down gradient of the impacted zone were shutdown to minimise the potential for plume migration and/or expansion.
- Local and international hydro-geological consultants were retained to advise the site on an appropriate strategy to manage the issue and mitigate any immediate risks.
- A comprehensive groundwater sampling and analysis programme was implemented to characterise the nature and extent of the impacted zone.
- Further to this, the hydro-geological consultants that had been retained by the site undertook a series of comprehensive studies of the site hydrogeology throughout 2004 in order to fully understand the nature and extent of the contamination issue. This included the deployment of various advanced geophysical surveying techniques, chemical sampling and analysis and extended well pump testing.
- Based on the data gathered during the studies of the site hydrogeology, an appropriate remediation strategy was designed by the consultants that would be implemented in order to remove the bulk of the MTBE from the groundwater and sustain the concentration within acceptable levels.
- The remediation strategy required the drilling and installation of a remedial well (now renamed Well 18) in December 2004 from which to pump and remove the MTBE impacted groundwater from the aquifer for discharge to the site wastewater treatment plant. The optimal location for this remediation well was based on the information gathered during the hydro-geological studies of the site. Similarly, six optimally located sentinel wells were drilled and installed up gradient and down gradient of the remedial well in order to monitor the success of the remediation efforts.
- Pumping of the remediation well to the site wastewater treatment plant commenced in December 2004 with an immediate and significant reduction in the measured MTBE concentration in the impacted area achieved.

Current Status of the MTBE in Groundwater at the site:

- The MTBE concentration in the impacted area has fluctuated to a certain extent in the intervening years as influenced by seasonal factors (i.e. rainfall and groundwater level) and by the rate of remediation pumping.
- However, the issue is now considered largely remediated with the measured concentration at the impacted area currently being sustained below the Agency's IGV of 30µg/l and the area of MTBE impacts significantly contracted and confined to the localised zone of the site aquifer at Well 18.
- The site continues to pump groundwater from Well 18 to the site wastewater treatment plant.

References:

(EPA, 2003) TOWARDS SETTING GUIDELINE VALUES FOR THE PROTECTION OF GROUNDWATER IN IRELAND - Interim Report, Environmental Protection Agency, Ireland, 2003

(EPA, 2010) CLASSIFICATION OF HAZARDOUS AND NON-HAZARDOUS SUBSTANCES IN GROUNDWATER – Version 1, Environmental Protection Agency, Ireland, December 2010

9.6 I.6 - Assessment of the Environmental Impact of On-Site Waste Disposal

There is no on-site waste disposal at the site therefore there is no requirement for Attachment I.6.

9.7 Attachment I.7 - Noise Impact

Ambient Noise Levels

Existing Environment

The site is located within a rural area, surrounded by fields. There are plantings around the boundary providing visual and noise screening from the site. Noise sensitive locations (NSLs) are once-off residential properties located on the roads along the northern and western boundaries of the site. The area to the south of the site is largely agricultural land. The wind direction is predominantly south-western.

The closest noise sensitive locations are the residential properties around the site. There are no other types of noise sensitive locations around the site and no activities which would be specifically sensitive to noise.

There are 42 no. occupied residences within 500 m of the site boundary. The majority of these dwellings are in cluster developments to the northwest and southwest of the site. These include 3 no. dwellings to the northeast near the former Dunderrow School near noise location S1, two dwellings to the northwest near S2 and S3, and a cluster of dwellings to the southwest near S4 and S5.

It is proposed to redistribute the existing boundary noise monitoring locations (S1-S5) with locations labelled N1-N4, as outlined on drawing ref. 008, to represent the expanded site boundary.

Noise Sources On-site

Noise sources on-site comprise internal equipment such as production plant and internal ancillary plant such as boilers, compressors and refrigeration equipment. All this equipment is contained within the production and plant buildings and breakout noise is not expected and therefore has a minimal contribution to site noise emissions.

External noise sources comprise plant located on roofs and adjacent to the production buildings. These primarily comprise air handling units, cooling towers with pumps and motors, and water/ glycol pumps. Drawing 007 illustrates the main noise sources on site with the noise monitoring locations.

Since the 2004 licence application, new noise sources have been introduced through further development of production facilities on the site, all of which were provided to the Agency during the planning process for each. The latest development is production building IE43 at the eastern boundary of the site. The noise sources for this building are similar in size and nature as the other manufacturing buildings. There are also additional noise sources for the CHP plant between buildings IE30 and IE42. These sources are the engine/generator set and the exhaust flue.

The external equipment added to the site noise model were:

- Five condensate return pumps: 75 dB(A) Lw
- Four cooling tower fans: 85 dB(A) LW
- Four cooling water pumps: 75 dB(A) Lw
- One CHP engine: 103 dB(A) Lw but attenuated to 65 dB(A) Lp at a distance of 1m using the acoustic attenuation provided by the building
- One engine flue: 122 dB(A) Lw but attenuated to 75 dB(A) Lp at a distance of 1m using silencers

The impact assessment of the new noise sources will be discussed further in Section I.7B Noise Impact Assessment.

Noise Conditions

Noise conditions are assessed on an annual basis in accordance with Condition 6.11 of the current licence requiring an annual noise survey. Condition 4.6 requires that noise should not exceed daytime and night-time limits at any noise sensitive location. Eli Lilly monitor five locations situated around the boundary of the site, S1 through S5.

Averaged noise levels recorded for surveys carried out in 2012 to 2014 are presented in Table 9.12. The surveys were completed in full accordance with ISO 1996 Acoustics – Description, Measurement and Assessment of Environmental Noise Part 1:2003 Basis Quantities and Assessment Procedures and Part 2:2007 Determination of environmental noise levels and the EPA Guidance Note NG4.

Table 9.12: Historical Noise Surveys

Survey	Compliance Limits, dB L _{Aeq}	S1, dB L _{Aeq}	S2, dB L _{Aeq}	S3, dB L _{Aeq}	S4, dB L _{Aeq}	S5, dB L _{Aeq}
2012 Day	55	51	50	51	48	46
2012 Night	45	42	44	39	34	36
2013 Day	55	55	49	50	51	45
2013 Night	45	35	44	41	41	42
2014 Day	55	51	48	49	48	44
2014 Night	45	34	41	40	41	45

Noise Incidents and Complaints

There have only been two complaints over the previous three years attributed to site noise. In each case, the engineering issue relating the noise complaint was identified and rectified quickly.

Table 9.13: Noise Complaints

Date	Description	Cause	Outcome
21/09/2011	Unusual vibrating sound emanating from the site	Source was a loose fan housing on air intake.	Housing repaired and noise eliminated
04/10/2012	Complaint regarding the frequency of use and the noise level of the site Public Address (PA) system	The PA system in a new construction area was identified as the cause of the complaint.	The volume of the system was reduced and a reminder issued internally as to its permitted terms of use

Noise Impact Assessment

Introduction

Fehily Timoney and Company was retained by Eli Lilly S.A. to update the site noise model for the inclusion of IE43 Biotech Manufacturing Facility and the CHP plant. This section:

- predicts the noise emissions from the entire site with IE43 and the CHP plant operating
- assesses the impact of the predicted noise on the existing environment (including the closest noise sensitive receptors) and
- determines compliance with the existing and possible new licence limits based on the Agency's Noise Guidance Note NG4 (2012).

Applicable Noise Criteria

The site is currently subject to noise limits as detailed in licence reference P0009-03. Conditions 4.6 and Section B.4 detailing the noise limit requirements is shown below.

4.6 Noise

Noise from the installation shall not give rise to sound pressure levels (Leq,30 min) measured at noise sensitive locations of the activity which exceed the limit value(s).

Section B.4 Noise Emission Limits

Daytime dB(A) L _{Aeq} (30 min)	Night-time dB(A) L _{Aeq} (30 min)
55 ^{Note 1}	45 ^{Note 1}

Note 1: There shall be no clearly audible tonal component or impulsive component in the noise emission from the activity at any noise sensitive location.

Receivers

Condition 6.11 requires that annual noise monitoring is undertaken. Eli Lilly currently monitors at five boundary locations, S1 through S5.

A sample of noise sensitive locations nearest to the site was also selected for the purpose of this noise prediction assessment. Table 9.12 details these locations and approximate distances to the site boundary.

Table 9.14: Closest Noise Sensitive Locations

NSL Reference	Description	Distance from Site Boundary
NSL1	North-east	157
NSL2	North-east	198
NSL3	North-west	192
NSL4	South-west	23
NSL5	South	339
NSL6	South	281
NSL7	North-west	260
NSL8	North-west	277

Noise Sources

A list of the on-site noise sources are presented in Table 9.15. The information is presented with the sound power levels used in the modelling exercise. All the sources detailed are external emitters as internal noise sources are contained within buildings and have no to limited contribution to ongoing site noise. This table contains the sources proposed for IE43 as per the IE43 EIS together with the sound power data provided to FTC by Eli Lilly.

Table 9.15: Noise Sources

Site Location	Description	Sound Power Level Octave Bands (Hz)								Total Sound Power Level, dB(A)
		63	125	250	500	1k	2k	4k	8k	Lw. Tot
Existing Sources										
IE1	IE1 Air Extract Fan	69	80	87	90	91	85	78	58	95
IE1	IE1 Tilmycosin refrigerator	58	76	81	78	79	75	58	58	85
IE3	IE3 EF5	74	80	83	85	84	82	79	68	91
IE3	IE3 Scrubber fan pe31	70	77	85	88	88	87	83	72	94
IE3	IE3 EF19	69	84	88	94	93	87	81	72	98
IE3	Extractor fan EF18 IE3	77	83	90	93	96	94	90	83	100
IE3	Scrubber fan SC53	69	76	81	85	89	87	86	81	94
IE3	IE3 extractor fan source	46	65	64	67	61	59	51	36	71
IE4	IE4 Cooling Towers	69	82	89	89	89	83	76	69	94
IE4	IE4 compressors a and b	67	77	84	88	95	93	92	87	99
IE4	IE4 Glycol pumps	58	81	91	92	98	97	92	79	102
IE4	IE4 Glycol return pumps to chiller	58	84	83	84	86	85	84	77	92
IE4	IE4 Nitrogen plant	58	74	85	82	92	89	91	88	97
IE4	IE4 Extractor fans on IE4 chiller	58	74	86	97	90	87	80	74	98
IE4	IE4 Chiller louvre	30	40	51	67	66	58	57	34	70
IE4	IE4 cooling tower 10	71	80	97	89	91	83	82	77	99
IE4	IE4 wwtp pumps x 3 (6 no.)	71	80	86	90	93	91	90	82	98
IE4	IE4 Cooling Towers (2 no.)	69	82	89	89	89	83	76	69	94
IE7	IE7 Zink incinerator main fan	74	81	88	96	103	97	93	81	105
IE7	IE7 Hydrosonics recycle pump	73	83	86	96	98	96	92	82	102
IE7	IE7 Zink incinerator cooling tower fan	89	101	92	95	100	96	93	89	105
IE7	zink incinerator absorption water pump	74	83	91	102	103	99	93	83	107
IE8	IE8 EF2	76	83	89	96	98	95	89	77	102
IE8	IE8 AHU3	72	77	82	97	88	82	74	58	98
IE8	IE8 Cooling Towers	67	78	83	90	89	89	83	74	95
IE8	IE8 EF6/EF10	72	80	85	89	87	84	78	71	93
IE8	IE8 EF35	68	80	90	89	91	90	88	83	97

Site Location	Description	Sound Power Level Octave Bands (Hz)								Total Sound Power Level, dB(A)
		63	125	250	500	1k	2k	4k	8k	Lw. Tot
Existing Sources										
IE8	IE8 EF22A	71	84	91	90	91	87	83	79	97
IE8	IE8 EF12 AHU	75	80	83	78	81	81	82	79	89
IE8	IE8 EF14 AHU	73	85	87	81	77	77	79	80	91
IE8	IE8 AHU2	71	73	82	83	84	81	78	74	89
IE8	IE8 EF106	73	77	90	84	87	86	81	71	94
IE8	IE8 EF13	78	87	97	93	89	86	82	74	100
IE11	IE11 Sludge press room	57	85	90	97	100	100	95	89	105
IE11	IE11 biofilter sc1 scrubber pump	58	71	77	79	84	86	85	80	91
IE11	IE11 effluent pumps 36a and b	61	66	66	74	70	70	74	70	79
IE11	IE11 sump pump	58	72	83	89	91	93	90	80	97
IE16	IE16 cooling tower	75	91	94	91	88	87	84	80	98
IE16	IE16 EF8 and EF7	62	68	66	68	71	71	66	66	77
IE16	IE16 AHU5	68	75	97	90	85	76	67	60	98
IE16	IE16 AHU6	71	74	91	89	87	84	79	71	95
IE16	IE16 AHU4	72	77	86	89	89	87	83	74	94
IE16	IE16 EF6	73	76	83	87	92	85	85	80	95
IE16	IE16 AHU1	72	81	101	95	88	82	76	66	102
IE16	IE16 AHU2	57	62	68	74	73	72	68	56	79
IE16	IE16 EF5	74	80	85	91	90	89	85	73	96
IE16	IE16 EF1	73	83	84	94	85	86	81	81	96
IE16	IE16 EF3	61	72	75	72	67	64	60	54	78
IE16	IE16 Scrubber exhaust fan 51-SC51	54	59	64	74	64	62	58	64	76
IE18	IE18 To reeco	69	81	91	90	90	85	77	70	96
IE28	IE28 AHU7A and B	75	84	98	95	99	96	93	94	104
IE28	IE28 Chillers	55	65	76	92	91	83	82	59	95
IE30	IE30 Cooling Tower_1	51	66	72	76	77	73	71	66	82
IE30	IE30 Cooling Tower Motor-1	54	63	72	75	78	74	73	69	82
IE30	IE30 Cooling Tower Motor-2	54	63	72	75	79	74	73	69	82
IE30	IE30 DMSO pump	57	72	78	81	82	79	75	71	87
IE30	IE30 External steam lines	43	60	70	70	76	78	82	71	84
IE30	IE30 Glycol Return Pump (2 no.)	47	65	71	76	75	72	78	68	82
IE30	IE30 Glycol Supply Pump (2 no.)	47	65	71	76	75	72	78	68	82
IE30	IE30 Cooling Tower (2 no.)	51	66	72	76	77	73	71	66	82
IE30	IE30 Cooling Tower Motor-1	54	63	72	75	78	74	73	69	82
IE30	IE30 Glycol Return Pump (3 no.)	47	65	71	76	75	72	78	68	82
IE31	IE31 Cooling tower fans	89	101	97	93	99	98	94	86	106

Site Location	Description	Sound Power Level Octave Bands (Hz)								Total Sound Power Level, dB(A)
		63	125	250	500	1k	2k	4k	8k	Lw. Tot
Existing Sources										
IE31	IE31 Air blower exhaust	69	79	83	88	103	98	92	79	105
IE34	cooling tower 5	81	88	97	98	97	88	86	77	103
IE34	IE34 AHU (2 no.)	62	71	80	84	83	78	72	61	88
IE34	IE34 cooling tower 6	81	88	97	98	97	88	86	77	103
IE34	IE34 cooling tower 4	81	88	97	98	97	88	86	77	103
IE42	IE42 Cooling Tower	51	66	72	76	77	73	71	66	82
IE42	IE42 Cooling Tower Motor-1	54	63	72	75	78	74	73	69	82
IE42	IE42 Cooling Tower Motor-2	54	63	72	75	78	74	73	69	82
IE42	IE42 Glycol Supply Pump-7	47	65	71	76	75	72	78	68	82
IE42	IE42 EF1 and EF2	78	62	44	43	43	43	43	43	78
IE42	IE42 AHU (14 no.)	0	84	69	66	64	51	48	45	84
IE42	IE42 AHU extract fan east side	62	71	80	84	83	78	72	61	88
IE42	IE42 AHU extract fan west side	62	71	80	84	83	78	72	61	88
Tank Farm	Near tank farm rainwater sump pump	58	80	88	88	88	86	85	76	94
Tank farm	Tank farm pumps 1 to 5	50	55	60	63	72	72	65	57	76
EG5	GenSet Generator	--	--	92	--	--	--	--	--	92
New Sources										
IE43	IE43 Cooling Towers 1 to 4	54	75	79	80	76	74	74	69	85
IE43	IE43 Cooling water pumps 1 to 4	47	56	65	68	71	67	66	62	75
IE43	IE43 Condensate Return pumps 1 to 5	47	56	65	68	71	67	66	62	75
CHP	Engine / Generator Set	97	103	101	96	95	94	96	97	103
CHP	Engine flue discharge	109	121	116	117	113	113	118	101	122

Noise Prediction Modelling

The noise prediction was undertaken using noise modelling software, Bruel & Kjaer Predictor Version 5.04: module ISO 9613, based on:

- ISO 9613 – 1 Attenuation of Sound During Propagation Outdoors, part 1: Calculation of the Absorption of Sound by the Atmosphere ¹
- ISO 9613 – 2: Attenuation of Sound During Propagation Outdoors, Part 2: General Method of Calculation ²

¹ Acoustics - Attenuation of Sound During Propagation Outdoors, ISO 9613 Part 1: Calculation of the absorption of sound by the atmosphere . International Organization for Standardization.

² Acoustics - Attenuation of Sound During Propagation Outdoors, ISO 9613 Part 2: General method of calculation. International Organization for Standardization.

The propagation model described in Part 2 of the ISO 9613 standard provides for the prediction of sound pressure levels based on either short-term, down-wind (i.e., worst case) conditions, or long term, down-wind overall averages. ISO 9613 is considered a conservative model as it assumes all receivers are down-wind from the noise sources.

In reality, when wind is blowing in the opposite direction (i.e. from receivers to sources), the source attributable noise levels are lower.

The noise sources detailed in Table 9.15 were set to emit on a continuous basis. It is unlikely that this will be the case in reality. Foliage (including trees) and other screening/ barriers were also not taken into account therefore the predicted noise levels together with the continuously emitting sources present the worst case scenario

The model was set up applying a ground correction factor of 1.0 to the agricultural lands outside the Eli Lilly site representing acoustically soft ground and 0.0 for lands inside the site representing acoustically hard ground (i.e. concrete). There was no meteorological correction applied and the temperature, pressure and humidity were standard parameters.

The noise receivers were set up as point receptors and grid receptors which provide both point results for receivers of note such as the closest noise sensitive locations and the licence noise monitoring points and also noise contours showing how the predicted noise emissions emanate from the site sources. Receivers were also set up at 1.5 m representing a receiver on ground level and at 4.0 m representing a receiver at a first storey of a building at the nearest noise sensitive locations.

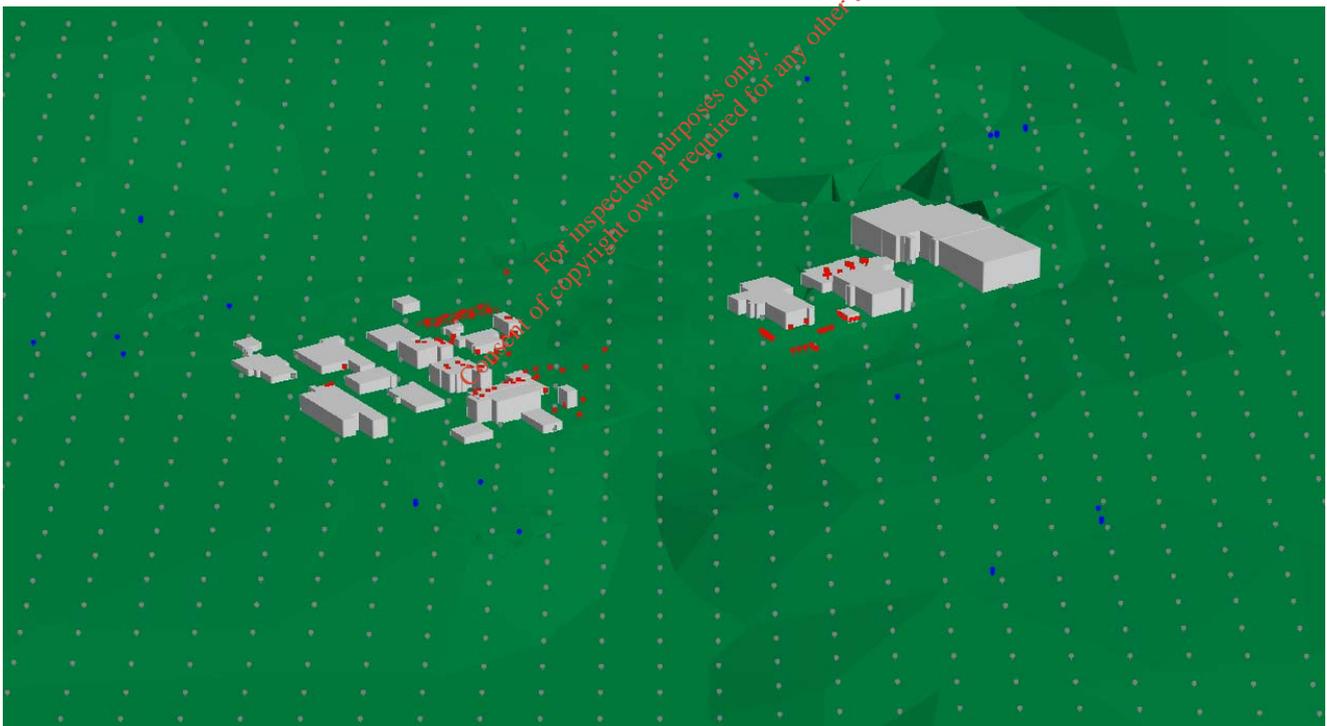


Figure 9.2: 3-D Perspective of Site Noise Model

Table 9.16: Noise Prediction Model Results

NSL Reference	With IE43 and CHP Operating		Without IE43 and CHP Operating		Predicted Increase, dB(A)
	Predicted Noise At 1.5 m, dB(A)	Predicted Noise At 4.0 m, dB(A)	Predicted Noise At 1.5 m, dB(A)	Predicted Noise At 4.0 m, dB(A)	
Closest Noise Sensitive Locations					
NSL1	44	46	44	46	0
NSL2	43	43	43	43	0
NSL3	47	48	47	48	0
NSL4	48	49	48	49	0
NSL5	43	44	43	44	0
NSL6	47	49	47	49	0
NSL7	41	42	41	42	0
NSL8	42	42	42	42	0
Existing Noise Monitoring Locations					
S1_A	47		47		0
S2A_A	51		51		0
S3_A	48		48		0
S4D_A	51		51		0
S5A_A	55		55		0
Proposed Noise Monitoring Locations					
New NS1	38		38		0
New NS2	36		36		0
New NS3	46		46		0
New NS4	44		44		0

Prediction Results

As described previously, the model is a conservative version of noise emitting from the site. The model was set up with all the external noise sources on-site emitting continuously and while the plant operates on 24 hour, seven day basis, a significant number of the HVAC systems are reduced during night-time hours. The model also assumes that each receiver is downwind of all sources, no meteorological correction is applied and there is no additional screening bar on-site buildings and ground contours.

The model was also run without IE43 and the CHP plant in place and the results show that there is no increase to the predicted noise levels with these noise sources in place.

All the predicted, conservative results are within the 55 dB(A) daytime limit and 50 dB(A) evening-time for the proposed monitoring locations and the closest noise sensitive locations.

In relation to the night-time limit of 45 dB(A), the predicted levels are conservative, as discussed, and should be less in reality. Due to the historical compliance of the site and the negligible impact of IE43 and CHP plant, night-time nuisance should not occur.

9.8 Attachment I.8. Environmental Considerations, Main Alternatives and BAT9.8.1A Main Alternatives

Discussion of alternatives is not applicable to this licence application.

9.8.1B Relevant Decisions

Identify all relevant decisions on BAT Conclusions, BAT reference document(s) (BREFs) and BAT guidance document(s).

