



**OF LICENSING
RESOURCE USE**

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INSPECTORS REPORT ON A LICENCE APPLICATION

To: Board

From: Gavin Clabby

ENVIRONMENTAL LICENSING PROGRAMME

Date: 03 DECEMBER 2015

RE: Application for the review of an Industrial Emissions Licence from AbbVie Ireland NL B.V., Licence Register P0643-03

Application Details

Class of activity (First Schedule of EPA Acts 1992 as amended):	5.16 – The production of pharmaceutical products including intermediates
Category of Activity under Industrial Emissions Directive (2010/75/EC):	4.5 - Production of pharmaceutical products including intermediates
Title of BREF Document (main):	Reference Document on Best Available Techniques for the Manufacture of Organic Fine Chemicals
CRO Number:	906838
Licence application received:	17 September 2015
Notices under Regulation 10(2)(b)(ii) issued:	12 November 2015
Information under Regulation 10(2)(b)(ii) received:	18 November 2015
Unsolicited Additional Information submitted by applicant:	02 December 2015
Submissions received:	HSE, 23 November 2015
Site notice inspected:	29 September 2015
Site visits:	23 November 2015

1. Background

Abbvie Ireland NL B.V. (hereafter Abbvie or the licensee) is a subsidiary of Abbvie Inc. North Chicago, Illinois, USA. Its installation at Sligo was originally licensed by the Agency in December 2002 (Licence No. 643-01, as Abbott Ireland) for the manufacture of a number of active pharmaceutical ingredients (API's) for medical applications.

The licensee requested a review of P0643-01 in 2005 to take account of the proposed introduction of new processes on site. The revised licence (P0643-02 issued to Abbott Ireland) provided for the introduction of a chlorinated solvent on-site (dichloromethane) and additional abatement equipment (cryogenic condenser) for the treatment of gaseous exhaust streams containing dichloromethane. The revised licence also provided for the expansion of the production, laboratory and storage areas, as well providing for the increase in volumetric flows through the existing thermal oxidiser (TO) and the volumetric flow through the process scrubber.

Licence Reg. No. P0643-02 also took into account changes in legislative requirements under the POE Act, 2003. This licence was amended on a number of occasions, principally for the purposes of changes to air emissions abatement, discharges to sewer and legislative requirements for certain hazardous substances, as well being amended for the purposes of compliance with the Industrial Emissions Directive. More recently, on the 23 July this year, the licence was transferred from Abbott Ireland to AbbVie.

On the 17 September this year Abbvie applied for a second review of its licence. This application for a review (licence Reg. No. P0643-03) is principally to allow for the manufacture of a new oncology drug at the installation. The new drug manufacturing process will include the increased use of dichloromethane (DCM). The licence review is intended to facilitate the abatement of chlorinated solvents by a new TO, which is currently being commissioned under an approved test programme.

2. Installation

The installation is located in the town lands of Ballytivnan and Rathbraughan on the outskirts of Sligo town, County Sligo and operates 24 hours a day, seven days a week. Currently there are approximately 195 employees.

3. Process Description

The plant operates in batch mode using standard reaction, extraction, purification, crystallisation, isolation and drying equipment. The installation includes a Drug Product Building which contains blending, milling and tablet compression equipment. A thermal oxidiser is used at the installation for the abatement of the current stream of non-chlorinated solvents used in the current licensable activity.

The licensee is proposing the use of a new direct-fired TO to abate both chlorinated (DCM) and non-chlorinated solvent waste gas streams from the pharmaceutical manufacturing processes resulting in a new main emission point A2-1(c) with the flows and limits in the licence remaining the same as per the existing TO emission point A2-1(a) with the addition of a HCl limit and Dioxin/Furans limit. On completion

of the commissioning phase of the new TO, it is proposed that the existing TO will be decommissioned.

4. Planning Permission, EIS and EIA Requirements

4.1 EIA Screening

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

4.2 Planning status

The licensee has provided a determination by Sligo County Council that the modification of the activity (installation of the new TO) constitutes development but is exempted development.

