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

Signed: *Date: 01/11/2016*

OFFICE OF ENVIRONMENTAL SUSTAINABILITY

REPORT OF THE TECHNICAL COMMITTEE ON OBJECTIONS TO A PROPOSED DETERMINATION

TO:	Directors
FROM:	Technical Committee – Environmental Licensing Programme
DATE:	1 November 2016
RE:	Objection to Proposed Determination for Eli Lilly S.A., trading as Eli Lilly S.A. – Irish Branch, IE License Register: P0009-04.

Application Details	
Classes of activity:	5.16: The production of pharmaceutical products including intermediates 11.2: Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving one or more of the following activities: (b) Physico-chemical treatment (c) Blending or mixing prior to submission to any of the other activities listed in paragraph 11.2 or 11.3; (e) Solvent reclamation or regeneration. 11.3: Disposal or recovery of waste in waste incineration plants or in waste co-incineration plants – (b) for hazardous waste with a capacity exceeding 10 tonnes per day 11.6: Temporary storage of hazardous waste, (other than waste referred to in paragraph 11.5) pending any of the activities referred to in paragraph 11.2, 11.3, 11.5 or 11.7 with a total capacity exceeding 50 tonnes, other than temporary storage, pending collection, on the site where the waste is generated.
Location of activity:	Dunderrow, Kinsale, County Cork
Licence application received:	17 August 2012
PD issued:	17 June 2016

First party objection received:	14 July 2016
Third Party Objection received:	None
Submissions on Objections received:	None

Company

Eli Lilly S.A., trading as Eli Lilly S.A. – Irish Branch is a subsidiary of the Eli Lilly International Corporation with its headquarters in Indiana USA. The installation, which has been in operation since 1981, is situated in Dunderrow, approximately 5 miles from Kinsale, County Cork.

Active pharmaceutical ingredients and intermediates for human and veterinary use are manufactured at the plant. The site is also expanding to become the main centre for the manufacture and supply of active ingredients for its new biopharmaceutical medicines. Eli Lilly holds EPA consent for the contained use of Class 1 GMMs (G0267-02) under the GMO (Contained use) Regulations, 2001 to 2010. This new biotechnology process will operate in Building IE42 and Building IE43.

The licence review is principally to provide for the operation of two new main air emission points (Combined Heat and Power Plant and additional Boiler), two biotechnology manufacturing facilities (Building IE42 and Building IE43), revision of the existing site boundary and operation of the incinerator on a dual temperature strategy. The review is also for the purposes of the European Communities Environmental Objectives (Surface Water) Regulations 2009, as amended and the European Communities Environmental Objectives (Groundwater) Regulations 2010, as amended.

One submission was received from the Health Service Executive in relation to the application and this was considered by the Board at Proposed Determination (PD) stage.

Consideration of the Objection

The Technical Committee, comprising of Jennifer Cope (Chair) and Gavin Clabby, has considered all of the issues raised in the objections and this report details the Committee's comments and recommendations following the examination of the objections. The Technical Committee consulted with Agency Senior Inspector Seán O'Donoghue.

This report considers the first party objection. No valid third party objections were received. The main issues raised in the objection are summarised below. However, the original objection should be referred to for greater detail and further expansion of particular points.

First Party Objection

The licensee makes three specific points of objection. The main issues raised in the objection are summarised below however the original objection should be referred to at all times for greater detail and expansion of particular points.

A.1. Schedule B.1 Emissions to Air

The licensee requests time (1 July 2018) to comply with the new Oxides of Nitrogen (NO and NO_2 expressed as NO_2) emission limit values for the KEU incinerator (emission point Reference No. A2-2) specified in the PD. The Proposed Determination specifies emission limit values specified in Annex VI Technical provision relating to waste incineration and waste co-incineration plants for existing incineration plants with a nominal capacity exceeding 6 tonnes per hour. The licensee states that the current SCR is not capable of meeting the proposed limits on a consistent basis and an upgrade of the KEU incinerator is required. The licensee notes that the current licence (P0009-03) limits are compliant with the Annex VI Part 3 of IED (2010/75/EU) requirements for units with a nominal capacity of less than 6 tonnes per hour as the KEU incinerator has a maximum capacity of 3.1 tonnes per hour.