Title of Document
Integrated Pollution Prevention and Control. Reference Document on Best Available Techniques (BREF) for the Manufacture of Organic Fine Chemicals, European Commission, 2006
BREF on Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector, European Commission, Final Draft 2014
BREF on Emissions from Storage, European Commission 2006
BREF on Industrial Cooling Systems, European Commission, 2001
BREF for Waste Incinerations, European Commission, 2006
REF on Economic and Cross-media Effects, European Commission, 2006
REF on the General Principles of Monitoring, European Commission, 2003 (monitoring of emissions from IED-installations)

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9.8.1C BAT Measures

Table 9.8(i) CONCLUSIONS ON BAT

Title of Document: <u>CWW BREF Draft 2014</u>			
BAT reference Number	BAT Statement	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
BAT 1	BAT is to implement and adhere to an environmental management system (EMS)	Detailed EMS in place, including management commitment, establishing and implementing procedures, roles and responsibilities etc.	Yes
BAT 2	BAT is to establish and to maintain an inventory of waste water streams	Inventory established through new process introduction (NPI) procedures of production processes and characteristics of waste streams	Yes
BAT 3	BAT is to monitor key process parameters relevant for emissions to water	Continuous monitoring systems in place of waste water flow, pH and temperature.	Yes
BAT 4	BAT is to monitor emissions to water in accordance with EN, ISO or National standards as applicable	Meeting parameter requirements under current license	Yes
BAT 5	BAT is to periodically monitor diffuse VOC emissions to air from relevant sources	Diffuse emissions from the WWTP collected and vented through a Bio-filter which is monitored on an annual basis	Yes
BAT 6	BAT is to periodically monitor odour emissions in accordance with EN standards	Bio-filter used as WWTP odour abatement system. Olfactometry measurements are completed on bio-filter inlet and exhaust gases on an annual basis.	Yes
BAT 7	BAT is to reduce the volume and/or load of waste water streams, to enhance the reuse of waste water within the production process and/or to recover and reuse raw materials	Optimisation of water use in production process, use of metering, proper waste stream segregation through NPI reviews, monitoring of waste volumes from production activities.	Yes
BAT 8	BAT is to segregate uncontaminated waste water streams from other waste water streams that require treatment.	Storm water/firewater retention pond in place with continuous emissions monitoring of TOC and pH	Yes

Title of Document: <u>CWW BREF Draft 2014</u>			
BAT reference Number	BAT Statement	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
BAT 9	BAT is to provide an appropriate buffer storage capacity for wastewater incurred during other than normal operating conditions based on a risk assessment and to take appropriate measures to treat, reuse etc.	Control of rainfall run off from production areas and general site, piped to storm water retention pond and monitored on discharge. All rainfall run off to bunded areas is routed to the WWTP.	Yes
BAT 10	BAT is to use an integrated waste water management and treatment strategy	Where possible pollutants are recovered at source (e.g. metals filtration). Pretreatment steps prior to waste water treatment include decanting of solvent residue, balancing of waste streams and pH adjustment.	Yes
BAT 11	BAT is to pretreat waste water that contains pollutants that cannot be dealt with adequately during final waste water treatment by using appropriate techniques.	Non-biodegradable/potentially toxic waste streams are routed to onsite incineration	Yes
BAT 12	BAT is to use an appropriate combination of final waste water treatment techniques.	Techniques employed in the WWTP include equalisation, neutralisation, physical separation, activated sludge process, settlement, filtration and Nitrogen removal, *See table footnote for further discussion of Phosphorus use on site and potential impact on BAT-AEL	*Yes
BAT 13	BAT is to set up and implement a waste management plan as part of the environmental management system (see BAT 1) that, in order of priority, ensures that waste is prevented, prepared for reuse, recycled or otherwise recovered	WWTP sludge is thickened, dewatered and dried prior to use as an industrial support fuel.	Yes
BAT 14	In order to reduce the volume of waste water sludge requiring further treatment or disposal, and to reduce its potential environmental impact, BAT is to use one or a combination of techniques such as conditioning, thickening, dewatering and drying.		

Title of Document: <u>CWW BREF Draft 2014</u>			
BAT reference Number	BAT Statement	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
BAT 15	In order to facilitate the recovery of compounds and the reduction of emissions to air, BAT is to enclose the emission sources and to treat the emissions, where possible.	WWTP and sludge holding tanks are all covered and vented to a Bio-filter	Yes
BAT 16	In order to reduce emissions to air, BAT is to use an integrated waste gas management and treatment strategy that includes process-integrated and waste gas treatment techniques.		Not applicable
BAT 17	BAT is to use flaring only for safety reasons or non-routine operational conditions		Not applicable
BAT 18	Also relates to flaring off gases		Not applicable
BAT 19	In order to prevent or, where that is not practicable, to reduce diffuse VOC emissions to air, BAT is to use a combination of techniques related to plant and equipment design and operation.	WWTP balance tank vented to Bio-filter	Yes
BAT 20	BAT is to set up, implement and regularly review an odour management plan, as part of the environmental management system	Odour response plan in place including protocol for responding to odour incidents, monitoring and identification of odour source and remediation of the source.	Yes
BAT 21	In order to prevent or, where that is not practicable, to reduce odour emissions from waste water collection and treatment and from sludge treatment, BAT is to use one or a combination of the techniques including minimizing residence time of waste water and sludge in storage vessels, optimisation of aerobic conditions, enclosure of WWTP and treatment of off-gases	All these techniques are currently employed in the operation of the WWTP	Yes

Title of Document: <u>CWW BREF Draft 2014</u>			
BAT reference Number	BAT Statement	Applicability Assessment	State technique and whether it is in place or state schedule for implementation
BAT 22	BAT is to set up and implement a noise management plan, as part of the environmental management system	Noise monitoring programme in place for monitoring of noise sources, response to noise incidents and remediation of significant noise sources as required. Noise attenuation measures already in place for significant noise sources.	Yes
BAT 23	In order to prevent or, where that is not practicable, to reduce noise emissions, BAT is to use one or a combination of techniques including strategic location of equipment, selection of low noise equipment, appropriate operational control and suitable abatement.	Operational controls and abatement systems in place	Yes

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Footnote:

Significant effort over the years has gone into finding alternative cleaning solutions to the traditional solvent cleaning process used in pharmaceutical manufacturing. An aqueous based cleaning process has now replaced many of the traditional solvent cleaning processes. This brings many environmental benefits, particularly in relation to reduced atmospheric VOC emissions. However these validated cleaning products are phosphorus based and as their use increases, particularly around Biotech manufacturing, we will not be in a position to meet the proposed BAT-AEL value for Phosphorus on our effluent discharge without significant capital investment to install a phosphorus removal step in our waste water treatment plant.

The removal process itself could prove to be technically challenging, particularly for treatment of incinerator effluent streams that contain a complexity of salts. Even if phosphorus removal from such waste streams was possible the problem still remains as to how to safely dispose of the phosphorus rich sludge as landfill facilities in Ireland are very reluctant to accept such material because of its eutrophication potential in the event of landfill leachate reaching surface waters.

The absence of a Coastal Waters Environmental Quality Standard (EQS) for Phosphorous in the Surface Water Regulations (2009) is also reflective of the fact that it is not a limiting nutrient or a cause for concern in the environment to which we discharge.

Years of monitoring around our discharge location in the outer reaches of Kinsale Harbour also continues to demonstrate that our phosphorus discharge is having no detrimental effect on the quality of the harbour, therefore its continued discharge in our final effluent is considered the best environmental option. This is in line with guidance outlined in the EU Reference Document on Economics and Cross Media Effects (July 2006) on the need to assess the choices to be made in disposing of a pollutant to different environmental media, having regard to its overall environmental and economic impact. In the definition of BAT in this reference document "available" techniques is interpreted as "those developed on a scale which allows implementation in the relevant industrial sector, under economically and technically viable conditions". Removal of phosphorus from an effluent discharge to sea is not considered an economically viable technique and poses significant technical challenges.

In making the case for derogation on the BAT-AEL for Phosphorus, consideration should be given to the significant upfront investment made in piping treated effluent from the site to a discharge location in the outer Kinsale Harbour, rather than to the nearby estuary, so as to minimise the overall environmental impact of site operations. We continue to monitor the impacts of our operation on the environmental quality of Kinsale Harbour through the ongoing monitoring programme as managed by the National University of Ireland, Galway (UCG). This programme has been running for the past 30 years making Kinsale Harbour one the most documented harbours in Europe. As stated previously all the research continues to demonstrate that existing emissions aren't having any detrimental effect on any aspect of harbour quality.

The results of effluent discharge modelling at current maximum license limits for all licensed parameters demonstrates compliance to the Coastal Waters Environmental Quality Standard (EQS) for the parameters outlined in the Surface Water Regulations (2009). Details of this assessment are provided in Appendix 2 of this document.

Consideration should also be given to the fact that the Company, at a global level, has introduced an environmental target of 15% reduction in the level of phosphorus in wastewater discharges by 2020. This has already led to the establishment of a global manufacturing working group to assess the current use of phosphorus based detergents and the alternative options available. The Kinsale site has representation on this group and is actively encouraging the research and development facilities to assess alternatives to the current phosphorus based cleaning agents at early product development stage. For established products, regulatory constraints prevent changes being made to existing validated manufacturing processes, while the impact of changes made to cleaning processes at the research and development stage of a product lifecycle will take a number of years to impact at a site manufacturing level. However with this ongoing focus on phosphorus reduction a downward trend in phosphorus emissions at all manufacturing sites is to be expected in the next five to ten year period.

Article 15 (4) of Directive 2010/75/EU on industrial emissions outlines the basis for allowing a derogation on the application of a BAT emission limit value (ELV) in situations where it can be demonstrated that the application of a BAT ELV would lead to disproportionately higher costs compared to the environmental benefits, while also ensuring that no significant pollution is caused and that a high level of protection of the environment as a whole is achieved.

The information outlined above supports the basis for such derogation in that the proposed phosphorus emission will not have any adverse environmental effect, while introducing a phosphorus removal step will require significant capital investment in additional treatment capability and increase operating costs significantly (raw materials, energy). The additional energy use associated with the phosphorus removal process and sludge transport will also negatively impact on the carbon footprint of the site.

The additional cost of providing and operating a Phosphorus removal system in our waste water treatment plant would place Kinsale at a distinct disadvantage in attracting new business to the site, with knock on effects on support businesses, therefore applying derogation on Phosphorus discharge to the ocean is considered applicable under the above referenced Article 15 (4).

Having reviewed Phosphorus use in current and projected processes, the proposal is to limit phosphorus in the final effluent discharge to 150kg/day, expressed as an annual rolling average as outlined in the following Table. This represents a 50% reduction on the current licence limit, and in light of the ongoing expansion of the Biotech processing facilities, represents a significant commitment to the overall phosphorus reduction goal.

A proposal for the expression of BAT-AEL values in our final effluent discharge for all of the parameters listed in Tables 4.1, 4.2 and 4.3 of the CWW BREF Draft 2014 is outlined in the following table. The proposal relates to the expression of emission limit values for the parameters listed as a mass emission rather than as a concentration limit.

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BAT-AEL expressed as mass emission limit value for final effluent discharge (Emission Point Ref. SW-1)			
Parameter	<u>CWW BREF 2014</u> BAT-AEL Max conc. (mg/l) as annual average	Final Effluent Discharge Volume (max m ³ /day)	Proposed BAT-AEL license limit (Kg/day as annual rolling average)
BOD	20	3000	60
COD	100	3000	300
TSS	35	3000	105
TN	25	3000	75
AOX	1	3000	3
Cr	0.025	3000	0.075
Cu	0.05	3000	0.15
Ni	0.05	3000	0.15
Zn	0.3	3000	0.9
AEL expressed as mass emission limit value for final effluent discharge (Emission Point Ref. SW-1)			
Parameter		Final Effluent Discharge Volume (max m ³ /day)	Proposed AEL license limit (Kg/day as annual rolling average)
TP		3000	150

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Table 9.8 (ii) CONCLUSIONS ON BAT

Ref: Waste Incineration 2006 BREF				
BAT reference Number	BAT Statement		Applicability Assessment	State technique and whether it is in place or state schedule for implementation
5.1 Generic BAT for all waste incineration				
1	Selection of an installation design that is suited to the characteristics of the waste to be treated.		Detailed design in collaboration with manufacturer	Yes
2	Maintenance of the facility		Robust inspection /PM programme in place	Yes
3	Management of wastes		Controls in place to manage waste received. Waste stream evaluation as part of the new product introduction (NPI) process. Regular screening of waste feed for solvent content and calorific value	Yes
4	BAT to store waste in areas that have sealed and resistant surfaces, with controlled and separated drainage	attack resistant bunded bulk tanks	Waste solvent storage tanks farm upgrade in 2010. Specification for new waste storage tanks based on typical waste profile. Tanks fitted with anodes to prevent corrosion.	Yes
		flanges and valves within bunded areas	Good containment measures in place with regular testing of bunds. Segregation of primary and secondary waste as per waste stream evaluation. All solvent storage tanks have nitrogen blanketing and appropriate conservation vent settings to minimize fugitive or odour emission. New solvent waste storage tanks have higher pressure rating allowing for higher vent pressure relief setting thus minimizing fugitive emissions.	Yes
		Minimisation of fugitive/odour releases		Yes
		segregated storage according to risk assessment		Yes
		special attention to the length of storage times		Not applicable
		automatic handling and loading devices		Yes
		cleaning facilities for surfaces and containers		Yes

Ref: Waste Incineration 2006 BREF				
BAT reference Number	BAT Statement		Applicability Assessment	State technique and whether it is in place or state schedule for implementation
5	Plan to manage fire hazards	Automatic fire detection and warning systems	Infrared fire detection system linked to high flow rate firewater sprinkler system. Trained firefighters (ERT) available on site to respond to a fire incident.	Yes
		The use of either a manual or automatic fire intervention and control system as required according to the risk assessment carried out.		Yes
		The provision of operators with a means to visually monitor, directly or using television screens or similar, waste storage and loading areas		CCTV available to site security personnel to monitor key waste storage areas
6	Optimisation and control of combustion conditions	the control of air (oxygen) supply, distribution and temperature, including gas and oxidant mixing	Operating conditions of the KEU managed by process control computer. Continuous monitoring of oxygen, air flow temperature etc. Operator intervention as required.	Yes
		the control of combustion temperature level and distribution, and the control of raw gas residence time		Yes
		in general it is BAT to use those operating conditions (i.e. temperatures, residence times and turbulence) as specified in Article 6 of Directive 2000/76.	Incinerator design meets these conditions	Yes

Ref: Waste Incineration 2006 BREF				
BAT reference Number	BAT Statement		Applicability Assessment	State technique and whether it is in place or state schedule for implementation
		the use of auxiliary burner(s) for start-up and shut-down and for maintaining the required operational combustion temperatures (according to the waste concerned) at all times when unburned waste is in the combustion chamber	Natural Gas burners available as back up as per current license conditions	Yes
7	Overall optimisation of installation energy efficiency and energy recovery	the use of a boiler to transfer the flue-gas energy for the production of electricity and/or supply of steam/heat with a thermal conversion efficiency of 60-70%	KEU has waste heat boiler for energy recovery.	Yes
8	General minimisation of overall installation energy demand	I. to use heat exchangers to heat the SCR inlet flue-gas with the flue-gas energy at the SCR outlet. ii. to generally select the SCR system that, for the performance level required (including availability/fouling and reduction efficiency), has the lower operating temperature where flue-gas reheating is necessary, the use of heat exchange systems to minimise flue-gas reheating energy demand. e. avoiding the use of primary fuels by using self-produced energy in preference to imported sources	SCR system employs a heat exchanger to optimise energy use as per the outlined BAT.	Yes

Ref: Waste Incineration 2006 BREF				
BAT reference Number	BAT Statement		Applicability Assessment	State technique and whether it is in place or state schedule for implementation
9	Operational ELV's associated with use of BAT for releases to air	Refer to Stack BAT ELV tab below for details. Parameters outlined are those already licensed.	Current operational controls and flue gas treatment systems meet BAT ELV's.	Yes
10	Flue Gas Treatment Systems	Refer to FGT systems tab below for details	The wet FGT system used on the KEU is listed as having many advantages in the BAT assessment.	Yes
		the use of on-site physico/chemical treatment of the scrubber effluents prior to their discharge from the site	Coagulation, flocculation, settlement and filtration of effluent streams to remove suspended solids together with effluent pH control	Yes
		the re-circulation of wet scrubber effluent within the scrubber system, and the use of the electrical conductivity (mS/cm) of the re-circulated water as a control measure, so as to reduce scrubber water consumption by replacing scrubber feed water	Optimisation of scrubber blow down by use of online monitoring systems (e.g. conductivity)	Yes
		In general SCR is considered BAT where higher NOX reduction efficiencies are required (i.e. raw flue-gas NOX levels are high) and where low final flue-gas emission concentrations of NOX are desired.	SCR system currently in use as NOx abatement device	Yes
11	BAT ELV's for effluent discharges from treatment plants receiving FGT scrubber effluent	Refer to Effluent BAT ELV tab below for details.	ELV's comparable to current license ELV's and within current operational controls	Yes

Ref: Waste Incineration 2006 BREF				
BAT reference Number	BAT Statement		Applicability Assessment	State technique and whether it is in place or state schedule for implementation
12	Optimisation of recirculation and reuse of water within the plant		Water use within the KEU is currently optimised and controlled accordingly.	Yes
13	Management of boiler ash	BAT refers primarily to reuse options, where applicable, for such material.	Conservative approach taken with this material in designating it as hazardous. Material shipped offsite in UN approved containers for further thermal treatment.	Not applicable
14	Management of solids removed from abatement system effluent streams	BAT refers primarily to reuse options, where applicable, for such material.	Dewatered sludges routed to offsite drying facility. Mixed dried sludges used as an auxiliary fuel source for other industries (e.g. Cement manufacturing)	Yes
15	Application of environmental management system (EMS)	BAT is to implement and adhere to an Environmental Management System (EMS) that incorporates such aspects as establishing necessary procedures, implementing procedures, checking performance and taking corrective and preventative actions as necessary.	Strong EMS operational on site and is subject to regular internal and external review.	Yes
5.2 Specific BAT for hazardous waste incineration				
16	Mixing and blending of waste	Mixing, blending and pretreating of the waste in order to improve its homogeneity, combustion characteristics and burn-out to a suitable degree with due regard to safety considerations	Segregation of solvent waste into Primary and Secondary streams. Batching and analysis of material prior to incineration to determine combustion characteristics	Yes

Ref: Waste Incineration 2006 BREF				
BAT reference Number	BAT Statement		Applicability Assessment	State technique and whether it is in place or state schedule for implementation
17	Minimisation of exposure by direct injection	Direct injection of liquid and gaseous hazardous wastes, where those wastes require specific reduction of exposure, releases or odour risk	High level of containment maintained around all incineration operations with direct injection from dedicated feed tanks.	Yes
18	Flue Gas Treatment Systems	For hazardous waste incinerators feeding wastes of highly varying composition and sources, the use of wet FGT, is generally BAT to provide for improved control of short-term air emissions	Wet FGT system in place	Yes

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Table 9.8 (iii) CONCLUSIONS ON BAT

Ref: Organic Fine Chemicals BREF (2006)				
BAT reference Number	BAT Statement		Applicability Assessment	State technique and whether it is in place or state schedule for implementation
4.3 Management and treatment of waste streams				
4.3.1.1	Process waste stream analysis	Waste streams are identified, analysed and appropriately routed.	Waste BOMs, Mass Balances for NPIs, Lab capabilities in waste stream analysis	Yes
4.3.1.4	Mass balances for solvents (VOC), highly hazardous substances and heavy metals	Fate and destination of all hazardous substance use assessed and determined	Yearly solvent mass balance completed.	Yes
4.3.1.7	Monitoring of exhaust gas volume flows from processes	Monitoring of exhaust gas volume flows from processes	<ul style="list-style-type: none"> • Individual flow measurement on RTO ducts • Surveys completed on scrubber flows • Process modelling includes consideration of flows 	Yes
4.3.1.8	Monitoring of waste gas emissions	Ability to characterise and understand individual waste gas streams feeding into waste gas treatment systems	<ul style="list-style-type: none"> • Continuous LEL monitoring on RTO ducts • GC monitoring capabilities for individual processes • Continuous monitoring of treated emissions 	Yes
4.3.2.3	Waste streams from condensations	Waste streams are appropriately routed from condenser processes.	Solvent waste streams from condenser processes are generally routed to onsite Thermal Oxidizer where heat recovery value can be realized	Yes
4.3.3	Recovery of aromatic solvents and lower alcohols	Solvent recovery to produce re-useable solvent volumes	Approach to recovery is as above, solvent recovery and reuse currently has limited applicability to the site due to quality / safety barriers	Not applicable

Ref: Organic Fine Chemicals BREF (2006)				
BAT reference Number	BAT Statement		Applicability Assessment	State technique and whether it is in place or state schedule for implementation
4.3.4	Re-use and recycling of solvents and by-products		Approach to recovery is as above, solvent recovery and reuse currently has limited applicability to the site due to quality / safety barriers	Not applicable
4.3.5.3	Scrubbing of HCl from exhaust gases and related emission levels	HCl abatement by passing exhaust gases through scrubbers	<ul style="list-style-type: none"> Caustic scrubbers used on all production rigs Caustic and Metabisulphite scrubbers used on Thermal Oxidation Systems 	Yes
4.3.5.6	Condensation of VOCs from reactors and distillations	Indirect cooling of highly loaded exhaust gases before downstream exhaust gas treatment, followed by separation of the gas and liquid phase	Condensers typically used on all production rigs on site. Solvent waste streams from condenser processes are generally routed to onsite Thermal Oxidizer where heat recovery value can be realized.	Yes
4.3.5.10	Strategy for prevention and abatement of VOC emissions	Reduce total VOC emissions to <5 % of the solvent input by following a combined strategy which involves: a) step-by-step implementation of integrated measures to prevent/reduce diffuse/fugitive emissions and to minimize the mass flow that requires abatement b) applying high level recovery/abatement techniques, such as thermal/catalytic oxidation or activated carbon adsorption	<ul style="list-style-type: none"> Programme to reduce fugitive emissions such as installation of conservation vents Routing of all process emissions to a Regenerative Thermal Oxidizer (RTO) 	Yes

Ref: Organic Fine Chemicals BREF (2006)				
BAT reference Number	BAT Statement		Applicability Assessment	State technique and whether it is in place or state schedule for implementation
4.3.5.16	Minimising emission concentration peaks	Batch processing can result in sharp peaks from processes that have potential to impair performance of abatement system.	<ul style="list-style-type: none"> Specialized scrubbers to dampen peaks (i.e. Glycol for the solvent MTBE) Process Modelling and Mapping to avoid overlapping peaks with multi-batch rigs Slowing cycling times where appropriate can minimize peaks 	Yes
4.3.5.19	NOx: recovery, abatement and emission levels	Where high thermal oxidation temperatures are used and where inputs to the system contain nitrogen, Selective Catalytic Reduction (SCR) abatement systems may be needed to achieve the required or desired NOx emissions	John Zink (KEU) Thermal Oxidiser is fitted with SCR providing significant NOx abatement capacity as required	Yes
4.3.5.22	Particulate removal from exhaust gases	Use of abatement techniques to minimize or eliminate particulate emissions	<ul style="list-style-type: none"> Filtration systems used in all production facilities as required Thermal Oxidation Systems fitted with Wet Scrubbing and Hydrosonic abatement systems 	Yes

Table 9.8 (iv) CONCLUSIONS ON BAT

Ref: Monitoring emissions from IED installations – JRC Ref Report Final Draft 2013				
BAT reference Number	BAT Statement		Applicability Assessment	State technique and whether it is in place or state schedule for implementation
4.2 Monitoring of emissions to Air				
4.2.2.2.1 4.2.2.2.2	EN standards	EN 14181:2004 Quality assurance system for online continuous monitors	Under current license conditions compliance is maintained to this standard for continuous emissions monitors on the Reeco and KEU thermal oxidisers.	Yes
4.2.2.2.3	Certified measuring systems	EN 15267:2009	AMS systems in place are validated MCert approved units	Yes
4.2.2.2.4	Sampling location	Representative sampling point location	Representative sampling point locations in place with safe access facilities.	Yes
4.2.2.2.5	Reference Conditions	Flue gas concentrations referenced to Standard Conditions	Current license requirement	Yes
4.2.4.4	Quantification of diffuse and fugitive emissions	Calculation of emissions from solvent storage tanks etc.	Annual emission calculated using US-EPA Tanks Model	Yes
4.2.4.5	Odour measurements	Olfactometry measurement	Efficiency of the Biofilter treating the WWTP off gases is assessed on an annual basis by Olfactometry measurement	Yes
4.3 Monitoring of emissions to Water				
4.3.2.4	Continuous online measurement of water parameters	Requires documented calibration and maintenance programme for measuring equipment in use	P.M. programme in place for all continuous emissions monitoring equipment on water/effluent discharge.	Yes
4.3.2.5.2	Measurement/Sampling Plan for periodic measurements	Representative sampling location and plan	Flow proportionate automatic samplers are used on effluent discharges.	Yes

Ref: Monitoring emissions from IED installations – JRC Ref Report Final Draft 2013				
BAT reference Number	BAT Statement		Applicability Assessment	State technique and whether it is in place or state schedule for implementation
4.3.2.5.7	Sample analysis	EN Standard test method or equivalent	Certified test methods used in the analysis of all effluent compliance parameters	Yes

Table 9.8 (V) CONCLUSIONS ON BAT

Ref: Bref on Industrial Cooling Systems, European Commission, 2001				
BAT reference Number	BAT Statement		Applicability Assessment	State technique and whether it is in place or state schedule for implementation
4.3	Reduction of energy consumption	<ul style="list-style-type: none"> Optimised cooling water treatment to maintain clean surfaces and avoid scaling, fouling and corrosion. This in turn reduces resistance to water and air flow thus reducing energy costs. Option for variable operation Modulation of air/water flow 	<p>All cooling tower (wet) systems are on a preventative maintenance programme that includes weekly checks on chemical dosing systems with adjustment as necessary to maintain the recommended residual chemical concentration in the cooling tower water.</p> <p>Cooling tower systems on site are (where feasible) interlinked so that units can be added or removed, dependent on site demand for cooling water.</p> <p>Most of the cooling tower systems on site have modular air flow that can be adjusted to meet demand</p>	Yes
4.4	Reduction of water requirements	<ul style="list-style-type: none"> Reduction of need for cooling Reduction of water use 	<p>Cooling requirements are process driven with optimizations applied where feasible.</p> <p>Optimisation of cooling tower blowdown leads to an overall reduction in water use</p>	Yes
4.6	Reduction of emissions to water	<ul style="list-style-type: none"> Reduction in treatment chemical discharge Use of less hazardous 	<p>Optimised treatment programme in place thus minimizing excessive dosing regimes.</p> <p>Where possible, treatment chemicals with</p>	Yes