A number of planning applications have been made by the applicant for previous development of the site of the activity since 2001. Details of these planning applications and permissions have been provided in the application form.

For the first planning permission granted in 2001 (PL01/481), Sligo County Council (in conjunction with Sligo Borough Council¹) had determined that the development related to this activity was likely to have a significant effect on the environment and that an EIA was required.

The planning authorities required an Environmental Impact Statement (EIS) in support of the planning application for PL01/481. The applicant has submitted this EIS with the licence application. (As part of this licence review application the licensee also submitted a letter from Sligo County Council confirming that the planning authority did not require EIA for any subsequent planning applications.)

Having specific regard to EIA, this report is intended to identify, describe and assess for the Agency the direct and indirect effects of the proposed activity on the environment, as respects the matters that come within the functions of the Agency, including any interaction between those effects and the related development forming part of the wider project, and to propose conclusions to the Agency in relation to such effects.

The EIS submitted, the licence application, the submissions and observations received from third parties, the assessment(s) carried out by the planning authority, consultations with the planning authority, the relevant planning decisions and any additional information submitted by the applicant have been examined and assessed and are considered below for that purpose.

¹ Sligo Borough Council was abolished in May 2014; functions transferred to Sligo County Council.

4.3 Content of EIS and licence application

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

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

1. An assessment of the impact of potential dioxin discharges from the TO.
2. Annual solvent usage
3. Details of oil separators installed on-site.

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

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

I have considered and examined the documents furnished by the planning authority in relation to the impacts assessed by it, in particular the planner's report and the planning decision (ref. PL01/481).

I have considered the issues that interact with the matters that were considered by the above authorities and which relate to the activity in Section 13 of this report.

Having considered the application and EIS, the submissions of state and public authorities, and the matters resulting from the planning authority decision, I consider that the likely significant effects of the activity on the environment are as set out in Section 12 below.

4.4 Consultation with Competent Authorities

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

Consultation	Date
Notice under Section 87(1E)(a) issued:	23 September 2015 to Sligo County Council
Response to Section 87(1E)(a) Notice received:	10 November 2015 from Sligo County Council

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

5. Submissions

There was one valid submission made in relation to this review.

This submission was received from Ms Rita O'Grady, Principal Environmental Health Officer with the Health Service Executive. In her correspondence, Ms O'Grady stated that a site visit was made by her colleagues on the 6 November 2015 and that at this visit observations were made on emissions to air, surface water and sewer, as well as observations on noise and waste. Ms O'Grady concluded that, on foot of observations made, and subject to the existing and proposed emissions being in compliance with licence conditions, her colleagues had no significant concerns, from an environmental health perspective, in respect of the licence review.

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

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

Reference Document on Best Available Techniques for the Manufacture of Organic Fine Chemicals (European Commission 2006).

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

Note that aspects of the following reference documents also have relevance:

Reference Document on Best Available Techniques for Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector, (European Commission 2003).

Reference Document on Best Available Techniques for Energy Efficiency, (European Commission 2009).

Reference Document on Best Available Techniques on Emissions from Storage, (European Commission 2006).

Reference Document on the General Principles of Monitoring, (European Commission 2003).

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

I consider that the applicable BAT Conclusion requirements are addressed through: (i) the technologies and techniques as described in the application; (ii) the standard conditions specified in the RD; and (iii) where applicable, the inclusion of additional specific conditions (see Table 1 below).

Table 1. Additional Conditions in RD to address BAT Conclusion requirements:

Reference Document on Best Available Techniques for the Surface Treatment of Metals and Plastics	
Additional Requirement:	Condition/ Schedule
To control minimum operating temperature and residence time in the new thermal oxidiser (Sections 4.3.2.5 and 4.3.2.9 of the sectoral BREF)	Schedule C.1.1

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

7. Emissions

7.1 Emissions to Air

The main emissions to air arise from the existing and proposed thermal oxidisers, the cryogenic condenser, process scrubber, boilers and from dust exhaust systems. Minor emissions on site are associated with boilers and smaller vents from the production area.