Technical Committee's Evaluation: The current licence P0009-03 specifies a daily emission limit value of 400 mg/m^3 Oxides of Nitrogen. The TC notes that the emission limit values specified in Part 3 of Annex VI Technical provisions relating to waste incineration and waste co-incineration plants applicable to existing incineration plants with a nominal capacity exceeding 6 tonnes per hour have been applied in the proposed determination. However, the KEU incinerator has a nominal capacity of less than six tonnes per hour (3.1 tonnes per hour). Therefore, the TC considers it reasonable to amend *Schedule B.1 Emissions to Air* such that the licence caters for the incinerator at its current capacity, and also at the higher capacity. The TC recommends that the following table in *Schedule B.1 Emissions* to Air be as outlined below.

Recommendation: Amend the following table in *Schedule B.1 Emission to Air* to read as follows:

Emission Point Reference No: A2-2 (KEU Incinerator)

Location: East of building IE7
(Grid Reference: 159989 E, 052723 N)

Volume to be emitted: Maximum in any one day: 407,640 m^3

Maximum rate per hour: 16,985m^3

Minimum discharges height: 25 m above ground

Minimum operating temperature: 850°C Note **1**

Minimum residence time: 2 seconds

Parameter	Units	Half Hour Average		Daily Average	10 minute average
Carbon monoxide (CO) Note 2	mg/m^3	100 Note 3		50 Note 4	150 Note 5
		A	B		
Total dust	mg/m^3	30 Note 6	10 Note 6	10	-
Volatile organic compounds expressed as total organic carbon	mg/m^3	20 Note 6	10 Note 6	10	-
Hydrogen chloride (HCl)	mg/m^3	60 Note 6	10 Note 6	10	-
Hydrogen fluoride (HF)	mg/m^3	4 Note 6	2 Note 6	1	-
Hydrogen bromide (HBr)	mg/m^3	5 Note 6	3 Note 6	2	-
Sulphur dioxide (SO_2)	mg/m^3	200 Note 6	50 Note 6	50	-
Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	mg/m^3	400 **Note 9**	200 **Note 9**	200 **Note 9** **400 Note 10**	-

Parameter	Emission Limit Value	
Cadmium (as Cd) + thallium (as Tl), and their compounds Note 7	30minute – 8 hour sample	Total 0.05 mg/m^3
Mercury (as Hg) and its compounds Note 7	30minute – 8 hour sample	0.05 mg/m^3
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 Note 7	30minute – 8 hour sample	Total 0.5 mg/m^3
Dioxins/furans (TEQ) Note 8	6 – 8 hour sample	0.1 ng/m^3

Note 1: If greater than 1% halogenated organic substances, expressed as chlorine, are combusted, the minimum operating temperature shall be 1100°C.

Note 2: The emission limit values of carbon monoxide (CO) concentration shall not be exceeded in the combustion gases (excluding the start-up and shut-down phase).

Note 3: Taken in any 24 hour period

Note 4: 97% of the daily average value over the year does not exceed this emission limit value

Note 5: 95% of all measurements determined as 10-minute average values shall not exceed the emission limit value.

Note 6: Either, none of the half-hourly average values shall exceed any of the emission limit values set out in column A, or, 97% of the half-hourly average values over the year shall not exceed any of the emission limit values set out in column B.

Note 7: Metals include gaseous, vapour and solid phases as well as their compounds (expressed as the metal or total as specified).

Note 8: The emission limit value refers to total concentration of dioxins and furans calculated using the concept of toxic equivalence in accordance with Part 2 of Annex VI of Council Directive 2010/75/EU.

Note 9: The emission limit values are applicable for the KEU incinerator with a nominal capacity exceeding 6 tonnes per hour.

Note 10: The emission limit value is applicable for the KEU incinerator with a nominal capacity of 6 tonnes per hour or less.

A.2. *Schedule C.1.1 Control of Emissions to Air*

The following table in *Schedule C.1.1 Control of Emissions to Air* states:

% halogenated organic substances, expressed as chlorine	Minimum thermal oxidiser operating temperature	Minimum residence time
Less than or equal to 1%	850°C	2 seconds
Greater than 1%	1100°C	2 seconds

The licensee requests the removal of the operational controls for the Regenerative Thermal Oxidiser (RTO) (A2-1) as outlined in the table above and permission to continue to operate the RTO to its original design criteria. The licensee states that the current licence (P0009-03) does not include operating temperatures, residence time or feed stream chlorine restrictions for the RTO. The licensee states that the RTO unit is not designed to operate at 1100ºC and is not capable of providing a 2 second residence time in the combustion chamber.

The licensee states that the RTO is used for treatment of process off gases (VOC abatement) and not the incineration of solid or liquid waste and therefore Chapter IV Special Provisions for waste incineration plants and waste co-incineration plants are not applicable.