Ref: Bref on Industrial Cooling Systems, European Commission, 2001				
BAT reference Number	BAT Statement		Applicability Assessment	State technique and whether it is in place or state schedule for implementation
		treatment chemicals	a low water hazard are used.	
4.7	Reduction of emissions to air	<ul style="list-style-type: none"> Avoid plume reaching ground level Avoid affecting indoor air quality Use of less hazardous treatment chemicals Reduction of drift loss 	<p>Location and design of onsite cooling towers is such that there is no impact from plume reaching ground level or entering building air conditioning systems. Drift eliminators are also in place on site cooling towers.</p> <p>A legionella monitoring programme is also in place for all site cooling tower systems.</p>	Yes
4.8	Reduction of noise emissions	Attenuation measures	Cooling towers that could potentially impact on site boundary noise levels have been fitted with attenuation devices.	Yes
4.9	Reduction of risk of leakage	<ul style="list-style-type: none"> Suitable heat exchanger design Operate to design 	Materials of construction and operational requirements for heat exchangers are based on the associated process requirements.	Yes
4.10	Reduction of biological risk	<ul style="list-style-type: none"> Reduction of biological growth and control of pathogens Reduce risk of infection 	<p>The chemical dosing programme in place for all cooling towers controls biological activity in the systems while the Legionella monitoring programme in place controls risk of pathogens and infection.</p> <p>Any invasive maintenance work on cooling tower systems requires the use of personal protective equipment as per site procedure.</p>	Yes

Table 9.8 (VI) CONCLUSIONS ON BAT

Ref: BREF on Emissions from Storage, European Commission 2006				
BAT reference Number	BAT Statement		Applicability Assessment	State technique and whether it is in place or state schedule for implementation
5.1.1	Storage of liquids in tanks	<ul style="list-style-type: none"> • Tank design, location and layout • Tank inspection and maintenance • Emissions minimization • Incident and accident prevention • Fire protection • Containment of contaminated extinguishant 	<p>All storage tanks are designed with appropriate safety systems for the material to be stored.</p> <p>All storage tanks are located above ground in bunded areas. These bunds are on a 3 year integrity test programme.</p> <p>All bulk storage tanks are on an inspection programme that includes external and internal inspection together with shell thickness testing as appropriate.</p> <p>VOC losses to atmosphere are controlled by nitrogen blanketing of solvent storage tanks together with the use of conservation vents to minimize breathing losses.</p> <p>As the site is ranked as a top tier Seveso II site it has a Major Accident Prevention Policy in place together with a site emergency response plan. There is also a trained onsite emergency response team available to deal with any incidents.</p> <p>All bulk solvent storage tanks have a sprinkler protection system in place in the event of a fire together with local fire hydrants/foam dosing that can be operated by the onsite emergency response team.</p> <p>All firewater runoff is collected in the fire water retention pond.</p>	Yes
5.1.2	Storage of packaged dangerous substances	<ul style="list-style-type: none"> • Incident and accident prevention • Storage area separation and segregation 	<p>Major Accident Prevention Policy in place together with a site emergency response plan.</p> <p>Specific storage areas on site for dangerous substances (e.g. flammable,</p>	Yes

Ref: BREF on Emissions from Storage, European Commission 2006				
BAT reference Number	BAT Statement		Applicability Assessment	State technique and whether it is in place or state schedule for implementation
			water reactive) while segregation systems are applied to non-compatible materials such as acids and bases. Containment measures are in place in all liquid storage areas.	
5.2	Transfer and handling of liquids	<ul style="list-style-type: none"> Above ground piping system Pump, valve and seal systems Vapour treatment during loading/unloading of volatile substances 	<p>All piping transport systems for hazardous liquids are located above ground with an impervious surface underneath the piping system to prevent soil or groundwater contamination in the event of loss of containment.</p> <p>All storage tank associated pumps and valves are located within the bunded area of the tank. Pumps are on a preventative maintenance system with seal replacement as required.</p> <p>A recently trialed pressure transfer system eliminates open tanker unloading operations. It is planned to have this system fully operational by the end of 2015.</p>	Yes
5.3	Storage of solids	As per section 5.1.2 above	As per section 5.1.2 above	Yes
5.4	Transfer and handling of solids	Minimisation of dust emission from handling and transfer operations	<p>A high level of containment is maintained for all raw material and product handling operations. This is achieved through good engineering design and the use of specialised containment techniques such as glove bag technology.</p> <p>HEPA filtration systems are also used to prevent potential atmospheric dust emissions.</p>	Yes

I.8.D Emerging Techniques

One emerging technique in production processes is that of continuous flow processing versus the traditional batch process arrangement. In flow chemistry, a chemical reaction /process is run in a continuously flowing stream rather than in a static batch environment, thus producing product at a steady rate. Fluids are moved into a tube/space and where tubes join the fluids contact one another and the process reaction occurs. The design of the "reactor" and flow through rates are based on reaction kinetics and the contact time required for the reaction to complete.

Continuous processing has advantages over batch in many aspects including process safety, environmental, quality and capital spend.

In terms of process safety the operational scale is much smaller than batch thus providing for better exotherm management while reducing the potential for high risk or safety critical operations.

From an environmental perspective continuous processing results in lower levels of emissions to atmosphere together with lower volumes of waste, particularly in cleaning operations, since equipment trains are much smaller and in many cases are dedicated to a particular process step, thus requiring less frequent cleaning.

The level of control employed in continuous processing can result in higher yields, improved efficiency while reducing the level of impurity present.

Capital costs associated with continuous process equipment and construction are much cheaper than that of batch manufacturing.

1.1.1. I.8.E and I.8.F Environmental Considerations

Environmental considerations which have been made with respect to the use of cleaner technologies, waste minimisation and raw material substitution:

(1) Overview of the Eli Lilly Global Product Stewardship Strategy:

Eli Lilly has a global Product Stewardship strategy that sets out the measures that are required across all elements of the company's business in order to minimize the Health, Safety and Environmental impacts of its product range right across the product 'value chain'. This value chain extends from product discovery and development, through to manufacturing, distribution and use, sales and marketing, to product recycling or final disposal.

The Eli Lilly facilities in Kinsale have evolved into one of the key commercialisation and manufacturing sites in the corporation and therefore the Kinsale site now plays an increasing role in the first two broad stages of the product value chain, i.e. (1) Product Discovery and Development, and (2) Manufacturing. The use of cleaner technologies, waste minimisation and raw material substitution are all key considerations for the global product discovery and development business units as well as the commercialisation and manufacturing functions undertaken at the Kinsale site.

The selection of raw materials used in the design and manufacture of the company's products involves a collaborative process between the divisions of the company involved in the discovery of new products and those involved in developing manufacturing processes and ultimately manufacturing the products at a commercial scale. During all stages of this process there is an emphasis on using or designing products and manufacturing processes that use less hazardous raw materials, lower volumes of raw materials and by extension that give rise to less hazardous and lower volumes of waste. Furthermore, a variety of technologies and systems are then used during product manufacturing (including techniques that can be considered best practice) in order to ensure the environmentally safe management of the manufacturing processes and the waste streams that arise from these processes. This also includes the application of robust Process Safety Management (PSM) techniques at various levels of the manufacturing and waste treatment systems. Significant environmental protection benefits also arise from the application of these PSM techniques because measures that ensure process safety incidents are avoided will in turn prevent potential environmental impairment that may arise from such incidents. (See section J for further details).

The discovery, development and manufacturing stages of the company's product stewardship strategy are becoming increasingly integrated. However, it is also useful to consider each of these stages individually when outlining in detail the environmental considerations that are made across these phases of the product stewardship strategy.

(2) Environmental Considerations at Product Discovery and Process Development Stages:

It is essential that environmental considerations are included as early as possible in the product discovery and process development phases. This is because as the products and the related manufacturing processes reach the various development milestones and are validated and approved the regulatory and logistical barriers to changing the processes in order to realize environmental improvements become increasingly more difficult to overcome. Therefore, at the product discovery and development stage there is a strong emphasis on using inherently safer design and this is achieved through the application of the principles of 'Green Chemistry'.

The company's approach to green chemistry is now twofold. Firstly, the foundation of the green chemistry strategy is based on the well-established principle that significant environmental improvements can be achieved by reducing the amount of hazardous material used to make a product, increasing overall materials efficiency, evaluating chemical alternatives, and avoiding use of the riskiest substances.

However, more fundamental development are also now being developed that can result in order-of-magnitude improvements—by advancing the state of the art in chemistry and developing and implementing new reactor technologies that can substantially reduce resource usage whilst also enhancing environmental safety.

Development scientists employed by the company are provided with useful information at key decision points which helps them make the best decisions when using chemistry to design processes. To accomplish this, the company has developed electronic lab notebooks used by chemists, which include information and tools regarding process efficiency, solvent selection, and materials of concern. When any researcher adds information to the notebook, it is easily available to all the company's researchers worldwide.

Accountability has also been established for the routine use of green chemistry principles. Expectations to use green chemistry are built into the company's product development objectives along with other important criteria, such as quality and cost. Development teams are accountable for process efficiency and safety from the point when candidate molecules are selected through the development of a manufacturing process, and progress is monitored at major development milestones.

To measure progress in this area, the company has established material use efficiency standards at critical steps in the product development process, including the Process Mass Intensity (PMI) factor, a ratio of the total mass of raw materials (including water) put into a process for every kilogram of drug produced. Failure to meet these standards triggers management review.

(3) Environmental Considerations as Processes are Transferred to Manufacturing:

Eli Lilly and Company uses an Environmental Development Review (EDR) process to evaluate potential environmental issues and opportunities during the production scale-up to manufacturing levels of many of its prospective new medicines. An environmental development review (EDR) is a systematic, detailed analysis of selected late-stage development processes to identify, understand, evaluate, prioritize, and resolve potential environmental issues of future manufacturing processes.

The goal of environmental development reviews is to ensure that Development and Manufacturing personnel are confident that a process with an acceptable environmental profile for long-term manufacturing will be delivered to the manufacturing site and that the manufacturing site will be prepared to handle wastes generated by that process. Overall, the goal is to ensure that production of products is not interrupted by unforeseen environmental issues. In addition, these reviews enhance the Company's overall understanding of environmental issues and provide general learning points to improve process development and product manufacturing. Environmental development reports provide information for benchmarking environmental impacts of processes and for identifying general opportunities to reduce environmental impact.

The products of an environmental development review are: 1) the discussions, consensus conclusions, and issue resolutions that occur during the review period and 2) the resulting environmental development report which documents the review process and archives findings, conclusions, and recommendations. As they emerge, important findings are shared with stakeholders via emails, meetings, and the continual availability of the evolving, draft environmental development report. By the time the report is finalised (prior to the manufacturing campaign), the environmental development review is completed.

Detailed environmental development reviews provide substantial value by:

- Allowing the manufacturing site advance knowledge of potential compliance issues to ensure compliance with existing environmental requirements and commitments.
- Substantially reduces risk of production interruptions due to unforeseen environmental or waste treatment issues and damage to waste treatment equipment.
- Increasing the use of environmentally-sustainable manufacturing processes.
- Identifying improved environmental infrastructure needed at manufacturing sites well before product reaches manufacturing sites.
- Helping to sustain the environmentally aware process development culture, i.e., increases incorporation of environmental considerations throughout the Company by providing specific process analysis, general learning points, and key environmental contact for questions about process changes and environmental issues.
- Documenting specific, quantitative environmental impacts and benefits of processes and alternatives at specific manufacturing sites.
- Reducing waste treatment costs and increases savings due to solvent and by-product recovery and other potential value recovery opportunities.
- Reducing capital costs by eliminating environmental issues prior to production, thus avoiding capital expenditures (to increase waste treatment capacity).

The scope of environmental development reviews generally consists of the following components (each of which is described under EDR Exercise): Process Definition/Data Collection, Production Levels, Mass Balances for Waste Streams and Waste Treatment, Estimation of Impacts, Evaluation of Impacts, Review with Environmental Experts, Review with Manufacturing Site, Review with Development Personnel, Finalise Conclusions and Recommendations, Finalise Report.

At the conclusion of an environmental development review, an environmental development report is published and circulated to document and archive the review process, its findings, conclusions, recommendations, and outstanding issues.

The EDR process includes a substantial contribution and level of review from both process development and manufacturing site personnel and involves a significant amount of coordination and input from a range of subject matter experts based at the company's Environmental Affairs group in Indianapolis, United States.

(4) Environmental Considerations during Product Manufacturing:

The increasing inclusion of environmental considerations during product development and process transfer described in the preceding sections also compliments a general trend in the industry in recent years away from high volume manufacturing processes that once used large quantities of raw materials to manufacture large quantities of low or medium potency final product. It is now more common for manufacturing processes at the Kinsale site to instead yield low volumes of highly potent final product and in the process use much lower quantities of raw materials. In addition water based 'Cleaning in Place' techniques have, to a significant extent, replaced many of the more traditional cleaning practices that relied primarily on the use of organic solvents. The hugely reduced organic solvent usage at the Kinsale site in recent years directly reflects both the changed cleaning practices and the overall move away from high volume products and the related trend of reduced quantities of raw materials required in the typical manufacturing processes. In the 10 years from 2003 to 2013 the gross bulk solvent usage at the Kinsale site has reduced by more than 65%).

The environmental benefits of this trend towards lower volume processes and reduced organic solvent usage are clear. However, further environmental benefits are also delivered by using 'Best Available Techniques' (or BAT) during the manufacturing processes as required.

There are many examples where techniques that can be considered as BAT, in line with the *Reference Document on Best Available Techniques for the Manufacture of Organic Fine Chemicals (European Commission, 2006)*, are used in the management of manufacturing processes at the Kinsale site. Such techniques include but are not limited to the use of; Indirect Cooling, Airtight Production Rig Vessels, 'Shock' type Inerting Techniques, Indirect Process Heating, Condensation of VOC process emissions for heat recovery value, Minimization of Peak VOC Emissions from Processes and Monitoring of Emissions from individual processes etc. (See Attachment D for further details of the typical manufacturing processes at the site).

In addition, various manufacturing process improvement projects have also been completed at the site for full scale manufacturing processes in recent years as the need and/or opportunity has arisen. Many of these initiatives have involved the application of techniques that would be considered as BAT and have as a result delivered environmental benefits. This has included some fundamental changes to processes that typically would only be possible during product development stages. Various such initiatives completed during recent years are reviewed individually, in outline below:

- **Phosgene Elimination:** In 2006, a major long term project was successfully completed to eliminate the use of Phosgene from a long established process for the manufacturing of a final Active Pharmaceutical Ingredient (API) at the site and replace this substance in the process with the much less toxic alternative Oxalyl Chloride. This project involved a significant amount of collaboration between process development and manufacturing personnel and has ensured that the process is now inherently safer from an environmental risk perspective.
- **Catalyst Substitution:** In 2007, a project was completed to change the catalyst used in the manufacturing process of an intermediate step of an API at the Kinsale site in order to increase product yield and reduce the quantity of raw material required per unit weight of manufactured final product. This involved changing from the 'Amberlyst' catalyst to a 'Clay' catalyst and has resulted in a 10% reduction in the quantity of raw material required in the process.
- **Minimisation of Peak VOC Gaseous Emissions to the Abatement Systems (1):** In 2009, a campaign of a manufacturing process was scheduled to be undertaken at the site for the first time since 2003. Experience from the earlier campaign in 2003 had shown that this process was likely at times to present a significant challenge to the gaseous emissions abatement system due to peak VOC emissions owing to the low water solubility and high vapour pressure of the main process solvent. In preparation for this campaign significant changes were completed on the production rig in order to minimise at source the peak VOC emissions routed to gaseous emissions abatement system. The changes included replacing the water based production rig scrubber solution with a glycol alternative with a much higher scrubbing efficiency for the process solvent, minimising the nitrogen purge rates and improving venting control through infrastructural and process management improvements and rerouting additional vent lines through a pre-condenser.
- **Minimisation of Peak VOC Gaseous Emissions to the Abatement Systems (2):** In 2010, a project was completed to re-route the gaseous VOC emissions arising from an existing manufacturing process. This involved re-routing the emissions from a dedicated emissions abatement system for the process to the main emissions abatement system treating the emissions from all other manufacturing process operating at the site. Significant energy use reduction benefits would be delivered by consolidating all gaseous emissions abatement in one system. However, a potential environmental risk was identified with this option that related to the potential for loading excessive peak VOC emissions to the abatement system that could in turn give rise to the generation of elevated Hydrogen Chloride (HCL) emissions from the abatement system. To eliminate this risk a significant amount modelling and mapping of the process was completed in order to identify the stages of the process that were most likely to give rise to VOC peak emissions and to determine if overlapping certain production steps was likely to exacerbate this risk. This process modelling and mapping directed the process team to reconfigure the operation of the manufacturing in such way as to minimize the peaks emissions and therefore eliminate the risk of excessive HCL emissions from the abatement system.

9.8.1G BAT Measures Proposed or in Place

- (a) *The best available techniques are or will be used to prevent or eliminate or, where that is not practicable, generally reduce an emission from the activity*

Eli Lilly applies the necessary BAT measures to control and monitor its waste emissions from manufacturing. Tables 9.8(i) to 9.8(iv) detail where the site design applies BAT to wastewater, waste gas, waste incineration, manufacture and monitoring. These measures are supplemented by corporate and site initiatives to reduce emissions at source. These initiatives are described under Environmental Considerations and are described in brief here.

Continuous flow processing
Green chemistry
Environmental Development Reviews
Changeover to low yields of high potency products
Cleaning in place practices
Particular initiatives

- (b) *no significant pollution is caused*

An EIS has been prepared of this development. This EIS was subject to EIA by Cork County Council with planning permission for the development granted (Planning reference 11/06594). The EUS states in summary "*Where unavoidable environmental effects have been identified during the environmental impact assessment process, measures have been proposed to mitigate these effects where possible*".

Appendix 3 of this licence submission also contains a Baseline Report which examines the impact of operations on the site.

- (c) *waste production is avoided in accordance with the waste hierarchy in Council Directive 98/2008/EC on waste and section 21A of the Waste Management Act 1996, as amended; where waste is produced, it is prepared for reuse, recycled or recovered or, where that is technically and economically impossible, it is disposed of while avoiding or reducing any impact on the environment (applicants should provide this information in the context of sections 29(2A), 32 and 38(5A) of the Waste Management Act 1996, as amended);*

Please refer to Attachment H.2 for further detail minimisation and H.4 and H.5 for further details on recovery.

- (d) *energy and other resources are used efficiently*

Please refer to Table 7.2 in this attachment, regarding BAT and energy efficiency and to Attachment G.

- (e) *the necessary measures are taken to prevent accidents and limit their consequences*

There is a Health and Safety Plan for the facility and Emergency Response Procedures. Please refer to Attachment J. The Health and Safety Plan for the site is held on site.

- (f) *the necessary measures are taken upon definitive cessation of activities to avoid any pollution risk and return the site of operation to a satisfactory state*

A CRAMP has been prepared and submitted to the Agency for approval, a copy of which is included in Appendix 4.

10 ATTACHMENT J – ACCIDENT PREVENTION & EMERGENCY RESPONSE

Describe the existing or proposed measures, including emergency procedures, to minimise the impact on the environment of an accidental emission or spillage.

The site employs measures to prevent or mitigate the impact of any spillage or accidental release. Engineering standards are in place for the design, installation, and maintenance of all equipment, piping and storage vessels that contain materials that could have an impact on the environment. An extensive commissioning and qualification process is in place to ensure and to document that these engineering standards are adhered to when installing new plant, piping or equipment on the site or for making significant changes for equipment and pipework.

The site employs a permit-to-work system including a line breaking permit system to control maintenance and non-routine operations on equipment and piping which have a higher risk of spillage inherent in the actual maintenance task.

As part of normal processing operations, the site will conduct pressure tests of lines to ensure lines and equipment are leak free prior to the introduction of any hazardous materials to a system. The site operates a formal pre start-up safety review process (PSSR) for production plant and major utilities to ensure among other items that there is no risk of a leak or accidental release of a hazardous material during start-up activities. The site operates a practise of walking lines into service during the initial movement of material in pipelines to verify that the lines remain integral and that no leaks or weeps are occurring.

On production plants; a series of solvent runs is carried out prior to the commencement of production operations. This assists in identifying issues on the plant including areas, equipment and pipelines where leaks or releases could occur. For new equipment and pipelines, water runs are carried out as part of the commissioning effort before solvent is introduced.

Site personnel are trained in routine operations including material transfer operations including training on standard operating procedures (SOPs). Process schools for operators are held prior to the commencement of any production campaign. As part of the process school curricula, any particular issues around specific materials, operating tasks or equipment issues that may give rise to a higher risk of a leak or accidental release are covered in detail together with the correct preventative or mitigating actions to be taken.

Most operations are highly automated which gives greater consistency of operation and reduces the potential for error. The automation systems also monitor many instruments and will alarm if any deviations occur from expected parameters. Thus early warning of any event which could potentially give rise to a release or a spillage can be given which will give time for remediation action to be taken to prevent or mitigate the situation.

Some toxic gases or materials that can give rise to toxic or flammable gases are used onsite (see Section H for further details). In the event of an emergency such gases could be released to the atmosphere. A number of systems and response procedures are in place to prevent the risk and / or minimise the risk consequence of such releases. Gas detectors are in use in certain areas of the site to detect and provide an early warning of a potential release when even at trace levels. In the event of a toxic gas release on site, the ERT can in many cases reduce the dispersion of the gas downwind by producing a water fog to knock down the gas. In the event of spills of flammable materials, foam is used to smother the spill and minimise the evolution of flammable or toxic gases.

Currently the site has ammonia detectors in its chiller rooms, has hydrogen detectors in areas of plant which use hydrogen and uses hydrogen chloride detectors in areas where there is a risk of a release of hydrogen chloride.

Bunding and secondary containment is extensively deployed where required throughout the site, consistent with Agency guidance and requirements. These structures will contain the vast majority of any spillages that could occur on site and therefore avoid any potential environmental impacts at source by the prevention of the release of such spillages to the environment (i.e. ground, groundwater or surface water). Furthermore, bunds and underground structure integrity test programmes are in place in line with Agency guidance and requirements, which help ensure that these structures will contain any materials in the event of a spillage.

A significant proportion of the non process areas of the site are covered by impermeable paving which further minimises the risk of environmental contamination (particularly to the ground and groundwater) in the event of an uncontained spillage.

Spill kits containing boons and absorbent materials etc. are located at key areas across the site. This spill response equipment can be used to isolate and contain and clean up a spillage that could potentially occur in an uncontained area of the site such as on a roadway during the transport of a material or from overhead piping etc. Spill kits can also be used to further confine and clean up spillages within contained areas such as production buildings or bunds. The required response to safely deal with spillages is clearly detailed in spill procedures and all relevant site personnel are trained in these procedures. In addition a fully equipped Spill Truck is available onsite.

All clean storm water run-off from the site is routed through a HDPE lined firewater retention pond located at the southern end of the site before discharge to the 'Doon Creek' stream. The retention pond is equipped with continuous pH and Total Organic Carbon (TOC) monitoring at both the inlet and outlet of the pond. Control limits are in place for both parameters that trigger the firewater retention pond outlet valve to automatically close should either parameter exceed the control limit set points. Therefore, in the unlikely event of contamination of site storm water due to a spillage, this will be detected by the continuous monitoring system and this will trigger the pond outlet valve to close and contain the contaminated water.

Furthermore, the Emergency Response Procedures include instructions on the manual closure of the outlet valve in the event of a site emergency as appropriate. The firewater retention pond also provides significant containment capacity for contaminated firewater in the event of an onsite fire (see section 6 for further details). The potential for ground or groundwater impacts from the contaminated contents of the pond are minimised because the retention pond is HDPE lined rendering it impermeable. The HDPE liner is also integrity tested in line with Agency expectations and any defects detected are repaired in a timely fashion. Facilities are also in place to allow the contents of the retention pond to be pumped for onsite treatment or for offsite disposal if required. All these storm water and firewater control measures help minimise the risk of environmental contamination due to site emergencies and incidents.

An accidental emission via the wastewater treatment plant could also potentially occur if a significant spill of a highly concentrated or poorly biodegradable material was routed to this plant. If such an event occurred it is possible that some of this material may pass through the plant untreated and be emitted to surface water resulting in an environmental impact. However, a number of systems and emergency response steps are in place to prevent or minimise the risk of such an event. These include; the spill response procedures outlined above, the option to contain spills in production building waste tanks and reroute these away from the wastewater treatment plant to a more appropriate treatment system. Furthermore, the main wastewater treatment balance tank itself can also contain the spill and be rerouted in an emergency if required. Extensive monitoring of the wastewater treatment plant further minimises the chances of such an event escalating to a point where an environmental impact could occur. (Refer to Section H for further details).

The most likely accidental atmospheric emission that may occur onsite would involve a short term automated by-pass of the primary emissions abatement equipment for safety reasons. A specific response procedure is in place that details the required emissions minimisation steps to be completed in the event of an abatement system by-pass and all relevant site personnel are trained on this procedure. This procedure is found to be very effective in minimising the atmospheric emissions in the relatively rare event of such a by-pass and further details of this procedure are included in section F.