There are six boilers on site, two of which are considered main emissions (A1-1 and A1-2) Both of these boilers are fuelled by kerosene, but are only used as back-up during peak demand. The individual rated thermal input of both these kerosene boilers is 6.31 MW. The remaining four boilers (A1-3 to A1-6) are fuelled by liquid petroleum gas and are regarded as minor emissions (individual thermal inputs approximately 1 MW).

There are seven other emission points to air at the installation (A2-1(a), (b) and (c), and A2-2 to A2-5 inclusive), all of which, due to their emission characteristics are regarded as main emissions to atmosphere.

A2-1(a) is the exhaust from the existing TO, which is used for destructing non-chlorinated solvents in the process emissions. A2-1(b) is the venting from the cryogenic condenser; the condenser is generally used to remove less volatile organic compounds from the process emissions and will continue to be used only as a back-up to the proposed new TO. A2-1(c) is the emission point for this proposed new TO, which will be used to destruct both chlorinated and non-chlorinated solvent emissions from the processes.

A2-2 is the emission point for the process scrubber (used for removing hydrochloric and formic acid from certain processes).

A2-3, A2-4 and A2-5 are emissions points associated with the extraction of pharmaceutical dust from the process buildings.

Condition 6.10 of the RD requires the licensee to maintain a programme for the identification and reduction of any fugitive emissions using an appropriate combination of best available techniques.

Impact of Air Emissions on the Receiving Environment

As part of the application, the applicant commissioned an Air Dispersion Modelling Report for the emissions from the proposed extended installation. The AERMOD Version 7.7 modelling software was used to complete the air dispersion modelling and predict the ambient pollutant concentrations resulting from all the major emissions listed above. Five years of hourly meteorological data for the Finner Meteorological Station was used; namely 2008 to 2010 inclusive, and 2012 to 2013 (data quality for 2009 was considered too poor for use in model). For background air quality, the modelling used 2013 Agency air monitoring data² (Zone C³). Complex terrain data has been incorporated into the modelling assessment and building wake effects have also been taken into consideration.⁴

² *Air Quality in Ireland 2013*, EPA 2014

³ Zone C (15 largest towns in Ireland, excluding Dublin and Cork). Using Zone C would be regarded as conservative, as the installation, strictly speaking is located in Zone D (rural).

⁴ Three grid system (20km x 20 km; 10km x 10 km; 100 m x 100m) incorporating digitised terrain data (using AERMAP), and data from engineering drawings of the installation.

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

- All major emission points operating simultaneously at the licence limits specified in the current licence P0643-02.
- All major emission points operating 24 hours a day, 7 days a week, 365 days a year.
- Ambient air quality for Zone C was used for background concentration.
- With respect to NO₂, the predicted environmental concentrations (PECs) are based on the assumption of 100% conversion of NO_x emitted from the thermal oxidiser to NO₂ in the atmosphere.

The dispersion model in this assessment was used to predict the impact of emissions of oxides of nitrogen, sulphur dioxide and carbon monoxide, hydrogen chloride, total organic carbon (TOC) and specific pollutants (Classes I and II organic substances as specified in the sectoral BAT note), as well as dioxins/furans. These are the pollutants which are characteristic of the proposed air emissions.

As part of this assessment regard was had to the EPA's *Air Dispersion Modelling from Industrial Installations Guidance Note (AG4)* which requires that the process contribution (PC) from industrial installations is added to the background concentration (BC) to obtain the PEC. In order to assess the impact, each PEC is compared with an appropriate environmental assessment level (EAL).

Dichloromethane (DCM) and Tetrahydrofuran (THF) constitute approximately 87 % of the proposed solvent loading to the new TO. Therefore, for the purposes of assessing the maximum hourly PECs of TOC, comparison has been made to the DCM and THF short term environmental assessment levels (EALs) specified in the UK Environment Agency guidance, *IPPC H1*.⁵ DCM and THF are also representative of Class II substances. Therefore, the UK EALs were also used for assessment of this class of organic compounds.