The licensee states that a commissioning test programme was completed on the RTO which demonstrated that the operating design condition of 850ºC and residence time of 1 second was sufficient to achieve a destruction removal efficiency of 99.2% to 99.5% at expected feed concentrations for both halogenated and non-halogenated solvent vapours.

Furthermore, the licensee states that the halogenated content of the process gases is consistently <1% (as chlorine) and it is not envisaged that the content of such gases should ever exceed 1%. The licensee states that operating the RTO at 1100ºC would impact the environment negatively with the requirement for substantial quantities of support fuel (gas) to maintain the higher bed temperature and would lead to increase in emission of combustion gases (NO_x, CO_2).

Technical Committee's Evaluation: The TC notes that the operational control requirements for the RTO specified in the PD are not required in the current licence (P0009-03). The TC notes that the RTO is used for VOC abatement and not for the incineration of liquid or solid wastes. Therefore, Article 50 Operating Conditions specified in Chapter IV *Special Provisions for waste incineration plants and waste co-incineration plants of IED* are not applicable to the RTO. The TC considers that regard should be had to the commissioning test programme and maintain the operating design condition of 850°C and residence time of 1 second for halogenated organic substances less than or equal to 1%. The licensee states that they do not envisage content of the process gases exceeding 1% halogenated organic substances, expressed as chlorine. The TC recommends that a new condition is inserted to specify that the Regenerative Thermal Oxidisers (duty/standby) emission point No. A2-1 shall not combust waste streams with a halogenated organic substances content greater than 1%, expressed as chlorine. The TC recommends that *Schedule B.1 Emissions to Air* for the RTO (A2-1) be amended to specify a minimum residence time of 1 second for the RTO and removal of note 3 "*If greater than 1% halogenated organic substances, expressed as chlorine, are combusted, the minimum operating temperature shall be 1100°C.* The TC recommends the removal of operational controls as specified in the table as outlined below from *Schedule C.1.1 Control of Emissions to Air*.

Recommendation: Insert a new condition 3.18 to read as follows:

The Regenerative Thermal Oxidisers (duty/standby) emission point No. A2-1 shall not combust waste streams with a halogenated organic substances content greater than 1%, expressed as chlorine.

Delete the following table from *Schedule C.1.1 Control of emissions to Air*:

% halogenated organic substances, expressed as chlorine	Minimum thermal oxidiser operating temperature	Minimum residence time
Less than or equal to 1%	850°C	2 seconds
Greater than 1%	1100°C	2 seconds

Amend the following table in *Schedule B.1 Emissions to Air to read as follows*:

Emission Point Reference No: A2-1 (Regenerative Thermal Oxidisers (duty/standby))
Location: East of building IE7
(Grid Reference 159989E, 052723N)

Volume to be emitted: Maximum in any one day: 1,047,600 m^3
Maximum rate per hour: 43,650m^3

Minimum discharges height: 25m above ground

Minimum RTO operating temperature: 850°C ~~Note 3~~

Minimum RTO residence time: **1 second**

Parameter	Emission Limit Value
Oxides of sulphur (as SO_2)	200 mg/m^3
Class I Organics Note 1	20mg/m^3 (at mass flows of >0.1 kg/hour)
Class II Organics Note 1	100mg/m^3 (at mass flows >0.5 kg/hour)
Class II Inorganics Note 1	3mg/m^3 (at mass flows >0.015kg/hour)
Class III Inorganics Note 1	30mg/m^3 (at mass flows >0.15kg/hour)
Total Organic Carbon (as C)	20 mg/m^3
Sum of individual VOCs (hazard statements H340, H350, H350i, H360D or H360F or risk phrases R45, R46, R49, R60, R61)	2 mg/m^3 (at mass flows >0.01kg/h)
Sum of Individual Halogenated VOCs (hazard statements H341, H351 or risk phrases R40, R68)	20 mg/m^3 (at mass flows >0.10kg/h)
Dioxin/furans (TEQ) Note 2	6 – 8 hour sample 0.1ng/m^3

Note 1: Limits set for a class total as specified in section 6.1 of BAT Guidance Note on Best Available Techniques for Pharmaceutical and Other Speciality Organic Chemicals.