A Site Emergency Plan (SEP) is in place to respond to all conceivable emergency situations that could arise on site, including many classes of accidental emissions and spillages. The SEP and the site emergency response procedures form an extensive and detailed body of controlled documentation that is available for review on request.

The prevention and minimisation of environmental impacts as a result of site emergencies is a key function of the SEP. Thus many of the related measures that are in place are to specifically respond to an emergency with the potential for an environmental impact and to prevent or limit an environmental impact in the event of an accidental emission or spillage.

Implementation of the SEP, depending on the type of emergency, can involve a significant degree of coordination between the site emergency teams and the offsite emergency services and other relevant agencies.

A site Emergency Response Team (ERT) fully trained in well-developed emergency response procedures and the site Management Control Group (MCG) works in tandem with the ERT to control and oversee the response to site emergencies. This group consists of a broad selection of site personnel including top management and members of key technical disciplines including those personnel responsible for environmental matters on the site.

Also outline what provisions have been made for response to emergency situations outside of normal working hours, i.e. during night-time, weekends and holiday periods.

The ERT consists primarily of site personnel who occupy shift work positions including night-time, weekends and holiday periods. It is a requirement that a minimum number of members of the ERT are onsite at all times commensurate with the operational risk. Special provision for Management Control Group cover is also provided during holiday periods.

Note: Various materials are used on site that could potentially cause an environmental impact if released to the environment (see Section H for further details).

Describe the arrangements for abnormal operating conditions including start-up, leaks, malfunctions or momentary stoppages.

The site employs measures to prevent or mitigate the impact of any spillage or accidental release during start-up operations. The site's commissioning and qualification process is in place to ensure and to document that the site's engineering standards are adhered to when installing new plant, piping or equipment on the site or for making significant changes for equipment and pipework.

Prior to any start-up of plant or significant unit operation on the site, the site operates a formal pre start-up safety review process (PSSR) for production plant and major utilities to ensure among other items that there is no risk of a leak or accidental release of a hazardous material during start-up activities.

Prior to start-up of production plants; a series of water runs, followed by solvent runs is carried out to assist in identifying issues where leaks or releases could occur.

As part of the start of normal processing operations, the site will conduct pressure tests of lines to ensure lines and equipment are leak free prior to the introduction of any hazardous materials to a system. The site operates a practise of walking lines into service during the initial movement of material in pipelines to verify that the lines remain integral and that no leaks or weeps are occurring.

Most operations are highly automated which gives greater consistency of operation and reduces the potential for error. The automation systems also monitor many instruments and will alarm if any deviations occur from expected parameters. Thus early warning of any event which could potentially give rise to a release or a spillage can be given which will give time for remediation action to be taken to prevent or mitigate the situation.

In addition the automation systems will bring the relevant unit operation, equipment item or pipeline to a safe point e.g. solvent pumping will be stopped, a vessel to vessel transfer will be stopped and automatic isolation valves on process lines will close, vessel vent valves will be closed and vessels will be buttoned up until the issue is resolved etc.

The plant will require to be restarted by operational personnel once the cause of the event is known, understood and resolved. The automation system includes detailed software phases to support such restarts.

The site employs a permit to work system including a line breaking permit system to control maintenance and non-routine operations on equipment and piping which have a higher risk of spillage inherent in the actual maintenance task.

Public Liability Insurance

Please refer to the appended letter in Attachment K from the 'Corporate Risk Management' department of Eli Lilly and Company for further details of this policy of self-insurance and how its applies to the Kinsale site.

11 ATTACHMENT K – REMEDIATION, DECOMMISSIONING, RESTORATION & AFTERCARE

11.1K.1 – Cessation of Activity

A revised Closure, Restoration and Aftercare Management Plan (CRAMP) has been prepared in support of this licence review application. This was prepared in accordance with the document "*Guidance on Environmental Liabilities Risk Assessment, Residuals Management Plans and Financial Provision*", EPA 2006 (which has subsequently been revised). This CRAMP builds on previous Residual Management Plans and Environmental Liabilities Risk Assessments prepared, revised and submitted to the Agency under the current license for the site.

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

A copy of the CRAMP and ELRA are included in Appendix 4 of this Application.

11.1.1 Financial Provisions for 'Known' Liabilities:

Please refer to the letter overleaf from the 'Corporate Risk Management' department of Eli Lilly and Company for further details of this policy of self-insurance and how it applies to the Kinsale site.

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May 11, 2012

Environmental Licensing Programme Administration
Environmental Protection Agency (EPA) Headquarters
PO Box 3000
Johnston Castle Estate
Co. Wexford
Ireland

To Whom It May Concern:

Request for certificate of insurance or letter of assurance.

We refer to your requirement for a certificate of insurance for environmental pollution insurance covering Eli Lilly and Company's (Lilly) Kinsale facility. Lilly's global property insurance policy does provide coverage for contamination and pollutant clean-up in the amount of US\$2,000,000 for environmental liabilities that result from covered perils such as flooding, fire, explosion, etc. For unknown liabilities not covered by the global property insurance policy, Lilly has determined it is not cost effective to purchase additional insurance but instead rely on the robust loss prevention practices and the strength of Lilly's balance sheet.

At the time of this letter, Kinsale has a near perfect Risk Mark score (99%) as determined by FM Global insurance company. This strong risk rating combined with Lilly's A2 credit rating assigned by Moody's Investor Services enables Lilly to confidently self-insure for any potential environmental liabilities.

Lilly also understands the obligations it has to the known liabilities at the site and will maintain its loss prevention efforts throughout any closure or partial closures of the Kinsale site. In addition, Lilly is committed to maintaining a self-insured program that is sufficient for these obligations.

Regards,



Jeffrey L. Williams
Consultant – Treasury/Risk Management
Corporate Risk Management
Eli Lilly & Company

12 ATTACHMENT L – STATUTORY DECLARATION

12.1 L.1 – Statutory Requirements

1. *Indicate how the requirements of Section 83(5)(a)(i) to (v) and (vii) to (x) of the EPA Act 1992, as amended, shall be met, having regard, where appropriate, to any relevant specification issued by the Agency under section 5 (3) of the Act and the reasons for the selection of the arrangements proposed.*

Sections 83(5) (a) (i) to (v) and (vii) to (x) of the EPA Acts 1992 and 2011 states that:

'5) The Agency shall not grant a licence or revised licence for an activity—

(a) unless it is satisfied that—

(i) any emissions from the activity will not result in the contravention of any relevant air quality standard specified under section 50 of the Air Pollution Act 1987, and will comply with any relevant emission limit value specified under section 51 of the Air Pollution Act 1987,

(ii) any emissions from the activity will comply with, or will not result in the contravention of, any relevant quality standard for waters, trade effluents and sewage effluents and standards in relation to treatment of such effluents prescribed under section 26 of the Local Government (Water Pollution) Act 1977,

(iii) any emissions from the activity or any premises, plant, methods, processes, operating procedures or other factors which affect such emissions will comply with, or will not result in the contravention of, any relevant standard including any standard for an environmental medium prescribed under regulations made under the European Communities Act 1972, or under any other enactment,

(iv) any noise from the activity will comply with, or will not result in the contravention of, any regulations under section 106,

(v) any emissions from the activity will not cause significant environmental pollution,

(vii) having regard to Part III of the Act of 1996, production of waste in the carrying on of the activity will be prevented or minimised or, where waste is produced, it will be recovered or, where that is not technically or economically possible, disposed of in a manner which will prevent or minimise any impact on the environment,

(vii*a*) without prejudice to subparagraph (vii), waste generated in the carrying on of an industrial emissions directive activity, in order of priority in accordance with section 21A (inserted by Regulation 7 of the European Communities (Waste Directive) Regulations 2011) of the Act of 1996, will be prepared for re-use, recycled, recovered or, where that is not technically or economically possible, disposed of in a manner which will prevent or minimise any impact on the environment,

(viii) energy will be used efficiently in the carrying on of the activity,

(ix) necessary measures will be taken to prevent accidents in the carrying on of the activity and, where an accident occurs, to limit its consequences for the environment and, in so far as it does have such consequences, to remedy those consequences,

(x) necessary measures will be taken upon the permanent cessation of the activity (including such a cessation resulting from the abandonment of the activity) to avoid any risk of environmental pollution and return the site of the activity to a satisfactory state,

(x*a*) in the case of an industrial emissions directive activity, necessary measures referred to in subparagraph (x) including measures of appropriate duration shall be taken in accordance with section 86B'

In response:

(i) An air impact assessment has been undertaken as part of the licence review as outlined in Attachment I. The results of the modelling assessment indicates that maximum ELV's stipulated in the facilities licence (Schedule B and technical amendments) from the main atmospheric emission point's onsite are in compliance with the statutory limits set out in the relevant Irish air quality regulations and the most stringent European standards, at and beyond the site boundary of the facility. In conclusion, the cumulative impact of licence (P0009-03) emission limit values, from the main atmospheric emissions points' onsite, will not adversely impact the ambient air quality of surrounding environment.

(ii) A surface water quality impact assessment was undertaken as part of this licence review and is included in Attachment I. This assessment concluded that discharges from the facility will not adversely impact water quality or breach of Environmental Quality Standards in the receiving water body in accordance with the EC Environmental Objectives (Surface Waters) Regulations (*S.I. No. 272/2009*).

(iii) The main environmental emissions from the facility are considered to be atmospheric, surface water, noise and waste emissions. Impact assessments relating to air, surface water and noise emissions from the facility are discussed in Attachment I of this application. Materials handling and waste management are discussed in Attachments G and H of this application.

These impact assessments conclude that emissions from the facility will not result in the contravention of any relevant standard including any standard for an environmental medium.

(iv) A noise impact assessment was undertaken as part of this licence review and is included in Attachment I. This assessment concludes that all the predicted results are within the EPA 55 dB(A) daytime limit for monitoring locations and the closest noise sensitive locations. The evening time and night-time operations would only use a fraction of the site noise sources therefore it is unlikely that the evening time and night-time emissions would exceed 50 and 55 dB(A) limit value respectively.

(v) The main environmental emissions from the facility are considered to be atmospheric, surface water, noise and waste emissions. Impact assessments relating to air, surface water and noise emissions from the facility are discussed in Attachment I of this application. Materials handling and waste management are discussed in Attachments G and H of this application. These impact assessments conclude that emissions will not cause significant environmental pollution.

(vi) Materials handling and waste management onsite are discussed in Attachments G and H of this application. The maximisation of resource usage and waste minimisation is also discussed in Section I Environmental Consideration of BAT. Waste usage is prevented and minimised by incorporating green chemistry onsite to reduce the amount of hazardous material used, to increase materials efficiency, assess chemical alternatives etc. Eli Lilly has established material use efficiency standards in the product development process to prevent and minimise waste.

Where waste streams are generated it is recycled and reused or recovered for heat generation where possible. Wastes which cannot be reused or recovered onsite are sent offsite for recycling and recovery if possible. Where recycling or recovery is not technically or economically possible disposal is the final option. However, all wastes are disposed of in a manner which will prevent or minimise any impact on the environment.

(vii) Attachment G of this application outlines the measures undertaken onsite to ensure that energy is used efficiently, such as undertaking energy assessments & auditing at the site, implementing an energy management system and incorporating energy efficient design as far as possible.

(viii) Attachment J summarises the accident prevention and emergency response procedures onsite, which prevent and minimise the impact on the environment of an accidental emission or spillage.

(ix) A revised CRAMP and an ELRA has been prepared in support of this licence review application and is included in Appendix 3 of this application.

2. Indicate whether or not the activity is carried out, or may be carried out, or is located such that it is liable to have an adverse effect on -
- (a) a site placed on a list in accordance with Part 3 of S.I. 477 of 2011, or
- (b) a site where consultation has been initiated in accordance with Article 5 of the EU Habitats Directive (92/43/EEC).

Undertake a screening for Appropriate Assessment and state whether the activity, individually or in combination with other plans or projects, is likely to have a significant effect on a European Site(s), in view of best scientific knowledge and the conservation objectives of the site(s). Where it cannot be excluded, on the basis of objective scientific information, following screening for Appropriate Assessment, that an activity, either individually or in combination with other plans or projects, will have a significant effect on a European Site, provide a Natura Impact Statement, as defined in Regulation 2(1) of the European Communities (Birds and Natural Habitats) Regulations (S.I. No. 477 of 2011). Where based on the screening it is considered that an Appropriate Assessment is not required, provide a reasoned response.

As part of the planning permission application to Cork County Council for the IE43 biotechnology manufacturing facility, an EIS was prepared to assess the impacts of the development on the environment. A flora and fauna impact assessment was undertaken as part of this EIS.

In the flora and fauna assessment it outlined that:

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

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

Appendix A13.3 of the EIS (which accompanies this application) includes the Natura Impact Statement Stage 1 Screening Report for reference.

3. Indicate whether or not the activity is liable to have an adverse effect on water quality in light of the European Communities Environmental Objectives (Surface Water) Regulations 2009 (S.I. No. 272 of 2009).

A surface water quality impact assessment was undertaken as part of this licence review and is included in Attachment I. This assessment concluded that discharges from the facility will not adversely impact water quality or breach of Environmental Quality Standards in the receiving water body in accordance with the EC Environmental Objectives (Surface Waters) Regulations (S.I. No. 272/2009).

4. Indicate whether or not the activity is liable to have an adverse effect on water quality in light of the European Communities Environmental Objectives (Ground Water) Regulations 2010 (S.I. No. 9 of 2010).

There are no direct discharges to groundwater from the facility.

5. Indicate whether any of the substances specified in the Schedule of the EPA (Industrial Emissions)(Licensing) 2013, S.I. No. 137 of 2013, are discharged by the activity to the relevant medium.

The following substances specified in the Schedule of the EPA (Industrial Emissions) (Licensing) 2013, S.I. No. 137 of 2013 are discharged by the activity to air:

- Sulphur dioxide and other sulphur compounds
- Oxides of nitrogen and other nitrogen compounds
- Carbon monoxide

- Volatile organic compounds
- Dust including fine particulate matter (trace)
- Chlorine and its compounds
- Fluorine and its compounds
- Substances and mixtures which have been proved to possess carcinogenic or mutagenic properties or properties which may affect reproduction via the air

and to water:

- Organohalogen compounds and substances which may form such compounds in the aquatic environment
- Metals and their compounds (trace)
- Arsenic and its compounds (trace)
- Materials in suspension
- Substances which contribute to eutrophication
- Substance which have an unfavourable influence on the oxygen balance
- Substances listed in Annex X to Directive 2000/60/EC.

6. *Indicate if the best environmental practices are in place for control of diffuse emissions from the installation as set out in the following legislation: a BAT Conclusions Implementing Decision published by the EC.*

a) a BAT Conclusions Implementing Decision published by the EC.

a specification prepared by the Agency in accordance with Section 5 of the Environmental Protection Agency Act 1992 as amended;

b) the Urban Waste Water Treatment Regulations 2001 (S.I. No. 254 of 2001) as amended by the Urban Waste Water Treatment (Amendment) Regulations 2004 (S.I. No. 440 of 2004) or any future amendment thereof;

This is not applicable to the Eli Lilly Dunderrow site.

c) the European Communities (Good Agricultural Practice for Protection of Waters) Regulations 20 (S.I. No. 610 of 2010) or any future amendment thereof;

This is not applicable to the Eli Lilly Dunderrow site.

d) the Local Government (Water Pollution) Act, 1977 (Control of Cadmium Discharges) Regulations 1985 (S.I. No. 294 of 1985);

This is not applicable to the Eli Lilly Dunderrow site.

e) the Local Government (Water Pollution) Act, 1977 (Control of Hexachlorocyclohexane and Mercury Discharges) Regulations 1986 (S.I. No. 55 of 1986);

This is not applicable to the Eli Lilly Dunderrow site.

f) the Local Government (Water Pollution) Acts, 1977 and 1990 (Control of Carbon Tetrachloride, DDT and Pentachlorophenol Discharges) Regulations 1994 (S.I. No. 43 of 1994); and,

This is not applicable to the Eli Lilly Dunderrow site.

g) measures or controls identified in a pollution reduction plan for the river basin district prepared in accordance with Part V of the EC Environmental Objectives (Surface Waters) Regulations 2009 S.I. No. 272 of 2009 for the reduction of pollution by priority substances or the ceasing or phasing out of emissions, discharges and losses of priority hazardous substances.

A surface water quality impact assessment was undertaken as part of this licence review and is included in Attachment I. This assessment examined the impacts of two surface water discharges from the site namely:

- Treated wastewater effluent discharge to coastal waters east of Sandy Cove Island, outside Kinsale Harbour
- Storm water run-off to Doon Creek

This assessment concluded that discharges from the facility will not adversely impact water quality or breach of Environmental Quality Standards in the receiving water body in accordance with the EC Environmental Objectives (Surface Waters) Regulations (*S.I. No. 272/2009*).

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Appendix 1

Schedule of Correspondence with EPA

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Schedule	Date of Correspondance	From	To	Reference (if available)	Re:
1	11/10/2005	Charlie McGuinness Eli Lilly	Regina Campbell		Proposals on Analysis Methods and frequencies
2	11/03/2006	Michael Owens EPA	Billy Sheehan Eli Lilly	M726/ap03mo	Request to commence operation of the Nano-filtration plant
3	31/08/2006	Billy Sheehan Eli Lilly	Michael Owens EPA		Criteria for Reporting of Bypass Emissions
4	15/09/2006	Michael Owens EPA	Billy Sheehan Eli Lilly	P0009-03/ap08mo	Assessment of signficance of Thermal abatement by-passes
5	16/07/2007	Dara Lynott EPA	Billy Sheehan Eli Lilly		EPA - Technical Amendment A to Integrated Pollution Prevention & Control Licence
6	05/11/2007	Martin O'Reilly EPA	Billy Sheehan Eli Lilly	P0009-03/ap10mor.doc	Phosphorous Licence Limits
7	11/02/2008	Billy Sheehan Eli Lilly	Suzanne Wylde EPA		Notification of a First Time Use of Premises for Class 1 GMMs
8	19/03/2008	Billy Sheehan Eli Lilly	Suzanne Wylde EPA		Further Infromation for GMM Licence Application
9	24/06/2008	Martin O'Reilly EPA	Billy Sheehan Eli Lilly	P0009-03/gc 15 mor.doc	Permission to suspend the requirement for phenol monitoring at emission point 6-1 (SW1)
10	08/01/2009	Martin O'Reilly EPA	Billy Sheehan Eli Lilly	P0009-03/gc21mor.doc	Operation of the SCR DENO _x unit
11	10/07/2009	Billy Sheehan Eli Lilly	Suzanne Wylde EPA		Notification of a First Time use of Premises for Class 1 GMMs
12	07/01/2010	Billy Sheehan Eli Lilly	Michael Owens EPA		Adjustments to the monitoring parameters for emission point 6-1 (SW1)
13	14/01/2010	Martin O'Reilly EPA	Billy Sheehan Eli Lilly	P0009-03/gc 29mor.doc	Monitoring frequency of parameters for emission point 6-1 (SW1)
14	08/09/2010	Joe Reilly EPA	Billy Sheehan Eli Lilly	P0009-03	Approval of technical Amendment B
15	09/12/2010	Martin O'Reilly EPA	Billy Sheehan Eli Lilly	P009-03/gc35mor.docx	Amendments to Monitoring frequency of certain parameters at the waste water treatment plant
16	14/06/2011	Martin O'Reilly EPA	Billy Sheehan Eli Lilly	P009-03/gc38mor.docx	Ambient monitoring and monitoring of oxides of sulphur and nitrogen oxides on emission point 7-1 (a)

Ms Regina Campbell,
Office of Environmental Enforcement,
EPA,
Inniscarra,
Co Cork

Date: 11th Oct 2005

Dear Ms. Campbell,
Following our recent discussions (meeting of Sept 5th 2005) on the monitoring conditions outlined in Schedule C of IPC Licence Ref. 726, I hereby submit proposals on Analysis Methods to be agreed with the Agency, together with proposals for the amendment of the monitoring frequency for the parameters outlined below, subject to condition 6.5 of the licence and condition 11(7) of the Council Directive 2000/76/EC.

IPC Licence Reg No. 726 - Schedule C: Monitoring & Control

C.1.2 *Monitoring of Emissions to Air*

Emission Point Reference No.s:
7-1(b) John Zinc Incinerator and
7-1(c) Thermal Incinerator

Parameters	Monitoring Frequency	Analysis Method
Total Dust	Continuous	Iso-Kinetic/gravimetric
<i>Proposal</i>		<i>Photometric</i>

This is included as a correction to the listed method as the monitoring system used is a photometric device. This was the analysis method outlined in the previous Licence Reg. No. 546.

Hydrogen fluoride (HF)	Bi-annually	To be agreed with Agency
<i>Proposed Method</i>		<i>Impinger & Ion Chromatography (or ISE)</i>
Hydrogen Bromide (HBr)	Bi-annually	To be agreed with Agency
<i>Proposed Method</i>		<i>Impinger & Ion Chromatography (or ISE)</i>

C.1.2

Monitoring of Emissions to Air (cont'd)

Cadmium (as Cd) and thallium (as Tl), and their compounds	Quarterly	To be agreed by the Agency
<i>Proposal</i>	<i>Annually</i> ^{Note 5}	<i>AA/ICP/ICP-MS</i>
Mercury (as Hg) and its compounds	Quarterly	To be agreed by the Agency
<i>Proposal</i>	<i>Annually</i> ^{Note 5}	<i>AA/ICP/ICP-MS</i>
Antimony (as Sb), arsenic (as As), lead (as Pb), chromium (as Cr), cobalt (as Co), copper (as Cu), manganese (as Mn), nickel (as Ni), and vanadium (as V) and their compounds	Quarterly	To be agreed by the Agency
<i>Proposal</i>	<i>Annually</i> ^{Note 5}	<i>AA/ICP/ICP-MS</i>
Dioxins/furans ^{Note 3}	Bi-annually ^{Note 4}	I.S. EN 1948 Parts 1-3
<i>Proposal</i>	<i>Quarterly on Zink only</i> <i>Bi-annual on Thermall</i> ^{Note 6}	

Note 1: Or other methods agreed in advance by the Agency.

Note 2: Monthly until upgrade and continuous thereafter.

Note 3: Average values shall be measured over a sampling period of 6 hours and a maximum of 8 hours.

Note 4: Quarterly for the first year after upgrade and bi-annually thereafter.

Note 5:

In relation to stack emission monitoring for metals, article 11 (7) of the Council Directive 2000/76/EC states that a reduction in the monitoring frequency from twice a year to once every two years may be authorised provided that the measured emissions are less than 50% of the emission limit value. As can be seen from the summary table (Appendix 1) metal emissions from both the Thermall and John Zink units are well below this value, and given the stability of the measured data over the years, the proposed annual monitoring frequency is considered more than adequate to meet the requirements of the Directive.

Stack sampling for metals is conducted as per USEPA Method 29, under the supervision of a reputable independent consultant. A contract laboratory with UKAS accreditation undertakes analysis of samples.

As you will appreciate stack metal sampling and analysis is a complex process incurring high costs in terms of site manpower and contract resources. By reducing the monitoring frequency it is felt that site resources can be better utilised in dealing with other elements of our Environmental Management Programme.

Note 6:

In relation to Note 4 above, which requires quarterly Dioxin/Furan analysis of both the Thermall and Zink units for the first year after upgrade, it should be noted that the only change impacting the Thermall unit relates to the de-rating of the Induced Draught Fan so that air flow through the chamber is reduced and residence time increased. This will result in an overall increase in the efficiency of the unit with a positive impact on the emission profile. As our current dioxin emission profile on the Thermall unit is orders of magnitude below the emission limit value (ELV) (see Appendix 2), increasing the monitoring frequency on this unit will again result in an inappropriate use of site resources and unnecessary cost burden. While the dioxin profile on the Zink unit is also orders of magnitude below the ELV, we accept that given the modifications involved in the upgrade of this unit that it will be necessary to demonstrate the units continued combustion efficiency by carrying out quarterly dioxin analysis for the first year after the upgrade.

C.1.2 Monitoring of Emissions to Air

Emission Point Reference No.: No. 7-1(a)

Regenerative Thermal Oxidiser Stack

Parameters	Monitoring Frequency	Analysis Method
Oxides of Sulphur	Bi-annually	To be agreed with the Agency
<i>Proposed method</i>		<i>NDIR</i>

Nitrogen Oxides (as NO ₂)	Bi-annually	To be agreed with the Agency
<i>Proposed Method</i>		<i>Chemiluminescence/IR</i>

C.2.2 Monitoring of Emissions to Water

Emission Point Reference No.: No. 6-1

Parameters	Monitoring Frequency	Analysis Method
Phenols	Weekly	Standard Method

At the time of the licence review a submission was made to have the monitoring requirements for both Cyanide and Phenol compounds removed from the relevant schedules, as the process giving rise to these by-products was no longer in use at the site. As the product involved has been outsourced there is little possibility of this product returning to the site in the future. While all references to Cyanide have been removed from the Licence (Reg. No.726), a weekly monitoring frequency for phenol still remains under schedule C.2.2. We request that this monitoring requirement be suspended for the reasons outlined above.