For Class I organic substances, the modelled PECs were compared to the air quality standard (AQS) for benzene taken from the Air Quality Standards Regulations, 2011 (SI 180/2011). Benzene may be regarded as a Class I organic substance but it is also a Class III carcinogenic substance as specified in the sectoral BAT note, with a stringent discharge limit and ambient standard. However, benzene is not used or intended to be used at the installation; but rather, the ambient benzene limit is used as part of a conservative assessment of Class I organic substances.

HCl emissions were assessed against the short term EAL as set in the above UK EA guidance.

Formic acid emissions were assessed against a short term EAL derived from a limit set in the Public Health England guidance⁶ and the UK EA guidance.

For all other parameters above the appropriate EAL is taken from the Air Quality Standards Regulations, 2011.

As can be seen from table 2 below, the PECs are below EALs for all relevant parameters at modelled emission concentrations indicated above. Emission limit

⁵ *Horizontal Guidance Note IPPC H1*, UK EA 2002

⁶ *Public Health England, Formic Acid, Incident Management*, PHE publications gateway number: 2014790, October 2015

values (ELVs) have been set with regard to these emission rates modelled by the applicant, as well as the BAT guidance note for the sector and the relevant legislation on emissions. As the modelling rationale is based on a very conservative scenario it is clear from the table that the emissions to air from the installation will not result in the breach of the air quality standards beyond the boundary of the installation.

Table 2: Emissions to air summary

Parameter	Averaging Period	Process Contribution ($\mu\text{g}/\text{m}^3$)	Max. PEC ($\mu\text{g}/\text{m}^3$) Predicted Environmental Conc. = Process contribution (PC) + Ambient Conc. (AC)	EAL ($\mu\text{g}/\text{m}^3$)	PEC as % of EAL
Nitrogen Oxides (as NO_2)	99.8%ile hourly	23.3	41.3	200	20.7
	Annual	1.23	10.2	40	25.6
SO_2	1 hour (99.73%ile)	7.88	13.9	350	3.96
	24 hour (99.18%ile)	2.8	8.8	125	7.0
	Annual	0.44	3.44	20	17.2
CO	Maximum 8 hour	22.1	622	10,000	6.2
TOC/Class II (as DCM)	1 hour	10.1	10.1	3,000	0.3
	Annual	0.82	0.82	700	0.1
TOC/Class II (as THF)	1 hour (100%ile)	10.1	10.1	59,900	0.2
	Annual	0.82	0.82	3,000	0.03
Class I (as Benzene)	Annual	0.16	0.66	5	13.2
HCl	1 Hour	2.85	2.85	800	0.36
Formic Acid	8 Hour	2.85	2.85	27,000	0.01

Dioxins/Furans (PCDD/F)

The combustion of chlorinated organic solvents can potentially lead to the formation of Dioxins/Furans if the correct thermal treatment controls are not maintained. In order to minimise the risk of Dioxins/Furans formation, the TO must ensure that two key design criteria are met;

- Combustion is as complete as possible by maintaining 2 second retention time at $>1100^{\circ}\text{C}$ – this minimises the risk of pre-cursor organic compounds being emitted from the combustion chamber. (In line with BAT)
- The temperature reduction from 1100°C to 200°C is achieved in an as rapid and controlled manner as possible to ensure the flue gas spends the minimum time within this range.

These operating criteria have been confirmed as part of the commissioning test programme (which is currently on-going) specified in Condition 6.1 of the RD. This condition specifies that the operation criteria must be incorporated into the installation's standard operating procedures. Furthermore, the above minimum combustion temperature and residence time have been incorporated into *Schedule C: Control and Monitoring* of the RD.