Note 2: *The emission limit value refers to total concentration of dioxins and furans calculated using the concept of toxic equivalence in accordance with Part 2 of Annex VI of Council Directive 2010/75/EU.*

Note 3: ~~If greater than 1% halogenated organic substances, expressed as chlorine, are combusted, the minimum operating temperature shall be 1100°C.~~

A.3. *Schedule C.2.2 Monitoring of Emissions to Water*

The licensee requests that the requirement to monitor TOC on a continuous basis at emission point reference number SW1 be removed. The licensee considers that the continuous monitoring of TOC is unnecessary. The licensee states that a composite sample of SW1 discharge is monitored for COD on a daily basis. The volume of final effluent tank holding tank is 680m^3 with an automatic pump-out range from 75% to 60%. With an average daily effluent discharge of approximately 1,200 m^3 the resulting numerous small volume pump outs over the day are considered representative of the mixed holding tank contents. All aqueous waste streams being processed through the waste water treatment plant are monitored from point of entry so as to eliminate the possibility of shock loading to the plant that could result in spikes in effluent COD/TOC.

Technical Committee's Evaluation: The TC notes that monitoring for TOC is not a requirement of the current licence (P0009-03). The Commission Implementing Decision for BAT conclusions for common waste water and water gas treatment/management systems in the chemical sector was published on 30 May 2016 (CID 2016/902). The CID 2016/902 specifies a minimum frequency of daily for TOC and COD monitoring. According to the CID 2016/902 *TOC monitoring and COD monitoring are alternatives.* Based on the above the TC considers it reasonable to remove the requirement of TOC monitoring and maintain the requirement for daily COD monitoring.

Recommendation: Delete the requirement for continuous monitoring for TOC from the following table in *Schedule C.2.2 Monitoring of Emissions to Water*.

C.2.2. Monitoring of Emissions to Water

Emission Point Reference No: SW1

Control Parameter	Monitoring Frequency [Note 1]	Key Equipment/Technique
Flow	Continuous	On-line flow meter with recorder
pH	Continuous	pH electrode/meter with recorder
~~**TOC**~~	~~Continuous~~	~~On-line TOC meter with recorder~~
Chemical Oxygen Demand	Daily [Note 2]	Standard Method
Biochemical Oxygen Demand	Monthly [Note 2]	Standard Method
Suspended Solids	Daily [Note 2]	Standard Method
Total Nitrogen (as N)	Monthly	Standard Method
Ammonia (as N)	Weekly	Standard Method
Total Phosphorus (as P)	Monthly [Note 2]	Standard Method
Metals (Hg, Cd, TI, As, Pb, Cr, Cu, Ni, Zn)	Monthly [Note 2]	Standard Method
Organic Compounds [Note 3]	Annually	Standard Method
Toxicity [Note 4]	Annually	To be agreed by the Agency

Note 1: Daily implies monitoring Monday to Friday inclusive, excluding weekends and Bank Holidays.
Note 2: All samples shall be collected on a 24 hour flow proportional composite sampling basis.
Note 3: Screening for priority pollutant list substances (such as US EPA volatile and/or semi-volatile compounds). This analysis shall include those organic solvents in use in the process, which are likely through normal process operators to be diverted to the wastewater streams.
Note 4: The number of toxic units (Tu) = 100/x hour EC/LC_{50} in percentage vol/vol so that higher Tu values reflect greater levels of toxicity. For test regimes where species death is not easily detected, immobilisation is considered equivalent to death.

Environmental Impact Assessment Directive – Reasoned Conclusion Update

The TC has reviewed the assessment in the Inspector's Report and, taking into account the objection received, and the contents of this TC report, the TC considers that the likely significant direct and indirect effects of the activity have been identified, described and assessed in an appropriate manner as respects the matters that come within the functions of the Agency, and as required by Section 83(2A) and Section 87(1G)(a) of the EPA Act 1992 as amended.

It is considered that the mitigation measures as proposed in the Inspector's Report, and as detailed in this TC report, will adequately control any likely significant environmental effects from the activity.

It is also considered that the proposed activity, if managed, operated and controlled in accordance with the licence conditions included in the PD, with the inclusion of the amendments proposed in this report, is unlikely to damage the environment as a whole and the risk of potential impacts occurring is not unacceptable.

It is further considered that the proposed activity, if managed, operated and controlled in accordance with the licence conditions included in the PD, with the inclusion of the amendments proposed in this report, will not cause environmental pollution or the breach of any environmental quality or emission standard, and can be authorised by the Agency in accordance with Section 83(5) of the EPA Act 1992 as amended.

Overall Recommendation

It is recommended that the Board of the Agency grant a revised licence to the licensee

(i) for the reasons outlined in the Proposed Determination, and

(ii) subject to the conditions and reasons for same in the Proposed Determination, and

(iii) subject to the amendments proposed in this report.

Signed

Jennifer Cope

Jennifer Cope

For, and on behalf of, the Technical Committee