C.4 Waste Monitoring

All parameters listed under this section require Analysis Method/Technique to be agreed with the agency.

The Proposed Analysis Methods/Techniques as are outlined in the Table below.

Waste Class	Frequency	Parameter	Proposed Analysis Method/Technique
Solvent/Aqueous Waste for Onsite Incineration	Per batch on non-routine waste Annually on routine wastes	% Solvents % Halogen	GC-FID
		Water	KF/Mass Balance
		Calorific value	Calorimeter
		Metals	AA/ICP
Solid Waste for onsite incineration	Per batch on non-routine waste Annually on routine wastes	% Halogen	Based on Estimate of Content
		Water	Based on Estimate of Content
		Calorific value	Based on Estimate of Content
		Metals	Based on Estimate of Content
WWTP Sludge for Landfill	Quarterly ^{Note 1}	Metals on Leachate* Organic Matter Water Content	AA/ICP Std. Methods Std Methods
	Annually ^{Note 1}	Organic Compounds	Purge & Trap GC/MS
Other - Kiln Ash ^{Note 2}	Annually	Loss on Drying (LOD)	Std Methods
		Loss on Ignition (LOI)	Std Methods
		Metals on Leachate*	AA/ICP

* Metal Listing: Copper, Chromium, Lead, Zinc, Cadmium, Nickel, Tin, Boron

Note 1:

As all WWTP sludge is currently disposed of by either onsite or offsite incineration there is no foreseen necessity to landfill this material, therefore the quarterly and annual monitoring frequencies outlined for this waste class should be reconsidered.

The proposal being put forward here for consideration by the Agency is that the requirements for monitoring of WWTP sludge for landfill should be suspended until such time as if and when the Company reverts to landfill of this waste class.

Note 2:

The Rotary Kiln is used for the incineration of solid waste onsite, including WWTP sludge. As the bottom ash from this process is not covered under the waste monitoring schedule it is proposed to include this material in the "Other" waste class and complete analysis on same as outlined above.

C.6.1 Groundwater Monitoring

Location: MW1, MW3, MW10, W7, and W9

During the course of the review of this licence agreement was reached with the Agency with regard to the substitution of the listed monitoring wells under Licence Reg. No. 546 with an updated monitoring well suite.

The list of updated wells is as follows; SW1, SW2, W9, SW5, SW6, RemW1, MW4 and W16.

This proposal was made to the Agency in a letter dated 4th Mar 2005 and subsequently approved by the Agency prior to the issue of the current licence.

We therefore request Agency approval to continue using this monitoring well suite.

Schedule B.1: Emissions to Air

It is proposed to carry out particulate analysis on the process vents as listed in the schedule (IE1V3 to IE30EV-2) on an annual basis. This is the same monitoring frequency as agreed under the terms of the previous licence (Reg. No.546). We therefore request that this monitoring frequency be retained for the current licence.

Condition 3.4

As a point of clarification with regard to the requirements outlined under this condition it is our understanding that the requirement to retain a refrigerated sub sample for Agency use relates only to effluent discharge, which under the terms of this licence relates to Emission Point Ref. 6-1 and W2.

We hope that all of the above proposals meet with the approval of the Agency and should any further detail be required in relation to any aspect of these proposals please do not hesitate to contact the undersigned.

Yours faithfully,
On behalf of Eli Lilly S.A

Charlie McGuinness
Environmental Chemist

Tel: 021-4702665
e-mail: mcguinness_charles@lilly.com

Mr Billy Sheehan
Eli Lilly S.A. - Irish Branch
Dunderrow
Kinsale
County Cork

South/South West Region
Environmental Protection Agency
Regional Inspectorate, Inniscarra
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11th March 2006

Our Ref: M726/ap03mo

Dear Mr Sheehan

I refer to your letter dated 11/04/06, received by the Agency on the 11/04/06, in relation to a request to commence operation of the nano-filtration plant as part of normal plant operations. The approval is sought under Condition 1.2 of the IPC licence 726 for an alteration to your facility that does not result in a material change in the nature or quantity of any emission. In reference to the above the Agency makes the following comment:

I am to advise you that the proposal submitted is to the satisfaction of the Agency.

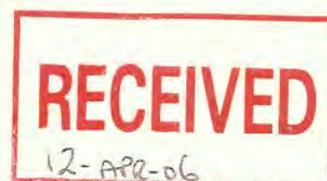
If you have any queries please contact Michael Owens at 021 4860815.

Please quote the above reference in any future correspondence in relation to this matter.

Yours sincerely



Michael Owens
Office of Environmental Enforcement



Mr. Michael Owens,
Office of Environmental Enforcement
Environmental Protection Agency
Regional Inspectorate
Inniscarra
Co Cork

August 31st, 2006

Subject: Reporting of Bypass Emissions

Dear Mr. Owens,

Arising from our discussions on August, 18th, I wish to make the following proposal with respect to the reporting of fume duct bypass events on site.

Using the IPPC Licensing Application Guidance note, we propose to use 20% of the TA Luft guidelines for Class I, II and III compounds factored up on a 24 hour basis as a guideline for assessing if the event is reportable to the Agency (Ref: Table 5.5 of the EPA Batneec Guidance Note for the Chemical Sector). On a daily basis therefore, the following limits would apply:

Class I	< 0.5 Kgs/day
Class II	< 10 Kgs/day
Class III	< 15 Kgs/day.

Emissions greater than the values outlined above would be reported to the Agency on the following working day. In order to assess the environmental significance of emissions, the actual emission value will be compared to the values input to the site air dispersion model. If the value exceeds the modelled data, then a further air dispersion model will be run and results will be compared to a recognised standard, namely the EAL. If the emission exceeds the standard, then the event will be considered significant.

I hope that this proposal is satisfactory to the Agency. Efforts will continue to on an ongoing basis to minimise the number of bypass events and the duct management procedure will continue to be implemented should a bypass occur.

Yours Sincerely,

Billy Sheehan
Senior Environmental Engineer

Mr Billy Sheehan
Eli Lilly S.A. - Irish Branch
Dunderrow
Kinsale
County Cork

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Environmental Protection Agency
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RECEIVED
18 SEP 2006

15th September 2006

Our Ref: P0009-03/ap08mo

Dear Mr Sheehan

I refer to your proposal dated 31/08/06 received by the Agency on 04/09/06, in relation to the assessment of significance of thermal abatement bypasses.

I am to advise you that the proposal submitted is to the satisfaction of the Agency. However, the following should be noted:

- Bypass emissions at a level greater than any of the limits proposed must be considered 'significant' and 'reportable'. Subsequent air dispersion modelling should be used to assess the impact of any significant emissions. The use of air dispersion modelling does not determine significance of the emission alone.
- In conjunction to the above, any single bypass event with a duration greater than one hour will continue to be reportable to the Agency on the day of the event as per Condition 11.1 of your IPPC Licence. It is accepted that this may not represent a significant emission, however, the Agency is satisfied that such events warrant notification.

This approach is to put into action from the 01/11/06. Until then, only single bypass events with a duration greater than one hour are required to be reported to the Agency.

Yours sincerely


Michael Owens
Office of Environmental Enforcement





Headquarters
P.O. Box 3000
Johnstown Castle Estate
County Wexford
Ireland

TECHNICAL AMENDMENT A
To
INTEGRATED POLLUTION PREVENTION &
CONTROL LICENCE

Licence Register Number:	P0009-03
Licensee:	Eli Lilly S.A. - Irish Branch
Location of Installation:	Dunderrow Kinsale County Cork

Reasons for the Decision

The Environmental Protection Agency is satisfied, on the basis of the information available, that subject to compliance with the conditions of licence Reg. No. P0009-03 granted on the 27/07/2005, as well as any amendments noted herein, any emissions from the activity will comply with and not contravene any of the requirements of Section 83(5) of the Environmental Protection Agency Acts, 1992 and 2003.

Technical Amendment

In pursuance of the powers conferred on it by Section 96(1)(c) of the Environmental Protection Agency Acts, 1992 and 2003, the Agency amends Licence Reg. No. P0009-03, granted to Eli Lilly S.A. - Irish Branch, Dunderrow, Kinsale, County Cork.

Henceforth, IPPC Licence Register No. P0009-03 shall be read in conjunction with the amendments set out below.

This technical amendment is limited to the following:-

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Amendments

Amend Condition 6

6.14 Test Programme

- 6.14.1 The licensee shall prepare, to the satisfaction of the Agency, a test programme for abatement equipment installed to heat treat biological waste water. This programme shall be submitted to the Agency in advance of implementation.
- 6.14.2 This programme, following agreement with the Agency, shall be completed within three months of the commencement of operation of the abatement equipment.
- 6.14.3 The criteria for the operation of the abatement equipment as determined by the test programme shall be incorporated into the standard operating procedures.
- 6.14.4 The test programme shall as a minimum:
- (i) Establish all criteria for operation, control and management of the abatement equipment to ensure compliance with the emission limit values specified in this licence.
 - (ii) Assess the performance of any monitors on the abatement system and establish a maintenance and calibration programme for each monitor.
- 6.14.5 A report on the test programme shall be submitted to the Agency within one month of completion.

To be inserted after Condition 6.13 of the existing licence.

Amend Schedule C

C.2.1 Control of Emissions to Water

Emission Point Reference No.: **6-1**

Description of Treatment: **Heat treatment of biological wastewater and Extended Aeration Biological Treatment Plant**

Control Parameter	Monitoring	Key Equipment ^{Note 1}
Input	Daily COD (Input)	Standard Methods
Flow	Continuous Flow (forward flow)	Flow Meter/Recorder
Neutralisation	Continuous pH (ex Correction Tank)	pH Meter/Recorder
Dissolved Oxygen (Aeration Basin)	Continuous	DO Meter/Recorder
Mixed Liquor	Mixed Liquor Suspended Solids Daily	Standard Methods
Sludge Volume	Sludge Volume Index Daily	Standard Methods
Sludge floc	Sludge floc microscopy 3 times/week	Standard Methods
Neutralisation	Continuous pH (Final adjustment sump)	pH Meter/Recorder
Heat treatment unit		
Temperature	Per batch	Steam plant

Note 1: The licensee shall maintain appropriate access to standby and/or spares to ensure the operation of the abatement system.

Amend Schedule C.2.1 Control of Emissions to Water of the existing licence as set out above.

This technical amendment shall be cited as Amendment A to IPPC licence Reg. No. P0009-03.

Sealed by the Seal of the Agency on this the 16th day of July, 2007

PRESENT when the seal of the Agency was affixed hereto

Dara Lynott, Director

Mr Billy Sheehan
Eli Lilly S.A. - Irish Branch
Dunderrow
Kinsale
County Cork

South/South West Region
Environmental Protection Agency
Regional Inspectorate, Inniscarra
County Cork, Ireland

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5th November 2007

Our Ref: P0009-03/ap10mor.doc

Dear Mr Sheehan

I refer to your letter dated 16th October 2007 received by the Agency in relation to phosphorous licence limits. The approval is sought under Condition 1.4 of the IPPC licence P0009-03 for an alteration to your facility as it results in a change in the nature or quantity of an emission to water.

I am to advise you that the letter submitted is to the satisfaction of the Agency contingent upon the following:-

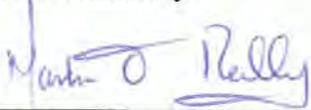
- The existing daily and hourly mass emissions limits of 300 Kg's and 12.5 Kg's P respectively are not exceeded.

The Agency reserves the right to reverse this approval at any time in the future should there be evidence that any pollution has taken place as a result of these emissions.

If you have any queries please contact Martin O' Reilly at 021-4875540.

Please quote the above reference in any future correspondence in relation to this matter.

Yours sincerely



Martin O' Reilly
Office of Environmental Enforcement

Appendix 5 - Form for the Notification of Site Changes (EPA)

Eli Lilly S.A. (Irish Branch), Dunderrow, Kinsale, Co. Cork, Ireland

Phone +353-21-477-2699
Fax: +353-21-477-5152

Position of person in charge: General Manager

Form for the notification to the Environmental Protection Agency of site changes

Reason for Notification

Material Change or Increase in

- nature or quantity of any emission
- abatement / treatment or recovery systems
- range of processes to be carried out
- fuels, raw materials, intermediates, products of wastes generated

Changes in site management infrastructure or control with adverse environmental significance

<input type="checkbox"/>
<input type="checkbox"/>
<input checked="" type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

(a) Description of change:

Application for a GMM licence for IE28, IE30.

(b) Description of impact of change:

Form Reviewed by: *Janette Walsh*

Date: *11-Feb-2008*

TL Process Safety & Environmental Compliance

New or Revised

Uncontrolled Copy

Date Printed: 11/02/2008 @ 14:05:22

If seven (7) or more days past print date, verify this is the current revision before using this procedure.

Suzanne Wylde
Office of Climate, Licensing & Resource Use,
EPA, PO Box 3000,
Johnstown Castle Estate
Wexford.

19th March, 2008

Subject: **Request for Further Information**

Dear Ms. Wylde,

The attached document outlines the additional information requested by the Agency on February 29th. The requested information refers to GMO Register No. 267. The document is marked confidential as it contains commercially sensitive information, specific to Eli Lilly SA (Irish Branch).

If any further clarification is required, please feel free to contact myself or Dr. Graham McCartney.

Yours sincerely,

Billy Sheehan

Senior Environmental Engineer

Encl(1)

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Reference: Register No: 267

- 1. Clarify if the two resulting GMMs that will be produced in IE28 and IE30 are the same. If different, please specify the differences. Is the recipient cell line the exact same in both IE28 and IE30? Do the vectors or inserts used in each case differ?**

The GMM consists of the GS-CHO cell line as well as the plasmid containing the gene encoding the therapeutic protein. Two similar GMM's will be handled in the IE28 laboratory facility (Glp-Fc and Teplizumab) and one of these will also be propagated in IE30 (Teplizumab). Both GMM's are the same with respect to the GS-CHO cell line which will produce the monoclonal antibody. The plasmid vector (pEE12.4 GS) that contains the gene of interest is also the same. This is stably integrated into the GS-CHO cell genome. However given that distinct antibodies will be produced from the final GMM (used to treat type 1 and 2 diabetes respectively) the sequence of DNA inserted into the expression plasmid is different for both. As outlined in the risk assessment, both GMM's do not pose a threat to human health or the environment.

- 2. Provide details of the insert(s) in the plasmid(s) –**

i) Specific identity and function of the insert (genes);

The genes inserted in the plasmid encode a monoclonal like therapeutic protein called Glp-Fc and an anti-CD3 monoclonal antibody respectively. Glp-Fc is a fusion protein containing the Fc portion of IgG₄ fused to a peptide called Glucagon Like Peptide 1 which stimulates insulin release from beta cells in the pancreas in a glucose dependent manner. Through this activity Glp-Fc will be used to treat type 2 diabetes. Glp-1 itself has a half life in blood of a matter of seconds. Through fusing it to the Fc portion of IgG₄ this half life is significantly extended.

The gene encoding anti-CD3, also called Teplizumab which will be propagated in IE28 on a laboratory scale and in IE 30 on a larger scale is a monoclonal antibody which will be used to treat type 1 diabetes. Teplizumab is aimed to target auto-immune T-lymphocytes which play a pivotal role in disease progression through destruction of pancreatic beta (insulin producing) cells.

ii) Level of expression of inserted genetic material;

The inserted material will be expressed at < 10g/L

iii) Source of the genetic material, identity of the donor organism(s) and characteristics where appropriate;

The genetic material was initially cloned into a murine NS0 hybridoma cell line prior to being stably subcloned into the GS-CHOK1SV cell line which results in greater expression and has a similar glycosylation pathway to human cells.

iv) History of prior genetic modifications if appropriate;

No genetic modifications have been made by Lilly.

v) Location of inserted genetic material.

Both inserts (Glp-Fc and Teplizumab) are randomly inserted via electroporation into the CHO cell genome upon cell line generation.

Mr Billy Sheehan
Eli Lilly S.A. - Irish Branch
Dunderrow
Kinsale
County Cork

South/South West Region
Environmental Protection Agency
Regional Inspectorate, Inniscarra
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24th June 2008

Our Ref: P0009-03/gc15mor.doc

Dear Mr Sheehan

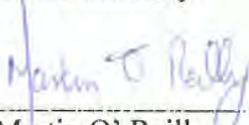
I refer to your correspondence of the 20/6/08 requesting permission to suspend the requirement for phenol monitoring at emission point 6-1. Based on the information submitted I am to advise you that the request is to the satisfaction of the Agency and phenol testing may be suspended or as requested by the Agency..

This approval is subject to the following:

- No phenolic by products are generated that contribute to emission point 6-1.
- The above agreement may be revoked at any time by the Agency.

Please quote the above reference in future correspondence in relation to this matter.

Yours sincerely



Martin O' Reilly
Office of Environmental Enforcement

RECEIVED

26 JUN 2008



Mr Billy Sheehan
Eli Lilly S.A. - Irish Branch
Dunderrow
Kinsale
County Cork

South/South West Region
Environmental Protection Agency
Regional Inspectorate, Inniscarra
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8th January 2009

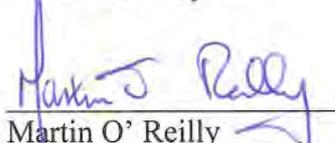
Our Ref: P0009-03 /gc21mor.doc

Dear Mr Sheehan

I refer to your correspondence dated 18/12/08 in relation to the operation of the SCR DENOX unit. Based on the information submitted I am to advise you that the request to operate without the SCR unit on line based on current production levels is to the satisfaction of the Agency. Please note that this approval may be revoked at any time by the Agency.

Please quote the above reference in future correspondence in relation to this matter.

Yours sincerely


Martin O' Reilly
Office of Environmental Enforcement

RECEIVED

10 JAN 2009



Suzanne Wylde
Office of Climate, Licensing & Resource Use,
EPA, PO Box 3000,
Johnstown Castle Estate
Wexford.

10th July, 2009

Subject: Notification of a First Time Use of Premises for Class 1 GMMs

Dear Ms. Wylde,

Please find enclosed a notification for the first time use of a new biopharmaceutical production facility, identified as IE42, at the Eli Lilly site in Dunderrow, Kinsale. This facility will be used to manufacture large scale quantities of Class 1 GMM's. It is anticipated that facility will be handed over to Lilly commissioning and validation staff in late 2009. The first production activity is expected to occur in late 2010. Register entry no: 267 was issued in April 2008 to cover our initial development and small scale production activities which are ongoing.

This application is based on the requirements set out in articles 16 and 17 of S.I. No. 73 (2001). A risk assessment is enclosed pertaining to the proposed activities. A cheque for €250 is enclosed as required in Schedule 8 of the S.I.

If any further clarification is required, please feel free to contact myself (021 4702242), Melanie Walsh (021 4706346) or Muiris MacPhaidin (021 4702287).

Yours sincerely,

Billy Sheehan

Senior Environmental Engineer

Encl(2)

Martin O'Reilly
Office of Environmental Enforcement
Environmental Protection Agency
Regional Inspectorate
Inniscarra
Co Cork

January 7th, 2010

Dear Mr. O'Reilly,

I refer to our telephone conversation in the week prior to Christmas where we discussed the possibility of making adjustments to the monitoring parameters for emission point 6-1, (emissions to water from the biological treatment plant). The parameters in question are Ammonia, Total Nitrogen and BOD. We would like to propose the following adjustments to the monitoring regime:

1. Ammonia from daily to weekly
2. Total Nitrogen from weekly to monthly
3. BOD from weekly to monthly
4. Sludge floc from 3 times per week to once a week.

The rationale is based on data showing that we are significantly under the concentration emission limits for all these parameters and have been for several years. Significant capital investment has been made in our waste treatment facilities leading to improvements in both operation and performance. In addition, there has been a reduction in the overall loading of the bio-treatment plant in recent years. This is due to the changing product profile and a move towards bio-tech processing which is almost totally aqueous based. The table below illustrates this trend for the past two years. This trend is expected to continue for the next several years. If there is any change in these trends due to introduction of new products or other significant changes, the Agency will be notified. In parallel, we also carry out extensive in process monitoring so any trends in any of the parameters will be highlighted at an early stage.

Timeframe: January 2008 to December 2009

Parameter	Average (mg/l)	Maximum (mg/l)	Limit (mg/l)
Ammonia	0.2	6	50
Total Nitrogen	5	18	100
BOD	4	40	600

We believe that these adjustments to the monitoring frequency will have no adverse effect on either effluent quality or compliance. We believe that the data provided demonstrates the level of control that exists within the treatment plant. I look forward to your response in due course.

Yours sincerely,

Billy Sheehan

Senior Environmental Engineer

Mr Billy Sheehan
Eli Lilly S.A. - Irish Branch
Dunderrow
Kinsale
County Cork

South/South West Region
Environmental Protection Agency
Regional Inspectorate, Inniscarra
County Cork, Ireland

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14th January 2010

Our Ref: P0009-03 /gc29mor.doc

Dear Mr Sheehan

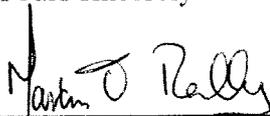
I refer to your correspondence, dated 7/1/2010, in relation to the monitoring frequency of certain parameters for emission point 6-1.

I am to advise you that your proposal to reduce the monitoring frequency for Ammonia, Total nitrogen and BOD has been approved under Condition 6.5 of your licence. Please note that this approval may be revoked at the discretion of the Agency.

It is considered that sludge floc is a critical parameter in the operation of the waste water treatment plant. As such the monitoring of this parameter shall be maintained at 3 times per week.

Please quote the above reference in future correspondence in relation to this matter.

Yours sincerely



Martin O' Reilly
Office of Environmental Enforcement

RECEIVED

19 JAN 2010



Mr Billy Sheehan
Eli Lilly S.A. - Irish Branch
Dunderrow
Kinsale
County Cork

Headquarters, PO Box 3000
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8th September, 2010

Reg No: **P0009-03**

Dear Mr Sheehan

I refer to your letter of 11th June, 2010 received by the Agency on 14th June, 2010 in respect of your existing licence.

The Agency has considered your request for a technical amendment to your existing licence, register no. P0009-03.

I am to advise that the Agency has amended your existing Licence Reg. No. P0009-03 under Section 96(1)(c) of the EPA Acts 1992 to 2007 to incorporate the changes as outlined in the attached "Technical Amendment B" document. The amendment shall be read in conjunction with and attached to your existing licence, Reg. No. P0009-01.

If you have any further queries please contact Marie O Connor at telephone no. 021-4875540

Yours sincerely,



Joe Reilly
Programme Officer
Office of Climate, Licensing & Resource Use

Encl.

Mr Billy Sheehan
Eli Lilly S.A. - Irish Branch
Dunderrow
Kinsale
County Cork

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LoCall: 1890 33 55 99

9th December 2010

Our Ref: P0009-03 /gc35mor.docx

Dear Mr Sheehan

I refer to your correspondence dated 1/12/2010, received by the Agency on 3/12/2010, in relation to the monitoring frequency of certain parameters for influent to the waste water treatment plant at your facility.

The contents of your letter have been noted and further to our phone conversation of the 30/11/2010, the Agency approves the proposal to reduce monitoring for COD, mixed liquor suspended solids and sludge volume index from daily to Monday to Friday inclusive. This approval has been granted under Condition 6.5 of your licence. Please note that the approval may be revoked at the discretion of the Agency should results indicate environmental pollution.

Please quote the above reference in future correspondence in relation to this matter.

Yours sincerely



Martin O'Reilly
Office of Environmental Enforcement



Mr Billy Sheehan
Eli Lilly S.A. - Irish Branch
Dunderrow
Kinsale
County Cork

South/South West Region
Environmental Protection Agency
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14th June 2011

Our Ref: P0009-03/gc38mor.docx

Dear Mr Sheehan

I refer to your letter dated 07/06/2011, received by the Agency on 09/06/2011 in relation to ambient monitoring and also monitoring of oxides of sulphur and nitrogen oxides on emission point 7-1(a).

The contents of your letter have been noted. In view of the discontinued use of HFO as a fuel the Agency approves the request to suspend ambient monitoring as per Condition 6.12.

As emission point 7-1(a) is now continuously monitored for oxides of sulphur and nitrogen oxides, your proposal to suspend bi annual tests for these parameters has been approved. This approval is being granted under Condition 6.5 of your licence.

Please quote the above reference in future correspondence in relation to this matter.

Yours sincerely



Martin O' Reilly
Office of Environmental Enforcement



Appendix 2

Marine Ecosystem Research Laboratory of the
Ryan Institute in the National University of
Ireland, Galway

Assessment of Near Field Dilution & Dispersion
Model of the Eli Lilly Outfall

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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).



Sandy Cove Island, Kinsale Harbour., Co. Cork

Submitted to Eli Lilly S.A., Dunderrow, Co. Cork, Ireland

by

Dr Robert Kennedy,
Marine Ecosystem Research Laboratory,
Zoology,
Ryan Institute,
School of Natural Sciences,
National University of Ireland, Galway,
Galway,
Ireland

31 May 2012

Executive Summary

This report describes a modelling study of the near field dilution and dispersion of the Eli Lilly treated wastewater emissions from its diffuser located east of Sandy Cove Island, Kinsale Harbour, Co. Cork. The modelling was performed to investigate whether the receiving surface water body would be compliant with EC Environmental Objectives (Surface Waters) Regulations (S.I. No. 272/2009) if the treated wastewater emissions load were discharged at the potential worst case limits permitted under the current IPPC License (P0009-03). These potential worst case limits are based on the calculated emissions loads that would result if each licensed parameter was discharged in the treated wastewaters at their respective licensed Emissions Limit concentrations and if these wastewaters were also discharged at the maximum total daily emission volume allowed by the license.