A conservative worst case scenario of the emissions limit value of $0.1\text{ng}/\text{Nm}^3$ as per Part 3, Annex VI of the Industrial Emissions Directive (IED) has been modelled by the applicant. No AQSs for ambient dioxins/furans are currently in force at national or European level. However, as a guide reference was made to air quality guidelines issued by the World Health Organisation.⁷ These guidelines do not propose AQSs for Dioxins/Furans because atmospheric exposure to Dioxins/Furans is considered low. Exposure to atmospheric Dioxins/Furans accounts for 'less than 5%' of the daily intake from food. Therefore, no direct comparison to an AQS can be made to determine whether predicted atmospheric concentrations should be considered environmentally significant. However, WHO does state that: 'Air concentrations of $0.3\text{ pg}/\text{m}^3$ or higher are indications of local emission sources that need to be identified and controlled'. On this basis, the Dioxins/Furans benchmark of $0.3\text{ pg}/\text{m}^3$ concentration has been used to provide an indication of whether predicted concentrations should be considered environmentally significant. Dioxins/Furans have a range of vapour pressures and thus exist in both vapour and particle bound states to various degrees. The air dispersion model submitted by the applicant assumes that all Dioxins/Furans remain in the vapour phase. Given that potential source of emissions is from the high temperature destruction of vapour phase solvents (as opposed to the incineration of liquid solvent waste, or municipal waste, etc.) the assumption that any dioxins/furans would remain in the vapour phase in the vicinity of the installation is deemed acceptable.

WHO provides an estimate of $0.1\text{pg}/\text{m}^3$ for urban ambient toxic equivalent air concentrations of Dioxins/Furans. The modelling results indicate a maximum predicted annual average concentration of $0.00062\text{pg}/\text{m}^3$. Combining with the estimated background value of $0.1\text{pg}/\text{m}^3$ gives a total concentration value of $0.10062\text{pg}/\text{m}^3$. Comparing this to the benchmark figure of $0.3\text{pg}/\text{m}^3$ indicates that the predicted concentrations of Dioxins/Furans resulting from the proposed thermal oxidiser would not be considered environmentally significant. The applicable BAT guidance has outlined stringent abatement system operating conditions in order to ensure that dioxin formation is minimised. The IED has outlined air emission limit

⁷ *Air Quality Guidelines for Europe, Second Edition*, World Health Organisation (2000)

values for dioxins which have been set at 0.1 ng/Nm³. The RD requires the licensee to meet all the requirements of the IED, as well as fulfilling the requirements of BAT, and in doing so, based on the applicant modelling, protect human health.

Solvent usage and Chapter V of the Industrial Emissions Directive (IED)

In addition to the general requirements for this class of activity (5.16) under the IED⁸, Chapter V⁹ of the same Directive also specifies separate requirements for solvent related activities which do not fall under the classes of activity specified in Chapter II of the Directive. Chapter V refers to Annex VII¹⁰.

Section 20 of Part 2 of Annex VII specifies a Chapter V threshold of 50 tonnes per annum solvent consumption¹¹. The installation has historically used varying quantities of solvent per annum; with the switchover to the new processes, the proposed annual consumption of solvents is 620 tonnes per annum. Therefore, Chapter V requirements will apply to this installation.

Section 20 specifies that a TOC limit of 20 mg/m³ is specified for relevant emissions to air. BAT for the sector also requires this TOC limit (It is also as proposed and modelled for by the applicant.) Therefore, the RD specifies a limit of 20 mg/m³ for the proposed new TO. In accordance with section 20, the RD (Condition 5.6) also specifies that fugitive emissions must not exceed 15% of the total solvent input, where solvent consumption is greater than 50 tonnes per calendar year.

In accordance with Article 59 of the IED, Condition 5.5 of the RD specifies that any substance or mixtures which, because of their content of VOCs are assigned or need to carry the hazard statements H340, H350, H350i, H360D or H360F, (or the risk phrases R45, R46, R49, R60 or R61) must be replaced, as far as possible by less harmful substances or mixtures within the shortest possible time. For all main emissions potentially containing volatile organic compounds with specific hazard/risk phrases, the RD also specifies ELVs in accordance with the requirements of Part IV of Annex VII.

7.2 Emissions to Sewer

With the installation of the TO, the average daily volume of wastewater at the installation will increase slightly, by approximately 2 m³/day. According to the applicant the average daily discharge from the installation is approximately 191 m³/day. Consequently the license does not require an increase in the current allowable maximum of 300 m³/day.