The Eli Lilly diffuser is located east of Sandy Cove Island, Kinsale, Co. Cork. It consists of twelve ports of 3.18cm diameter spaced at 3.12m centres. The ports are on risers 1m off bottom. Water depth at the site is 12m chart datum (a level that closely approximates the lowest astronomical tidal level).

Where available, water quality data from the EPA monitoring program was used to model the assimilative capacity of the water body. Eli Lilly has commissioned extensive environmental monitoring of the potential effects of the outfall on habitats in the area in a Harbour Study performed by the Ryan Institute, School of Natural Sciences, National University of Ireland, Galway (NUIG). This has included long term monitoring of water column nutrients, characterisation of local currents and physical oceanography, dilution studies using dye tracers and site suitability modelling for location outfall. The data gathered has been used to support the modelling in this study. Where no data were available, background concentrations were conservatively estimated at 10% of the Environmental Quality Standard (EQS) or at a level near the limit of detection, whichever was larger.

The Updated Merge (UM3) model from the United States Environmental Protection Agency (USEPA) program Visual Plumes to simulate the Eli Lilly discharge. Simulations were run using the maximum discharge rates and discharge concentrations for each substance allowed under the current license.

None of the emissions exceeded the relevant EQS at a distance of 100m from the diffuser. Most emission limits were an order of magnitude less than that needed to exceed the EQS.

Dissolved Inorganic Nitrogen (DIN) emission limits (assuming that all Total Nitrogen is discharged as DIN) are at 24.4% of the exceedence concentration. This is in part due to elevated background DIN originating from the Bandon Estuary. The Bandon Estuary has been classified as eutrophic because of high DIN levels.

The results of this modelling study indicate that the wastewater discharges up to and including maximum loads permitted by the current license will not adversely impact the Ecological Status or cause a breach of Environmental Quality Standards in the receiving water body.

Introduction

This report outlines near field dispersion modelling of the Eli Lilly outfall, Kinsale, Co. Cork in relation to the EC Environmental Objectives (Surface Waters) Regulations (S.I. No. 272/2009). The Surface Waters Regulations seek to maintain or improve the quality of surface waters by setting Environmental Quality Standards for these surface waters that must not be exceeded. As part of a review of Integrated Pollution Prevention and Control (IPPC) Licences, the EPA may require license holders discharging to coastal surface waters to model the dispersion of emissions in their effluents. This is to ensure that all authorisations under the EPA Act 1992 to 2007 and the Waste Management Acts 1996 to 2010 having discharges liable to cause water pollution are in compliance with the Surface Waters Regulations.

Methods

The Eli Lilly diffuser is located in coastal waters east of Sandy Cove Island, Kinsale, Co. Cork. Effluent travels 9 km from the Eli Lilly plant at Dunderrow, Co. Cork in a purpose built pipeline of approximately 25 cm diameter. It is discharged from a multiport subtidal diffuser in oceanic water outside Kinsale Harbour and south of Money Point, designated as the end of the Bandon Estuary by the EPA.

Two modelling approaches were used. The first employed a simple dispersion / dilution model developed by the Scottish Environmental Protection Agency (SEPA) for un-stratified coastal water bodies and lakes and published as guidance by the Irish EPA in 2011. It assumes that the effluent discharges from a single point, is fully mixed in the water column and disperses to form a triangular prism. The dilution is simply a function of the volume of the prism and the volume of the effluent. This model was largely used so that the UM3 model could be compared to an alternative approach, and to make the study comparable to other work.

The second approach used the three-dimensional Updated Merge (UM3) model from the United States Environmental Protection Agency (USEPA) program Visual Plumes to simulate the Eli Lilly discharge. UM3 is a model for simulating single and multi-port submerged discharges. It is a Lagrangian model that features the projected-area-entrainment (PAE) hypothesis (Winiarski and Frick, 1976; Frick, 1984). This established hypothesis (Rawn, Bowerman, and Brooks, 1960) quantifies forced entrainment, the rate at which mass is incorporated into the plume in the presence of current.

In UM3 it is assumed that the plume is in steady state; in the Lagrangian formulation this implies that successive elements follow the same trajectory (Baumgartner et al., 1994). The plume envelope remains invariant while elements moving through it change their shape and position with time. To make UM three-dimensional, the PAE forced entrainment hypothesis has been generalized to include an entrainment term corresponding to the third-dimension: a cross-current term. As a result, single-port plumes are simulated as truly three-dimensional entities. Merged plumes (as in this study) are simulated less rigorously by distributing the cross-current entrainment over all plumes.

While performing numerical simulation, UM3 runs an algorithm that controls the simulation time step to optimise performance. In addition to being controlled by the amount of entrainment, the time step is also sensitive to the amount of trajectory curvature.

The Eli Lilly diffuser was modelled using the following characteristics:

- Number of ports = 12
- Port diameter = 0.03176 metre (m) (1.25 inches)
- Port spacing = 4.116 m (13.5 feet)
- Port orientation = vertical (90°)
- Port distance above bottom = 1 m
- Diffuser orientation = perpendicular to ambient flow
- Distance from shore = 975.6 m (3200 feet)
- Effluent Temperature = 15°C
- Effluent Salinity = 0
- Maximum flow rate from Emission Point 6.1 = 3,000m³ d⁻¹, from Emission Point W2 = 1500m³ d⁻¹

Effluent concentration was simulated at the maximum emission limits (Appendix 1) for each substance. Time series monitoring data from the EPA monitoring program stations near to the diffuser were used to calculate the background concentrations for Total Nitrogen, Total Phosphorous (taken as being equivalent to Molybdate Reactive Phosphate; MRP), Ammonia and Dissolved Inorganic Nitrogen (DIN). These data were used in accordance to guidance issued by the EPA. Similar data were available from the NUIG monitoring program (O'Brien 2000; Kennedy 2005, 2006, 2007, 2012). The median value was used as the background concentration. In the case of DIN and MRP, the median winter concentration was used.

Chemical Oxygen Demand (COD) was estimated at 1 mg l⁻¹ as this is a low level, likely to reflect the ambient levels in coastal waters of Good ES.

For metals, the background level was estimated to be 10% of the Environmental Quality Standard (EQS) from S.I. No. 272 of 2009, or $1 \mu\text{g l}^{-1}$, whichever was the larger. Similarly, the background concentration for the combined emission of benzene, toluene and xylene was estimated as $1 \mu\text{g l}^{-1}$.

In the case of dioxins and furans, the background concentrations were estimated at low levels that approximate the limits of detection in seawater.

In the case of Total Nitrogen, the emission limit includes organic compounds, but the EQS has been set for inorganic compounds only: DIN in the case of nitrogen. Total Nitrogen emissions were modelled as being 100% DIN for the purposes of assessing potential exceedence of the EQS. Background data were available for both Total Organic Nitrogen (TON) and DIN (Appendix 3).

Total Phosphorous emissions were modelled as being 100% Molybdate Reactive Phosphorous (MRP). This was for two reasons: the only data available for the water body are MRP concentrations, and MRP is a potential nutrient in transitional, but not coastal waters.

Where an EQS has been established, the calculated concentrations at 100m from the diffuser were assessed to determine if it had exceeded the EQS. The percentage change from the background level was calculated. The emission concentration level necessary to exceed the EQS (Exceedance Concentration) was determined by numerical simulation. The ratio of the current emission limit to the Exceedance Concentration was expressed as a percentage.

The EQS chosen was the most conservative option in each case. Generally, the Annual Average (AA) EQS was used. The EQS for waters already achieving Good ES was used. The EPA has classified ES in Kinsale Harbour as Good (McGarrigle et al 2010). Toluene and xylene both have an AA EQS of $10 \mu\text{g l}^{-1}$, but the AA-EQS of benzene ($8 \mu\text{g l}^{-1}$) was used for the combined emission of all three substances.

Ambient currents were measured with an acoustic Doppler current profiler (ADCP) deployment (O'Connor, 2003). The average current speed and direction were used to model dispersion (17.5 cm s^{-1} , 178° West). Water depth was set to the level of the lowest astronomical tide (LAT), 12m for testing compliance with Surface Waters Regulations. The water column was considered to be not stratified for modelling purposes. Full model outputs are shown in Appendix 2.

Results

Model outputs are listed in Table 1. There was generally good agreement between the outputs from the SEPA model and the UM3 model. The UM3 model tends to report slightly higher concentrations in the plume at 100m from the diffuser than the SEPA model. This is because the Lilly plume is very buoyant because of its low salinity. UM3 models it as rising rapidly through the water column with less entrainment than the SEPA model.

Most of the emissions were predicted to produce concentrations at 100m that are an order of magnitude below the relevant EQS when being discharged at the emission limits. This was true for copper and zinc in both 6.1 and W2. It was also the case for benzene, toluene and xylene in 6.1.

Total Nitrogen, which has no EQS, increased by 15% relative to the background levels. Modelled DIN concentrations increased by 16%, and the maximum emission limits were 24.4% of the Exceedence Concentration.

Ammonia levels were increased by 59% relative to the background level. Similarly, Tin increased by 4000% from the nominal background level of $1\mu\text{g l}^{-1}$. Neither of these emissions has an EQS.

Dioxins and Furans increased only marginally in the model simulation.

Molybdate Reactive Phosphate concentrations were modelled using the conservative assumption that all Total-Phosphorous emissions would be in the form of MRP. Total-P / MRP increased by 189% on background levels. There is no EQS associated with Total-P or MRP in coastal waters.

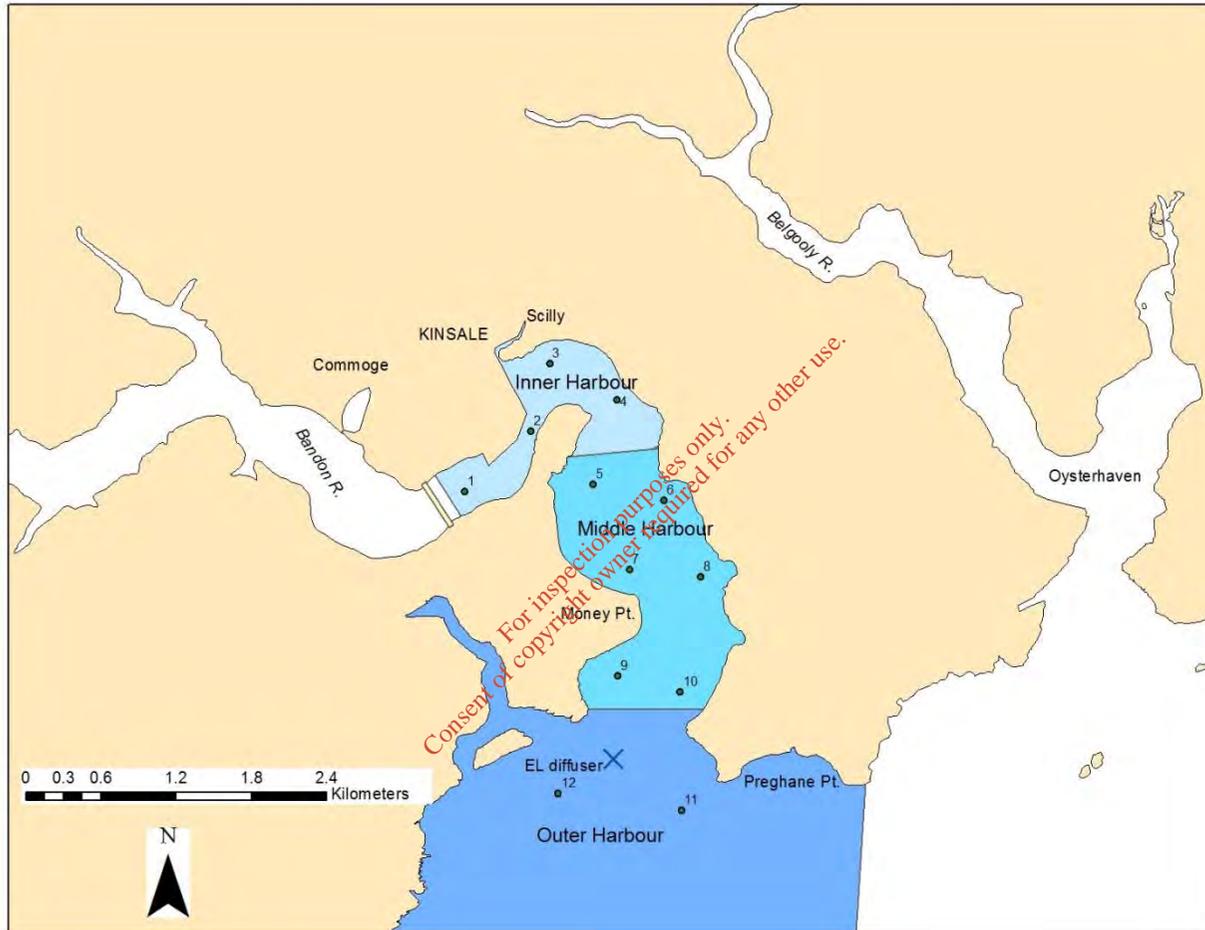


Figure 1: Map of Kinsale showing Eli Lilly diffuser location and the hydrographic stations monitored in the NUI, Galway study. The EPA designates Money Point as the end of the Bandon Estuary.

			SEPA model	UM model (LAT)		Compliance		C_100m (UM)	Change relative to background	Exceedance concentration	Emission Limit as % of Exceedance Conc.
	D	C_effluent	C_background	C_100m	C_100m	EQS	SW Regs	EQS			
6.1	mg/l		mg/l	mg/l	mg/l	mg/l				mg/l	
BOD	8572.8	600	3.100	3.170	3.280	n/a			6%		
COD	8572.8	1500	1.000	1.175	1.530	n/a			53%		
Total N	8572.8	100	0.326	0.338	0.357	n/a			15%		
Total P / MRP*	8572.8	100	0.021	0.033	0.060	n/a			183%		
DIN*	8572.8	100	0.200	0.212	0.232	0.350	pass	66%	16%	410	24.4%
NH4-N	8572.8	50	0.030	0.0358	0.0477	n/a			59%		
Tin	8572.8	100	0.001	0.0127	0.0410	n/a			4000%		
Copper	8572.8	0.5	0.001	0.0011	0.0012	0.0050	pass	23%	16%	10.5	4.8%
Zinc	8572.8	0.6	0.004	0.0041	0.0042	0.0400	pass	10%	4%	185	0.3%
Benzene, Xylene and Toluene	8572.8	0.1	0.001	0.0010	0.0010	0.0080	pass	13%	2%	17.9	0.6%
W.2	µg/l		µg/l	µg/l	µg/l	µg/l				µg/l	
Copper and its compounds	17145.6	500	1	1.0	1.1	5.0	pass	21%	7%	10,500	4.8%
Zinc and its compounds	17145.6	1500	4	4.1	4.2	40	pass	5%	5%	185,000	0.8%
Dioxins, Furans	17145.6	0.30	0.01	0.01	0.01	n/a			0.40%		

Table 1: Model outputs for contaminant concentrations 100m from Eli Lilly diffuser, Kinsale, Co. Cork. Maximum discharge volumes and emission limits were simulated for all substances. Outputs from two models are shown. SEPA is a simple diffusion model for surface waters. "UM model (LAT) C_100m" is the concentration at 100m calculated using an Updated Merge Lagrangian model of near field and far field dispersion, calculated using the water level of the lowest astronomical tide (LAT). EQS is the Environmental Quality Standard from S.I. No. 272 of 2009. C_100m (UM)/ EQS is the calculated concentration at 100m from the diffuser as a percentage of the EQS. "Change relative to background" is the percentage increase that the calculated C_100m represents relative to the background concentration. "Exceedance concentration" is the effluent emission concentration from the diffuser necessary for C_100m to exceed the EQS

Discussion

The Eli Lilly outfall has been very well characterised in the past. Monahan et al (1978, 1979) described the physical oceanography of Kinsale Harbour with a view to siting of the Lilly outfall. The area near the outfall is largely oceanic in character with salinity rarely dropping below 33. North of Money point the Bandon Estuary is partially mixed with horizontal and vertical gradients in salinity. The average flushing time of the entire harbour is less than one day (Mulyaert and Raine, 1999).

Cawley and Keegan (1999) used a combination of initial dilution estimates, residence time estimates and hydrodynamic modelling to assess the suitability of the Harbour as a site for an outfall location. They found that initial dilution was Good (the second best classification on a 5 point scale) and residence time was excellent (<5 days) in the area of the outfall. They combined these measures with biological diversity and sediment characteristics to classify the outfall location as Good in terms of suitability. Only a small area to the west of Easter point and east of the diffuser was classified as Excellent.

Monahan and Spillane (1980) and O'Connor (2003) both carried out dye studies to determine near field dilution factors, but on a different spatial scale to the present study. They both concentrate on finding the attenuation of released rhodamine dye fluorescence with distance from the diffuser on scales of hundreds of meters to several kilometres. Both studies characterise the site as highly dispersive with dilutions in the order of 10^4 (Monahan and Spillane, 1980) and 10^5 (O'Connor, 2003). Monahan and Spillane (1980) determined a minimum dilution at a buoy moored approximately 200m from the diffuser as 12,200. A run of UM3 to approximate their study using the conservative assumptions of this study produced a minimum dilution of 2,080 at 200m. This illustrates the conservative nature of this study. O'Connor (2003) released dye near the diffuser by pumping it from a small boat. Monahan and Spillane (1980) released dye from the wet well at the Lilly plant, which much more closely approximates the assumptions of the UM3 model.

In this study, none of the emissions exceeded the relevant EQS at a distance of 100m from the diffuser. Most emission limits were an order of magnitude less that needed to exceed the EQS. The dispersive nature of the diffuser location appears dilute the emissions very effectively.

The emission limit for DIN is at approximately 25% of the concentration necessary to exceed the EQS for Good status. The calculated concentration at 100m from the diffuser was 66% of the EQS. The actual increase in concentration over the background level is much lower at 15% for Total N and 16% for DIN. The background levels of DIN originate from the Bandon Estuary including potential inputs from Bandon town, Kinsale, agricultural and industrial sources in the Bandon catchment area.

Both the NUI, Galway / Eli Lilly (Appendix 4) and EPA (Appendix 3) monitoring programmes show that DIN levels increase in the more estuarine areas. The Upper and Lower Bandon Estuary were both classified as eutrophic in part because of DIN levels exceeding the EPA's Trophic Status Assessment Scheme (TSAS) criteria. There is no evidence from the results of this study that DIN inputs from the Eli Lilly diffuser, at the maximum emission limits, are likely to cause DIN levels to breach the Surface Water Regulations.

Molybdate Reactive Phosphate (MRP) levels in the plume calculated at 100m from the diffuser using the UM3 model were 0.060 mg/l. There is no EQS for MRP in coastal waters, but there is a possibility of transport of excess MRP to the transitional waters of the Lower Bandon Estuary. This is considered unlikely for the following reasons:

- UM3 simulation of the plume indicates that MRP levels will be below 0.040 mg/l (the transitional waters EQS applicable) within 270m from the diffuser. MRP concentrations are predicted to reach background levels within 340m. The diffuser is located 1250m from the Money Point, the southern boundary of the Lower Bandon Estuary.
- The average flow velocity at the diffuser is 178° west at 17.5 cm s⁻¹, away from Money Point.
- The calculated concentration at 100m from the SEPA model is 0.033 mg/l, which is below the EQS for the transitional waters. The UM3 model predicts the concentration in the plume, whereas the SEPA model predicts the concentration in the water body assuming total mixing and no density effects. The high concentration of MRP in the UM3 plume at 100m is limited to the plume and is a local effect caused by the large concentration and density differences between the effluent and the receiving water. The UM3 plume at that point has dimensions of 100m (Distance to diffuser) x 12m (Depth) x 54m (plume width), a volume much smaller than that of the available receiving waters.

Tin concentrations are calculated to be 40 times ambient concentration 100m from the diffuser. Inorganic tin is generally not toxic to vertebrates, invertebrates or macroalgae. There is no EQS for tin in coastal waters. Provided that the tin does not include organotins, this emission is very unlikely to act as a pollutant.

Conclusion

The results of this modelling study indicate that the wastewater discharges up to and including maximum loads permitted by the current license will not adversely impact the Ecological Status or cause a breach of Environmental Quality Standards in the receiving water body.

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Appendix 1: Emission limits in Eli Lilly Integrated Pollution Prevention and Control (IPPC) Licence No. –P0009-03

Emission Point Reference No.: 6-1
Name of Receiving Waters: Outer Kinsale Harbour
Location: East of Sandy Cove Island
Volume to be emitted: Maximum in any one day: 3,000 m³
 Maximum rate per hour: 125 m³

Parameter	Emission Limit Value
pH	6-9
Toxicity	10 TU
	mg/l
BOD	600
COD	1500
Suspended Solids	500
Total Nitrogen	100
Total Ammonia (as N)	50
Total Phosphorus (as P)	100
Tin	100
Copper	0.5
Zinc	0.6
Benzene Toluene and Xylene	0.1

Emission Point Reference No.: W2
Location: Wastewater from the cleaning of exhaust gases from incineration activities prior to mixing with other on-site effluent.
Volume to be emitted: Maximum in any one day: 1,500 m³

Parameter	Emission Limit Value	
	Expressed in mass concentrations for unfiltered samples	
	A	B
Totalsuspended solids as defined by Directive 91/271/EEC ^(Annex 1)	30mg/l	45mg/l
Copper and its compounds expressed as copper (Cu)	0.5 mg/l	
Zinc and its compounds expressed as zinc (Zn)	1.5 mg/l	
Dioxins/furans (TEQ) ^(Annex 2)	0.3ng/l	

Note 1: These emission limit values shall apply from 28th December 2005. None of the values shall exceed the emission limit values set out in column B, and, 80% until 1 January 2008 and 95% thereafter, of the values shall not exceed the emission limit values set out in column A.

Note 2: The emission limit value refers to the total concentration of dioxins and furans calculated using the concept of toxic equivalence in accordance with Annex I of Directive 2000/76/EC.

Appendix 2: UM3 Model Outputs for emissions from the Lilly diffuser, east of Sandy Cove, Kinsale, Co. Cork.

Chemical Oxygen Demand, Lowest Astronomical Tide

/ UM3. 06/05/2012 11:15:46

Case 1; ambient file C:\Plumes\LillyOutfallPlumesResults\LillyOutfall030512_1.001.db; Diffuser table record 1: -----

Ambient Table:

Depth	Amb-cur	Amb-dir	Amb-sal	Amb-tem	Amb-pol	Decay	Far-spnd	Far-dir	Disprsn	Density
m	m/s	deg	psu	C	kg/kg	s-1	m/s	deg	m0.67/s2	sigma-T
0.0	0.175	178.0	35.0	10.0	1.0000E-6	0.0	0.175	178.0	0.0005	26.97
12.0	0.175	178.0	35.0	10.0	1.0000E-6	0.0	0.175	178.0	0.0005	26.97

Diffuser table:

P-dia	P-elev	V-angle	H-angle	Ports	Spacing	AcuteMZ	ChrncMZ	P-depth	Ttl-flo	Eff-sal	Temp	Polutnt
(m)	(m)	(deg)	(deg)	()	(m)	(m)	(m)	(m)	(MLD)	(psu)	(C)	(kg/kg)
0.03176	1.0	90.0	0.0	12.0	3.1167	100.0	1000.0	11.0	3.0	0.0	15.0	1.50E-3

Simulation:

Froude number: 39.23; effleunt density (sigma-T) -0.836; effleunt velocity 3.652(m/s);

Step	Depth	Amb-cur	P-dia	Polutnt	Dilutn	x-posn	y-posn	Build-up
	(m)	(m/s)	(m)	(kg/kg)	()	(m)	(m)	()
0	11.0	0.175	0.0318	0.0015	1.0	0.0	0.0	0.0;
100	10.6	0.175	0.218	0.000208	7.075	-0.0534	0.00187	0.0;
200	9.872	0.175	0.981	2.956E-5	51.09	-0.729	0.0254	0.0;
300	8.468	0.175	2.768	4.942E-6	370.0	-5.97	0.208	0.0;
312	8.19	0.175	3.121	4.108E-6	469.2	-7.459	0.26	0.0; merging;
387	3.805	0.175	10.82	1.704E-6	2071.8	-34.95	1.221	0.0; matched energy radial vel = 0.126m/s;
400	2.142	0.175	13.91	1.544E-6	2680.1	-45.73	1.597	0.0;
401	1.995	0.175	14.18	1.533E-6	2733.7	-46.69	1.63	0.0; surface;

Const Eddy Diffusivity. Farfield dispersion based on wastefield width of 48.45 m

conc	dilutn	width	distnce	time			
(kg/kg)		(m)	(m)	(hrs)	(kg/kg)	(s-1)	(m/s)(m0.67/s2)
1.52E-6	2741.7	48.85	50.0	0.00521	1.00E-6	0.0	0.175 5.00E-4
1.53E-6	2737.2	50.08	60.0	0.0211	1.00E-6	0.0	0.175 5.00E-4
1.53E-6	2735.8	51.27	70.0	0.037	1.00E-6	0.0	0.175 5.00E-4
1.53E-6	2735.1	52.44	80.0	0.0528	1.00E-6	0.0	0.175 5.00E-4
1.53E-6	2735.2	53.58	90.0	0.0687	1.00E-6	0.0	0.175 5.00E-4
1.53E-6	2736.7	54.7	100.0	0.0846	1.00E-6	0.0	0.175 5.00E-4

Biochemical Oxygen Demand, Lowest Astronomical Tide

/ UM3. 06/05/2012 11:10:34

Case 1; ambient file C:\Plumes\LillyOutfallPlumesResults\LillyOutfall030512_1.002.db; Diffuser table record 1: -----

Ambient Table:

Depth	Amb-cur	Amb-dir	Amb-sal	Amb-tem	Amb-pol	Decay	Far-spd	Far-dir	Disprsn	Density
m	m/s	deg	psu	C	kg/kg	s-1	m/s	deg	m0.67/s2	sigma-T
0.0	0.175	178.0	35.0	10.0	3.1000E-6	0.0	0.175	178.0	0.0005	26.97
12.0	0.175	178.0	35.0	10.0	3.1000E-6	0.0	0.175	178.0	0.0005	26.97

Diffuser table:

P-dia	P-elev	V-angle	H-angle	Ports	Spacing	AcuteMZ	ChrncMZ	P-depth	Ttl-flo	Eff-sal	Temp	Polutnt
(m)	(m)	(deg)	(deg)	()	(m)	(m)	(m)	(m)	(MLD)	(psu)	(C)	(kg/kg)
0.03176	1.0	90.0	0.0	12.0	3.1167	100.0	1000.0	11.0	3.0	0.0	15.0	6.00E-4

Simulation:

Froude number: 39.23; effleunt density (sigma-T) -0.836; effleunt velocity 3.652(m/s);

Step	Depth	Amb-cur	P-dia	Polutnt	Dilutn	x-posn	y-posn	Build-up
(m)	(m)	(m/s)	(m)	(kg/kg)	()	(m)	(m)	()
0	11.0	0.175	0.0318	0.0006	1.0	0.0	0.0	0.0;
100	10.6	0.175	0.218	8.549E-5	7.075	-0.0534	0.00187	0.0;
200	9.872	0.175	0.981	1.447E-5	51.09	-0.729	0.0254	0.0;
300	8.468	0.175	2.768	4.670E-6	370.0	-5.97	0.208	0.0;
312	8.19	0.175	3.121	4.338E-6	469.2	-7.459	0.26	0.0; merging;
387	3.805	0.175	10.82	3.380E-6	2071.8	-34.95	1.221	0.0; matched energy radial vel = 0.126m/s;
400	2.142	0.175	13.91	3.317E-6	2680.1	-45.73	1.597	0.0;
409	0.713	0.175	16.58	3.281E-6	3203.0	-55.03	1.922	0.0; surface;

Const Eddy Diffusivity. Farfield dispersion based on wastefield width of 50.84 m

conc	dilutn	width	distnce	time			
(kg/kg)	(m)	(m)	(m)	(hrs)	(kg/kg)	(s-1)	(m/s)(m0.67/s2)
3.27E-6	3210.8	51.46	60.0	0.00784	3.10E-6	0.0	0.175 5.00E-4
3.28E-6	3206.8	52.7	70.0	0.0237	3.10E-6	0.0	0.175 5.00E-4
3.28E-6	3205.3	53.91	80.0	0.0396	3.10E-6	0.0	0.175 5.00E-4
3.28E-6	3204.6	55.1	90.0	0.0555	3.10E-6	0.0	0.175 5.00E-4
3.28E-6	3204.7	56.26	100.0	0.0713	3.10E-6	0.0	0.175 5.00E-4

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Total Nitrogen, Lowest Astronomical Tide

/ UM3. 06/05/2012 11:18:13

Case 1; ambient file C:\Plumes\LillyOutfallPlumesResults\LillyOutfall1030512_1.001.db; Diffuser table record 1: -----

Ambient Table:

Depth	Amb-cur	Amb-dir	Amb-sal	Amb-tem	Amb-pol	Decay	Far-spd	Far-dir	Disprsn	Density
m	m/s	deg	psu	C	kg/kg	s-1	m/s	deg	m0.67/s2	sigma-T
0.0	0.175	178.0	35.0	10.0	3.2600E-7	0.0	0.175	178.0	0.0005	26.97
12.0	0.175	178.0	35.0	10.0	3.2600E-7	0.0	0.175	178.0	0.0005	26.97

Diffuser table:

P-dia	P-elev	V-angle	H-angle	Ports	Spacing	AcuteMZ	ChrncMZ	P-depth	Ttl-flo	Eff-sal	Temp	Polutnt
(m)	(m)	(deg)	(deg)	()	(m)	(m)	(m)	(m)	(MLD)	(psu)	(C)	(kg/kg)
0.03176	1.0	90.0	0.0	12.0	3.1167	100.0	1000.0	11.0	3.0	0.0	15.0	1.00E-4

Simulation:

Froude number: 39.23; effleunt density (sigma-T) -0.836; effleunt velocity 3.652(m/s);

Step	Depth	Amb-cur	P-dia	Polutnt	Dilutn	x-posn	y-posn	Build-up
	(m)	(m/s)	(m)	(kg/kg)	()	(m)	(m)	()
0	11.0	0.175	0.0318	0.0001	1.0	0.0	0.0	0.0;
100	10.6	0.175	0.218	1.408E-5	7.075	-0.0534	0.00187	0.0;
200	9.872	0.175	0.981	2.225E-6	51.09	-0.729	0.0254	0.0;
300	8.468	0.175	2.768	5.881E-7	370.0	-5.97	0.208	0.0;
312	8.19	0.175	3.121	5.327E-7	469.2	-7.459	0.26	0.0; merging;
387	3.805	0.175	10.82	3.728E-7	2071.8	-34.95	1.221	0.0; matched energy radial vel = 0.126m/s;
400	2.142	0.175	13.91	3.622E-7	2680.1	-45.73	1.597	0.0;
407	1.053	0.175	15.94	3.575E-7	3078.6	-52.82	1.844	0.0; surface;

Const Eddy Diffusivity. Farfield dispersion based on wastefield width of 50.20 m

conc	dilutn	width	distnce	time
(kg/kg)		(m)	(m)	(hrs)
3.57E-7	3084.7	51.1	60.0	0.0114
3.57E-7	3081.9	52.33	70.0	0.0272
3.57E-7	3080.7	53.53	80.0	0.0431
3.57E-7	3080.1	54.7	90.0	0.059
3.57E-7	3080.5	55.85	100.0	0.0748

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Dissolved Inorganic Nitrogen, Lowest Astronomical Tide

/ UM3. 06/05/2012 11:26:25

Case 1; ambient file C:\Plumes\LillyOutfallPlumesResults\LillyOutfall1030512_1.001.db; Diffuser table record 1: -----

Ambient Table:

Depth	Amb-cur	Amb-dir	Amb-sal	Amb-tem	Amb-pol	Decay	Far-spd	Far-dir	Disprsn	Density
m	m/s	deg	psu	C	kg/kg	s-1	m/s	deg	m0.67/s2	sigma-T
0.0	0.175	178.0	35.0	10.0	2.0000E-7	0.0	0.175	178.0	0.0005	26.97
12.0	0.175	178.0	35.0	10.0	2.0000E-7	0.0	0.175	178.0	0.0005	26.97

Diffuser table:

P-dia	P-elev	V-angle	H-angle	Ports	Spacing	AcuteMZ	ChrcMZ	P-depth	Ttl-flo	Eff-sal	Temp	Polutnt
(m)	(m)	(deg)	(deg)	()	(m)	(m)	(m)	(m)	(MLD)	(psu)	(C)	(kg/kg)
0.03176	1.0	90.0	0.0	12.0	3.1167	100.0	1000.0	11.0	3.0	0.0	15.0	1.00E-4

Simulation:

Froude number: 39.23; effleunt density (sigma-T) -0.836; effleunt velocity 3.652(m/s);

Step	Depth	Amb-cur	P-dia	Polutnt	Dilutn	x-posn	y-posn	Build-up
	(m)	(m/s)	(m)	(kg/kg)	()	(m)	(m)	()
0	11.0	0.175	0.0318	0.0001	1.0	0.0	0.0	0.0;
100	10.6	0.175	0.218	1.397E-5	7.075	-0.0534	0.00187	0.0;
200	9.872	0.175	0.981	2.101E-6	51.09	-0.729	0.0254	0.0;
300	8.468	0.175	2.768	4.625E-7	370.0	-5.97	0.208	0.0;
312	8.19	0.175	3.121	4.070E-7	469.2	-7.459	0.26	0.0; merging;
387	3.805	0.175	10.82	2.469E-7	2071.8	-34.95	1.221	0.0; matched energy radial vel = 0.126m/s;
400	2.142	0.175	13.91	2.362E-7	2680.1	-45.73	1.597	0.0;
406	1.218	0.175	15.63	2.322E-7	3018.2	-51.74	1.807	0.0; surface;

Const Eddy Diffusivity. Farfield dispersion based on wastefield width of 49.90 m

conc	dilutn	width	distnce	time
(kg/kg)		(m)	(m)	(hrs)
2.32E-7	3023.7	50.92	60.0	0.0131
2.32E-7	3021.2	52.15	70.0	0.0289
2.32E-7	3020.2	53.34	80.0	0.0448
2.32E-7	3019.7	54.51	90.0	0.0607
2.32E-7	3020.3	55.65	100.0	0.0765

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Total Phosphorous / Molybdate Reactive Phosphate, Lowest Astronomical Tide

/ UM3. 06/05/2012 17:04:19

Case 1; ambient file C:\Plumes\LillyOutfallPlumesResults\LillyOutfall030512_1.001.db; Diffuser table record 1: -----

Ambient Table:

Depth	Amb-cur	Amb-dir	Amb-sal	Amb-tem	Amb-pol	Decay	Far-spd	Far-dir	Disprsn	Density
m	m/s	deg	psu	C	kg/kg	s-1	m/s	deg	m0.67/s2	sigma-T
0.0	0.175	178.0	35.0	10.0	2.1000E-8	0.0	0.175	178.0	0.0005	26.97
12.0	0.175	178.0	35.0	10.0	2.1000E-8	0.0	0.175	178.0	0.0005	26.97

Diffuser table:

P-dia	P-elev	V-angle	H-angle	Ports	Spacing	AcuteMZ	ChrncMZ	P-depth	Ttl-flo	Eff-sal	Temp	Polutnt
(m)	(m)	(deg)	(deg)	()	(m)	(m)	(m)	(m)	(MLD)	(psu)	(C)	(ppm)
0.03176	1.0	90.0	0.0	12.0	3.1167	100.0	1000.0	11.0	3.0	0.0	15.0	100.0

Simulation:

Froude number: 39.23; effleunt density (sigma-T) -0.836; effleunt velocity 3.652(m/s);

Step	Depth	Amb-cur	P-dia	Polutnt	Dilutn	x-posn	y-posn	Build-up
	(m)	(m/s)	(m)	(ppm)	()	(m)	(m)	()
0	11.0	0.175	0.0318	100.0	1.0	0.0	0.0	0.0;
100	10.6	0.175	0.218	13.82	7.075	-0.0534	0.00187	0.0;
200	9.872	0.175	0.981	1.926	51.09	-0.729	0.0254	0.0;
300	8.468	0.175	2.768	0.284	370.0	-5.97	0.208	0.0;
312	8.19	0.175	3.121	0.228	469.2	-7.459	0.26	0.0; merging;
387	3.805	0.175	10.82	0.068	2071.8	-34.95	1.221	0.0; matched energy radial vel = 0.126m/s;
397	2.564	0.175	13.12	0.0595	2525.5	-42.99	1.501	0.0; surface;

Const Eddy Diffusivity. Farfield dispersion based on wastefield width of 47.39 m

conc	dilutn	width	distnce	time				
(ppm)	(m)	(m)	(hrs)	(ppm)	(s-1)	(m/s)	(m0.67/s2)	()
5.94E-2	2530.5	48.24	50.0	0.0111	0.021	0.0	0.175 5.00E-4	
5.95E-2	2528.1	49.45	60.0	0.027	0.021	0.0	0.175 5.00E-4	
5.95E-2	2527.2	50.62	70.0	0.0428	0.021	0.0	0.175 5.00E-4	
5.95E-2	2526.8	51.77	80.0	0.0587	0.021	0.0	0.175 5.00E-4	
5.95E-2	2527.3	52.89	90.0	0.0746	0.021	0.0	0.175 5.00E-4	
5.94E-2	2529.6	53.99	100.0	0.0904	0.021	0.0	0.175 5.00E-4	
5.92E-2	2534.3	55.07	110.0	0.106	0.021	0.0	0.175 5.00E-4	
5.90E-2	2541.9	56.13	120.0	0.122	0.021	0.0	0.175 5.00E-4	
5.86E-2	2552.0	57.17	130.0	0.138	0.021	0.0	0.175 5.00E-4	
5.81E-2	2564.4	58.19	140.0	0.154	0.021	0.0	0.175 5.00E-4	
5.75E-2	2579.0	59.19	150.0	0.17	0.021	0.0	0.175 5.00E-4	
5.68E-2	2595.5	60.17	160.0	0.186	0.021	0.0	0.175 5.00E-4	
5.59E-2	2613.5	61.14	170.0	0.202	0.021	0.0	0.175 5.00E-4	
5.49E-2	2633.4	62.1	180.0	0.217	0.021	0.0	0.175 5.00E-4	
5.38E-2	2654.1	63.04	190.0	0.233	0.021	0.0	0.175 5.00E-4	
5.25E-2	2675.9	63.96	200.0	0.249	0.021	0.0	0.175 5.00E-4	
5.11E-2	2698.2	64.87	210.0	0.265	0.021	0.0	0.175 5.00E-4	
4.95E-2	2721.5	65.77	220.0	0.281	0.021	0.0	0.175 5.00E-4	
4.78E-2	2745.4	66.66	230.0	0.297	0.021	0.0	0.175 5.00E-4	
4.60E-2	2769.6	67.54	240.0	0.313	0.021	0.0	0.175 5.00E-4	
4.40E-2	2794.3	68.4	250.0	0.329	0.021	0.0	0.175 5.00E-4	
4.19E-2	2819.4	69.26	260.0	0.344	0.021	0.0	0.175 5.00E-4	
3.97E-2	2844.5	70.1	270.0	0.36	0.021	0.0	0.175 5.00E-4	
3.73E-2	2869.9	70.94	280.0	0.376	0.021	0.0	0.175 5.00E-4	

3.48E-2	2895.5	71.76	290.0	0.392	0.021	0.0	0.175	5.00E-4
3.21E-2	2921.2	72.57	300.0	0.408	0.021	0.0	0.175	5.00E-4
2.93E-2	2946.9	73.38	310.0	0.424	0.021	0.0	0.175	5.00E-4
2.63E-2	2972.6	74.18	320.0	0.44	0.021	0.0	0.175	5.00E-4
2.32E-2	2998.3	74.96	330.0	0.456	0.021	0.0	0.175	5.00E-4

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Total Ammonia, Lowest Astronomical Tide

/ UM3. 06/05/2012 11:31:55

Case 1; ambient file C:\Plumes\LillyOutfallPlumesResults\LillyOutfall030512_1.001.db; Diffuser table record 1: -----

Ambient Table:

Depth	Amb-cur	Amb-dir	Amb-sal	Amb-tem	Amb-pol	Decay	Far-spd	Far-dir	Disprsn	Density
m	m/s	deg	psu	C	kg/kg	s-1	m/s	deg	m0.67/s2	sigma-T
0.0	0.175	178.0	35.0	10.0	3.0000E-8	0.0	0.175	178.0	0.0005	26.97
12.0	0.175	178.0	35.0	10.0	3.0000E-8	0.0	0.175	178.0	0.0005	26.97

Diffuser table:

P-dia	P-elev	V-angle	H-angle	Ports	Spacing	AcuteMZ	ChrncMZ	P-depth	Ttl-flo	Eff-sal	Temp	Polutnt
(m)	(m)	(deg)	(deg)	()	(m)	(m)	(m)	(m)	(MLD)	(psu)	(C)	(kg/kg)
0.03176	1.0	90.0	0.0	12.0	3.1167	100.0	1000.0	11.0	3.0	0.0	15.0	5.00E-5

Simulation:

Froude number: 39.23; effleunt density (sigma-T) -0.836; effleunt velocity 3.652(m/s);

Step	Depth	Amb-cur	P-dia	Polutnt	Dilutn	x-posn	y-posn	Build-up
	(m)	(m/s)	(m)	(kg/kg)	()	(m)	(m)	()
0	11.0	0.175	0.0318	5.000E-5	1.0	0.0	0.0	0.0;
100	10.6	0.175	0.218	6.928E-6	7.075	-0.0534	0.00187	0.0;
200	9.872	0.175	0.981	9.821E-7	51.09	-0.729	0.0254	0.0;
300	8.468	0.175	2.768	1.614E-7	370.0	-5.97	0.208	0.0;
312	8.19	0.175	3.121	1.336E-7	469.2	-7.459	0.26	0.0; merging;
387	3.805	0.175	10.82	5.347E-8	2071.8	-34.95	1.221	0.0; matched energy radial vel = 0.126m/s;
400	2.142	0.175	13.91	4.814E-8	2680.1	-45.73	1.597	0.0;
401	1.995	0.175	14.18	4.778E-8	2733.7	-46.69	1.63	0.0; surface;

Const Eddy Diffusivity. Farfield dispersion based on wastefield width of 48.45 m

conc	dilutn	width	distnce	time				
(kg/kg)		(m)	(m)	(hrs)	(kg/kg)	(s-1)	(m/s)	(m0.67/s2)
4.76E-8	2741.7	48.85	50.0	0.00521	3.00E-8	0.0	0.175	5.00E-4
4.77E-8	2737.2	50.08	60.0	0.0211	3.00E-8	0.0	0.175	5.00E-4
4.78E-8	2735.8	51.27	70.0	0.037	3.00E-8	0.0	0.175	5.00E-4
4.78E-8	2735.1	52.44	80.0	0.0528	3.00E-8	0.0	0.175	5.00E-4
4.78E-8	2735.2	53.58	90.0	0.0687	3.00E-8	0.0	0.175	5.00E-4
4.77E-8	2736.7	54.7	100.0	0.0846	3.00E-8	0.0	0.175	5.00E-4

Tin, Lowest Astronomical Tide

/ UM3. 06/05/2012 11:36:07

Case 1; ambient file C:\Plumes\LillyOutfallPlumesResults\LillyOutfall030512_1.001.db; Diffuser table record 1: -----

Ambient Table:

Depth	Amb-cur	Amb-dir	Amb-sal	Amb-tem	Amb-pol	Decay	Far-spd	Far-dir	Disprsn	Density
m	m/s	deg	psu	C	kg/kg	s-1	m/s	deg	m0.67/s2	sigma-T
0.0	0.175	178.0	35.0	10.0	1.0000E-9	0.0	0.175	178.0	0.0005	26.97
12.0	0.175	178.0	35.0	10.0	1.0000E-9	0.0	0.175	178.0	0.0005	26.97

Diffuser table:

P-dia	P-elev	V-angle	H-angle	Ports	Spacing	AcuteMZ	ChrncMZ	P-depth	Ttl-flo	Eff-sal	Temp	Polutnt
(m)	(m)	(deg)	(deg)	()	(m)	(m)	(m)	(m)	(MLD)	(psu)	(C)	(kg/kg)
0.03176	1.0	90.0	0.0	12.0	3.1167	100.0	1000.0	11.0	3.0	0.0	15.0	1.00E-4

Simulation:

Froude number: 39.23; effleunt density (sigma-T) -0.836; effleunt velocity 3.652(m/s);

Step	Depth	Amb-cur	P-dia	Polutnt	Dilutn	x-posn	y-posn	Build-up
(m)	(m)	(m/s)	(m)	(kg/kg)	()	(m)	(m)	()
0	11.0	0.175	0.0318	0.0001	1.0	0.0	0.0	0.0;
100	10.6	0.175	0.218	1.380E-5	7.075	-0.0534	0.00187	0.0;
200	9.872	0.175	0.981	1.906E-6	51.09	-0.729	0.0254	0.0;
300	8.468	0.175	2.768	2.640E-7	370.0	-5.97	0.208	0.0;
312	8.19	0.175	3.121	2.084E-7	469.2	-7.459	0.26	0.0; merging;
387	3.805	0.175	10.82	4.796E-8	2071.8	-34.95	1.221	0.0; matched energy radial vel = 0.126m/s;
395	2.832	0.175	12.62	4.108E-8	2427.4	-41.25	1.441	0.0; surface;

Const Eddy Diffusivity. Farfield dispersion based on wastefield width of 46.89 m

conc	dilutn	width	distnce	time
(kg/kg)	(m)	(m)	(m)	(hrs)
4.10E-8	2431.6	47.95	50.0	0.0138
4.10E-8	2429.7	49.15	60.0	0.0297
4.11E-8	2428.9	50.31	70.0	0.0456
4.11E-8	2428.6	51.45	80.0	0.0615
4.10E-8	2429.5	52.57	90.0	0.0773
4.10E-8	2432.2	53.66	100.0	0.0932

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Copper 6.1 at Lowest Astronomical Tide

/ UM3. 06/05/2012 11:37:38

Case 1; ambient file C:\Plumes\LillyOutfallPlumesResults\LillyOutfall030512_1.001.db; Diffuser table record 1: -----

Ambient Table:

Depth	Amb-cur	Amb-dir	Amb-sal	Amb-tem	Amb-pol	Decay	Far-spd	Far-dir	Disprsn	Density
m	m/s	deg	psu	C	kg/kg	s-1	m/s	deg	m0.67/s2	sigma-T
0.0	0.175	178.0	35.0	10.0	1.0000E-9	0.0	0.175	178.0	0.0005	26.97
12.0	0.175	178.0	35.0	10.0	1.0000E-9	0.0	0.175	178.0	0.0005	26.97

Diffuser table:

P-dia	P-elev	V-angle	H-angle	Ports	Spacing	AcuteMZ	ChrcMZ	P-depth	Ttl-flo	Eff-sal	Temp	Polutnt
(m)	(m)	(deg)	(deg)	()	(m)	(m)	(m)	(m)	(MLD)	(psu)	(C)	(kg/kg)
0.03176	1.0	90.0	0.0	12.0	3.1167	100.0	1000.0	11.0	3.0	0.0	15.0	5.00E-7

Simulation:

Froude number: 39.23; effleunt density (sigma-T) -0.836; effleunt velocity 3.652(m/s);

Step	Depth	Amb-cur	P-dia	Polutnt	Dilutn	x-posn	y-posn	Build-up
	(m)	(m/s)	(m)	(kg/kg)	()	(m)	(m)	()
0	11.0	0.175	0.0318	5.000E-7	1.0	0.0	0.0	0.0;
100	10.6	0.175	0.218	6.988E-8	7.075	-0.0534	0.00187	0.0;
200	9.872	0.175	0.981	1.050E-8	51.09	-0.729	0.0254	0.0;
300	8.468	0.175	2.768	2.312E-9	370.0	-5.97	0.208	0.0;
312	8.19	0.175	3.121	2.035E-9	469.2	-7.459	0.26	0.0; merging;
387	3.805	0.175	10.82	1.234E-9	2071.8	-34.95	1.221	0.0; matched energy radial vel = 0.126m/s;
400	2.142	0.175	13.91	1.181E-9	2680.1	-45.73	1.597	0.0;
406	1.218	0.175	15.63	1.160E-9	3018.2	-51.74	1.807	0.0; surface;

Const Eddy Diffusivity. Farfield dispersion based on wastefield width of 49.90 m

conc	dilutn	width	distnce	time				
(kg/kg)		(m)	(m)	(hrs)	(kg/kg)	(s-1)	(m/s)	(m0.67/s2)
1.15E-9	3023.7	50.92	60.0	0.0131	1.00E-9	0.0	0.175	5.00E-4
1.16E-9	3021.2	52.15	70.0	0.0289	1.00E-9	0.0	0.175	5.00E-4
1.16E-9	3020.2	53.34	80.0	0.0448	1.00E-9	0.0	0.175	5.00E-4
1.16E-9	3019.7	54.51	90.0	0.0607	1.00E-9	0.0	0.175	5.00E-4
1.16E-9	3020.3	55.65	100.0	0.0765	1.00E-9	0.0	0.175	5.00E-4

Zinc, Lowest Astronomical Tide

/ UM3. 06/05/2012 11:40:52

Case 1; ambient file C:\Plumes\LillyOutfallPlumesResults\LillyOutfall030512_1.001.db; Diffuser table record 1: -----

Ambient Table:

Depth	Amb-cur	Amb-dir	Amb-sal	Amb-tem	Amb-pol	Decay	Far-spd	Far-dir	Disprsn	Density
m	m/s	deg	psu	C	kg/kg	s-1	m/s	deg	m0.67/s2	sigma-T
0.0	0.175	178.0	35.0	10.0	4.0000E-9	0.0	0.175	178.0	0.0005	26.97
12.0	0.175	178.0	35.0	10.0	4.0000E-9	0.0	0.175	178.0	0.0005	26.97

Diffuser table:

P-dia	P-elev	V-angle	H-angle	Ports	Spacing	AcuteMZ	ChrcMZ	P-depth	Ttl-flo	Eff-sal	Temp	Polutnt
(m)	(m)	(deg)	(deg)	()	(m)	(m)	(m)	(m)	(MLD)	(psu)	(C)	(kg/kg)
0.03176	1.0	90.0	0.0	12.0	3.1167	100.0	1000.0	11.0	3.0	0.0	15.0	6.00E-7

Simulation:

Froude number: 39.23; effleunt density (sigma-T) -0.836; effleunt velocity 3.652(m/s);

Step	Depth	Amb-cur	P-dia	Polutnt	Dilutn	x-posn	y-posn	Build-up
(m)	(m)	(m/s)	(m)	(kg/kg)	()	(m)	(m)	()
0	11.0	0.175	0.0318	6.000E-7	1.0	0.0	0.0	0.0;
100	10.6	0.175	0.218	8.627E-8	7.075	-0.0534	0.00187	0.0;
200	9.872	0.175	0.981	1.536E-8	51.09	-0.729	0.0254	0.0;
300	8.468	0.175	2.768	5.567E-9	370.0	-5.97	0.208	0.0;
312	8.19	0.175	3.121	5.236E-9	469.2	-7.459	0.26	0.0; merging;
387	3.805	0.175	10.82	4.280E-9	2071.8	-34.95	1.221	0.0; matched energy radial vel = 0.126m/s;
400	2.142	0.175	13.91	4.216E-9	2680.1	-45.73	1.597	0.0;
410	0.538	0.175	16.9	4.177E-9	3267.0	-56.17	1.961	0.0; surface;

Const Eddy Diffusivity. Farfield dispersion based on wastefield width of 51.17 m

conc	dilutn	width	distnce	time			
(kg/kg)	(m)	(m)	(m)	(hrs)	(kg/kg)	(s-1)	(m/s)(m0.67/s2)
4.17E-9	3276.1	51.65	60.0	0.00603	4.00E-9	0.0	0.175 5.00E-4
4.17E-9	3271.2	52.89	70.0	0.0219	4.00E-9	0.0	0.175 5.00E-4
4.17E-9	3269.6	54.11	80.0	0.0378	4.00E-9	0.0	0.175 5.00E-4
4.18E-9	3268.8	55.3	90.0	0.0536	4.00E-9	0.0	0.175 5.00E-4
4.18E-9	3268.7	56.47	100.0	0.0695	4.00E-9	0.0	0.175 5.00E-4

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Benzene, xylene and toluene, Lowest Astronomical Tide

/ UM3. 06/05/2012 11:43:23

Case 1; ambient file C:\Plumes\LillyOutfallPlumesResults\LillyOutfall030512_1.001.db; Diffuser table record 1: -----

Ambient Table:

Depth	Amb-cur	Amb-dir	Amb-sal	Amb-tem	Amb-pol	Decay	Far-spd	Far-dir	Disprsn	Density
m	m/s	deg	psu	C	kg/kg	s-1	m/s	deg	m0.67/s2	sigma-T
0.0	0.175	178.0	35.0	10.0	1.0000E-9	0.0	0.175	178.0	0.0005	26.97
12.0	0.175	178.0	35.0	10.0	1.0000E-9	0.0	0.175	178.0	0.0005	26.97

Diffuser table:

P-dia	P-elev	V-angle	H-angle	Ports	Spacing	AcuteMZ	ChrcMZ	P-depth	Ttl-flo	Eff-sal	Temp	Polutnt
(m)	(m)	(deg)	(deg)	()	(m)	(m)	(m)	(m)	(MLD)	(psu)	(C)	(kg/kg)
0.03176	1.0	90.0	0.0	12.0	3.1167	100.0	1000.0	11.0	3.0	0.0	15.0	1.00E-7

Simulation:

Froude number: 39.23; effleunt density (sigma-T) -0.836; effleunt velocity 3.652(m/s);

Step	Depth	Amb-cur	P-dia	Polutnt	Dilutn	x-posn	y-posn	Build-up
(m)	(m)	(m/s)	(m)	(kg/kg)	()	(m)	(m)	()
0	11.0	0.175	0.0318	1.000E-7	1.0	0.0	0.0	0.0;
100	10.6	0.175	0.218	1.466E-8	7.075	-0.0534	0.00187	0.0;
200	9.872	0.175	0.981	2.886E-9	51.09	-0.729	0.0254	0.0;
300	8.468	0.175	2.768	1.260E-9	370.0	-5.97	0.208	0.0;
312	8.19	0.175	3.121	1.205E-9	469.2	-7.459	0.26	0.0; merging;
387	3.805	0.175	10.82	1.046E-9	2071.8	-34.95	1.221	0.0; matched energy radial vel = 0.126m/s;
400	2.142	0.175	13.91	1.035E-9	2680.1	-45.73	1.597	0.0;
410	0.538	0.175	16.9	1.029E-9	3267.0	-56.17	1.961	0.0; surface;

Const Eddy Diffusivity. Farfield dispersion based on wastefield width of 51.17 m

conc	dilutn	width	distnce	time			
(kg/kg)		(m)	(m)	(hrs)	(kg/kg)	(s-1)	(m/s)(m0.67/s2)
1.02E-9	3276.1	51.65	60.0	0.00603	1.00E-9	0.0	0.175 5.00E-4
1.02E-9	3271.2	52.89	70.0	0.0219	1.00E-9	0.0	0.175 5.00E-4
1.02E-9	3269.6	54.11	80.0	0.0378	1.00E-9	0.0	0.175 5.00E-4
1.02E-9	3268.8	55.3	90.0	0.0536	1.00E-9	0.0	0.175 5.00E-4
1.02E-9	3268.7	56.47	100.0	0.0695	1.00E-9	0.0	0.175 5.00E-4

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Copper W2 at Lowest Astronomical Tide

/ UM3. 06/05/2012 11:49:10

Case 1; ambient file C:\Plumes\LillyOutfallPlumesResults\LillyOutfall030512_1.001.db; Diffuser table record 1: -----

Ambient Table:

Depth	Amb-cur	Amb-dir	Amb-sal	Amb-tem	Amb-pol	Decay	Far-spd	Far-dir	Disprsn	Density
m	m/s	deg	psu	C	kg/kg	s-1	m/s	deg	m0.67/s2	sigma-T
0.0	0.175	178.0	35.0	10.0	1.0000E-9	0.0	0.175	178.0	0.0005	26.97
12.0	0.175	178.0	35.0	10.0	1.0000E-9	0.0	0.175	178.0	0.0005	26.97

Diffuser table:

P-dia	P-elev	V-angle	H-angle	Ports	Spacing	AcuteMZ	ChrcMZ	P-depth	Ttl-flo	Eff-sal	Temp	Polutnt
(m)	(m)	(deg)	(deg)	()	(m)	(m)	(m)	(m)	(MLD)	(psu)	(C)	(kg/kg)
0.03176	1.0	90.0	0.0	12.0	3.1167	100.0	1000.0	11.0	1.5	0.0	15.0	5.00E-7

Simulation:

Froude number: 19.61; effleunt density (sigma-T) -0.836; effleunt velocity 1.826(m/s);

Step	Depth	Amb-cur	P-dia	Polutnt	Dilutn	x-posn	y-posn	Build-up
	(m)	(m/s)	(m)	(kg/kg)	()	(m)	(m)	()
0	11.0	0.175	0.0318	5.000E-7	1.0	0.0	0.0	0.0;
100	10.72	0.175	0.203	6.988E-8	7.075	-0.0662	0.00231	0.0;
200	10.3	0.175	0.72	1.050E-8	51.09	-0.758	0.0265	0.0;
300	9.316	0.175	1.964	2.312E-9	370.0	-5.573	0.195	0.0;
347	8.395	0.175	3.132	1.517E-9	938.3	-12.26	0.428	0.0; merging;
400	6.023	0.175	7.181	1.181E-9	2680.1	-33.15	1.158	0.0;
423	3.924	0.175	11.09	1.114E-9	4226.2	-52.38	1.829	0.0; matched energy radial vel = 0.124m/s;
444	0.967	0.175	16.67	1.075E-9	6405.5	-79.68	2.783	0.0; surface;

Const Eddy Diffusivity. Farfield dispersion based on wastefield width of 50.93 m

conc	dilutn	width	distnce	time				
(kg/kg)		(m)	(m)	(hrs)	(kg/kg)	(s-1)	(m/s)	(m0.67/s2)
1.07E-9	6435.7	50.97	80.0	4.30E-4	1.00E-9	0.0	0.175	5.00E-4
1.07E-9	6415.7	52.22	90.0	0.0163	1.00E-9	0.0	0.175	5.00E-4
1.07E-9	6411.4	53.45	100.0	0.0322	1.00E-9	0.0	0.175	5.00E-4

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Zinc W2, Lowest Astronomical Tide

/ UM3. 06/05/2012 11:52:58

Case 1; ambient file C:\Plumes\LillyOutfallPlumesResults\LillyOutfall030512_1.001.db; Diffuser table record 1: -----

Ambient Table:

Depth	Amb-cur	Amb-dir	Amb-sal	Amb-tem	Amb-pol	Decay	Far-spd	Far-dir	Disprsn	Density
m	m/s	deg	psu	C	kg/kg	s-1	m/s	deg	m0.67/s2	sigma-T
0.0	0.175	178.0	35.0	10.0	4.0000E-9	0.0	0.175	178.0	0.0005	26.97
12.0	0.175	178.0	35.0	10.0	4.0000E-9	0.0	0.175	178.0	0.0005	26.97

Diffuser table:

P-dia	P-elev	V-angle	H-angle	Ports	Spacing	AcuteMZ	ChrncMZ	P-depth	Ttl-flo	Eff-sal	Temp	Polutnt
(m)	(m)	(deg)	(deg)	()	(m)	(m)	(m)	(m)	(MLD)	(psu)	(C)	(kg/kg)
0.03176	1.0	90.0	0.0	12.0	3.1167	100.0	1000.0	11.0	1.5	0.0	15.0	1.50E-6

Simulation:

Froude number: 19.61; effleunt density (sigma-T) -0.836; effleunt velocity 1.826(m/s);

Step	Depth	Amb-cur	P-dia	Polutnt	Dilutn	x-posn	y-posn	Build-up
	(m)	(m/s)	(m)	(kg/kg)	()	(m)	(m)	()
0	11.0	0.175	0.0318	1.500E-6	1.0	0.0	0.0	0.0;
100	10.72	0.175	0.203	2.105E-7	7.075	-0.0662	0.00231	0.0;
200	10.3	0.175	0.72	3.250E-8	51.09	-0.758	0.0265	0.0;
300	9.316	0.175	1.964	7.934E-9	370.0	-5.573	0.195	0.0;
347	8.395	0.175	3.132	5.551E-9	938.3	-12.26	0.428	0.0; merging;
400	6.023	0.175	7.181	4.543E-9	2680.1	-33.15	1.158	0.0;
423	3.924	0.175	11.09	4.344E-9	4226.2	-52.38	1.829	0.0; matched energy radial vel = 0.124m/s;
445	0.794	0.175	17.0	4.223E-9	6533.6	-81.29	2.839	0.0; surface;

Const Eddy Diffusivity. Farfield dispersion based on wastefield width of 51.26 m

conc	dilutn	width	distnce	time
(kg/kg)		(m)	(m)	(hrs)
4.22E-9	6545.3	52.35	90.0	0.0137
4.22E-9	6540.2	53.59	100.0	0.0296

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Dioxins, Furans W2, Lowest Astronomical Tide

/ UM3. 06/05/2012 12:00:56

Case 1; ambient file C:\Plumes\LillyOutfallPlumesResults\LillyOutfall030512_1.001.db; Diffuser table record 1: -----

Ambient Table:

Depth	Amb-cur	Amb-dir	Amb-sal	Amb-tem	Amb-pol	Decay	Far-spd	Far-dir	Disprsn	Density
m	m/s	deg	psu	C	kg/kg	s-1	m/s	deg	m0.67/s2	sigma-T
0.0	0.175	178.0	35.0	10.0	0.0	0.0	0.175	178.0	0.0005	26.97
12.0	0.175	178.0	35.0	10.0	0.0	0.0	0.175	178.0	0.0005	26.97

Diffuser table:

P-dia	P-elev	V-angle	H-angle	Ports	Spacing	AcuteMZ	ChrncMZ	P-depth	Ttl-flo	Eff-sal	Temp	Polutnt
(m)	(m)	(deg)	(deg)	()	(m)	(m)	(m)	(m)	(MLD)	(psu)	(C)	(ppb)
0.03176	1.0	90.0	0.0	12.0	3.1167	100.0	1000.0	11.0	1.5	0.0	15.0	0.3

Simulation:

Froude number: 19.61; effleunt density (sigma-T) -0.836; effleunt velocity 1.826(m/s);

Step	Depth	Amb-cur	P-dia	Polutnt	Dilutn	x-posn	y-posn	Build-up
	(m)	(m/s)	(m)	(ppb)	()	(m)	(m)	()
0	11.0	0.175	0.0318	0.3	1.0	0.0	0.0	0.0;
100	10.72	0.175	0.203	0.05	7.075	-0.0662	0.00231	0.0;
200	10.3	0.175	0.72	0.0155	51.09	-0.758	0.0265	0.0;
300	9.316	0.175	1.964	0.0108	370.0	-5.573	0.195	0.0;
347	8.395	0.175	3.132	0.0103	938.3	-12.26	0.428	0.0; merging;
400	6.023	0.175	7.181	0.0101	2680.1	-33.15	1.158	0.0;
423	3.924	0.175	11.09	0.0101	4226.2	-52.38	1.829	0.0; matched energy radial vel = 0.124m/s;
449	0.0628	0.175	18.38	0.01	7072.2	-88.05	3.075	0.0; surface;

Const Eddy Diffusivity. Farfield dispersion based on wastefield width of 52.65 m

conc	dilutn	width	distnce	time				
(ppb)	(m)	(m)	(m)	(hrs)	(ppb)	(s-1)	(m/s)	(m0.67/s2)
1.00E-2	7098.3	52.89	90.0	0.00301	0.01	0.0	0.175	5.00E-4
1.00E-2	7082.5	54.15	100.0	0.0189	0.01	0.0	0.175	5.00E-4

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Rhodamine modelled to 200m, Lowest Astronomical tide

/ UM3. 26/03/2012 21:48:25

Case 1; ambient file C:\Plumes\LillyOutfall020212_4.vpp.001.db; Diffuser table record 1: -----

Ambient Table:

Depth	Amb-cur	Amb-dir	Amb-sal	Amb-tem	Amb-pol	Decay	Far-spd	Far-dir	Disprsn	Density
m	m/s	deg	psu	C	kg/kg	s-1	m/s	deg	m0.67/s2	sigma-T
0.0	0.175	178.0	33.0	10.0	0.0	0.0	0.175	178.0	0.0005	25.42
12.0	0.175	178.0	33.0	10.0	0.0	0.0	0.175	178.0	0.0005	25.42

Diffuser table:

P-dia	P-elev	V-angle	H-angle	Ports	Spacing	AcuteMZ	ChrcMZ	P-depth	Ttl-flo	Eff-sal	Temp	Polutnt
(m)	(m)	(deg)	(deg)	()	(m)	(m)	(m)	(m)	(MLD)	(psu)	(C)	(kg/kg)
0.03176	1.0	90.0	0.0	12.0	3.1167	100.0	1000.0	11.0	3.71	0.0	15.0	1.34E-3

Simulation:

Froude number: 49.93; effleunt density (sigma-T) -0.836; effleunt velocity 4.517(m/s);

Step	Depth	Amb-cur	P-dia	Polutnt	Dilutn	x-posn	y-posn	Build-up
(m)	(m)	(m/s)	(m)	(kg/kg)	()	(m)	(m)	()
0	11.0	0.175	0.0318	0.00134	1.0	0.0	0.0	0.0;
100	10.58	0.175	0.22	0.000185	7.084	-0.0479	0.00167	0.0;
200	9.699	0.175	1.071	2.553E-5	51.17	-0.725	0.0253	0.0;
300	8.131	0.175	3.078	3.524E-6	370.5	-6.146	0.215	0.0;
302	8.082	0.175	3.14	3.387E-6	385.5	-6.39	0.223	0.0 merging;
375	3.843	0.175	10.55	7.981E-7	1636.1	-30.73	1.073	0.0 matched energy radial vel = 0.122m/s;
384	2.761	0.175	12.55	6.678E-7	1955.3	-37.19	1.299	0.0 surface;

Const Eddy Diffusivity. Farfield dispersion based on wastefield width of 46.81 m

conc	dilutn	width	distnce	time
(kg/kg)	(m)	(m)	(m)	(hrs)
6.66E-7	1961.4	47.16	40.0	0.00443
6.67E-7	1957.8	48.37	50.0	0.0203
6.67E-7	1956.8	49.55	60.0	0.0362
6.67E-7	1956.3	50.7	70.0	0.052
6.67E-7	1956.4	51.83	80.0	0.0679
6.67E-7	1957.6	52.94	90.0	0.0838
6.66E-7	1960.5	54.02	100.0	0.0997
6.64E-7	1965.6	55.08	110.0	0.116
6.62E-7	1972.8	56.12	120.0	0.131
6.59E-7	1981.9	57.14	130.0	0.147
6.56E-7	1992.8	58.14	140.0	0.163
6.52E-7	2005.1	59.13	150.0	0.179
6.47E-7	2018.8	60.1	160.0	0.195
6.43E-7	2033.8	61.06	170.0	0.211
6.38E-7	2049.8	62.0	180.0	0.227
6.33E-7	2066.6	62.92	190.0	0.243
6.28E-7	2083.9	63.84	200.0	0.258

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Appendix 3: Summary Water quality monitoring data from the EPA monitoring program of the Lower Bandon Estuary and Kinsale Harbour 2007-2009, after McGarrigle et al, 2010 (Appendix 5).

Lower Bandon Estuary														TSAS criteria	Threshold	Value	Eutrophic
	Summary Stats	Salinity	Temp (°C)	pH	Secchi (m)	DO sat. (%)	DO (mg/l)	BOD (mg/l)	TON (mg/l)	NH ₃ (mg/l)	DIN (mg/l)	MRP (µg/l)	Chl. a (µg/l)				
Winter	MINIMUM	0.07	4.57	7.2	0.6	66.4	8.4	< 1	0.16	0.02	0.166	17	< 0.5	Winter DIN	1.682	2.054	Fail
	MEDIAN	13.85	8.36	7.9	1.3	92.2	9.8	< 1	1.89	0.06	2.054	28	1.2	Winter MRP	60	28	Pass
	MAXIMUM	35.19	9.82	8.1	2.0	98.5	12.2	1.0	4.96	0.65	4.997	42	7.1	DIN-	0.889	0.537	Pass
	No. of samples	42	48	48	30	48	42	11	48	48	48	48	47	MRP-	51	11	Pass
															Chloro. Median	12.8	5.4
Summer	MINIMUM	0.29	12.33	7.4	0.5	73.6	6.3	< 1	0.01	0.02	0.015	< 10	< 0.5	Chloro 90 percentile	25.6	35.6	Fail
	MEDIAN	25.27	15.71	8.1	1.3	98.0	8.3	2.2	0.48	0.03	0.537	11	5.4	Opportunistic algae	0.6		
	MAXIMUM	35.15	19.70	8.7	4.6	199.9	16.5	8.8	3.10	0.42	3.329	118	92.3	DO%sat 5 percentile	74	78.3	Pass
	No. of samples	130	131	135	48	130	130	56	135	135	135	135	135	DO%sat 95 percentile	126	158.0	Fail
															BOD	4	6.3

Kinsale Harbour														TSAS criteria	Threshold	Value	Unpolluted
	Summary Stats	Salinity	Temp (°C)	pH	Secchi (m)	DO sat. (%)	DO (mg/l)	BOD (mg/l)	TON (mg/l)	NH ₃ (mg/l)	DIN (mg/l)	MRP (µg/l)	Chl. a (µg/l)				
Winter	MINIMUM	18.54	6.34	7.9	2.0	93.2	8.5		0.16	0.02	0.167	18	< 0.5	Winter DIN	0.314	0.200	Pass
	MEDIAN	34.96	9.51	7.9	2.0	97.8	9.0		0.18	0.02	0.200	21	0.9	Winter MRP	41	21	Pass
	MAXIMUM	35.19	9.83	8.1	2.0	106.3	10.4		1.07	0.19	1.264	37	4.1	DIN-	0.314	0.050	Pass
	No. of samples	8	8	8	1	8	8		8	8	8	8	8	MRP-	41	5	Pass
															Chloro. Median	10.3	1.3
Summer	MINIMUM	27.74	12.13	7.8	3.5	87.1	7.5	< 1	0.01	0.02	0.015	< 5	< 0.5	Chloro 90 percentile	20.6	3.1	Pass
	MEDIAN	34.29	14.50	8.1	5.0	102.0	8.5	1.6	0.03	0.03	0.050	5	1.3	Opportunistic algae	0.6		
	MAXIMUM	35.20	17.45	8.3	5.8	113.3	9.4	3.5	6.00	0.82	6.040	14	4.6	DO%sat 5 percentile	79	91.5	Pass
	No. of samples	30	30	30	8	29	28	12	30	30	30	30	30	DO%sat 95 percentile	121	112.9	Pass
															BOD	4	3.1

Appendix 4: Summary Water quality monitoring data from the NUI, Galway and Eli Lilly monitoring program of the Lower Bandon Estuary and Kinsale Harbour 2005-2012.

Inner Harbour / Lower Bandon Estuary

Winter	Summary	Salinity	TON (mg/l)	NH ₃ (mg/l)	DIN (mg/l)	MRP (µg/l)	SPM	TSAS criteria	Threshold	Value		
Winter	MINIMUM	12.34	-	0.01	0.31	8.73	17.53	Winter DIN	1.16	1.07	Pass	
	MEDIAN	21.18	-	0.04	1.07	95.12	26.98	Winter MRP	55.36	95.12	Fail	
	MAXIMUM	30.33	-	0.08	1.66	390.98	65.20	DIN-	0.65	0.09	Pass	
	No. of samples	54.00	-	54.00	54.00	54.00	52.00	MRP-	47.08	23.65	Pass	
Summer	MINIMUM	19.42	-	0.01	0.03	9.70	16.93	Chloro. Median				
	MEDIAN	28.63	-	0.05	0.09	23.65	23.55	Chloro 90 percentile				
	MAXIMUM	32.36	-	0.07	0.79	48.35	32.29	Opportunistic algae				
	No. of samples		68.00	-	68.00	68.00	68.00	68.00	DO%sat 5 percentile			
									DO%sat 95 percentile			
								BOD				

Middle Harbour

		Salinity	TON (mg/l)	NH ₃ (mg/l)	DIN (mg/l)	MRP (µg/l)	SPM	TSAS criteria	Threshold	Value		
Winter	MINIMUM	26.44	-	0.02	0.19	10.47	18.40	Winter DIN	0.35	0.54	Pass	
	MEDIAN	33.06	-	0.04	0.54	22.55	25.75	Winter MRP	42.15	22.55	Pass	
	MAXIMUM	35.04	-	0.08	1.27	60.89	50.18	DIN-	0.27	0.09	Pass	
	No. of samples	54.00	-	54.00	54.00	54.00	52.00	MRP-	40.94	23.65	Pass	
Summer	MINIMUM	3.73	-	0.02	0.03	9.70	17.13	Chloro. Median				
	MEDIAN	34.16	-	0.04	0.09	23.65	22.46	Chloro 90 percentile				
	MAXIMUM	35.08	-	0.07	0.36	48.35	32.85	Opportunistic algae				
	No. of samples		68.00	-	68.00	68.00	68.00	68.00	DO%sat 5 percentile			
									DO%sat 95 percentile			
								BOD				

Outer Harbour

		Salinity	TON (mg/l)	NH ₃ (mg/l)	DIN (mg/l)	MRP (µg/l)	SPM	TSAS criteria	Threshold	Value		
Winter	MINIMUM	32.21	-	0.02	0.18	10.72	19.93	Winter DIN	0.35	0.24	Pass	
	MEDIAN	34.95	-	0.03	0.24	23.68	24.61	Winter MRP	40.06	23.68	Pass	
	MAXIMUM	35.45	-	0.07	0.39	55.80	45.61	DIN-	0.27	0.08	Pass	
	No. of samples	54.00	-	54.00	54.00	54.00	52.00	MRP-	40.15	29.88	Pass	
Summer	MINIMUM	33.72	-	0.01	0.02	9.57	19.37	Chloro. Median				
	MEDIAN	34.86	-	0.04	0.08	29.88	23.63	Chloro 90 percentile				
	MAXIMUM	35.49	-	0.07	0.22	57.17	31.59	Opportunistic algae				
	No. of samples		68.00	-	68.00	68.00	68.00	68.00	DO%sat 5 percentile			
									DO%sat 95 percentile			
								BOD				

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