Other sources of sewer discharges are: direct and indirect process wastewater from production (Including the aqueous fraction from the installation's solvent stripper); utility waste water and sanitary wastewater. All wastewaters streams are combined and passed through the solvent stripper a second time. This wastewater is then stored in a holding tank, prior to testing and release to sewer. Other than the

⁸ DIRECTIVE 2010/75/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (Recast)

⁹ CHAPTER V - SPECIAL PROVISIONS FOR INSTALLATIONS AND ACTIVITIES USING ORGANIC SOLVENTS

¹⁰ ANNEX VII - Technical Provisions For Installations And Activities Using Organic Solvents

¹¹ Section 20 - Manufacturing of pharmaceutical products

removal of solvent, the wastewater streams receive no other treatment prior to their discharge to sewer.

These wastewaters are discharged to Irish Water's sewer network for the Sligo agglomeration.

The Sligo agglomeration incorporates a municipal waste water treatment plant (MWWTP), which has secondary treatment (activated sludge/phosphorous removal), and also incorporates UV treatment. It has a design capacity of approximately 50,000 p.e. The Sligo MWWTP final effluent discharges to the transitional waters of Garavoge River (Garavoge Estuary). These urban wastewater discharges from the Sligo agglomeration are licenced by the Agency under waste water discharge licence (Reg. No. D0014-01).

The maximum discharge volumes from the installation represent about 1.48 % of effluent discharge volumes from Sligo MWWTP. The Agency's most recent national annual report on urban waste water¹² indicates that the Sligo MWWTP is in compliance with the discharge limits for BOD and COD, but not in compliance for ammonia, total phosphorous and dissolved oxygen. However, given the unchanged nature and quantity of the discharges, the proposed pollutant loadings from the installation are not predicted to impact negatively on the water quality in the Garavoge Estuary, which currently has a Water Framework Directive (WFD) classification of 'good' status.

Irish Water, under Section 99E of the EPA Act 1992 as amended, gave its consent¹³ for the discharges from the installation, subject to certain conditions, emission limits, and monitoring requirements which have been incorporated into the RD.

The emission limit values (ELV's) applied by the Agency to this discharge must satisfy the following criteria:

The treatment provided on-site at the installation must satisfy the consent conditions specified by Irish Water, as required by Section 99E of the EPA Act 1992 as amended.

It must be demonstrated that the level of treatment of an installation's effluent, on and off site, is *collectively equivalent* to BAT. BAT for the installation's licensable activity is specified in the BAT Guidance Note for the Pharmaceutical & Other Speciality Organic Chemicals (EPA 2008) and the Reference Document on Best Available Techniques for the Manufacture of Organic Fine Chemicals (European Commission 2005).

In granting a licence for an installation, and in accordance with Section 83(5)(a)(iii) of the EPA Act 1992 as amended, as well as in accordance with Articles 5 and 7 of S.I. 272 of 2009, the Agency must ensure that the quality of any relevant receiving water is not impaired or that the relevant Environmental Quality standards are not exceeded.

As can be seen from table 2 below, there are eleven parameters characterising the discharges from the installation. As also can be seen from the table the majority of the parameters have BAT associated emission levels (BAT-AELs) from the sectoral BAT note (no relevant emission levels associated with 'Potential BAT' were indicated

¹² Focus on Urban waste Water Treatment 2013 (EPA 2014).

¹³ Section 99E response received by the Agency on 12 November 2015.

the sectoral BREF). As part of this assessment it was determined that these proposed limits were in accordance with BAT when on and off-site treatment was taken into account.

The resultant concentrations specified in column 4 below indicate the maximum concentration of the installation's effluent following on and off-site treatment. These maximum concentrations are all well below the corresponding BAT-AELs specified in column 2. Note that the figures in column 4 are based on *dilution only*, and do not take into account any further reduction in concentration achieved by the MWWTP treatment process itself.

Also, comparing columns 4 and 5, it can be seen that, at the point of discharge from the Sligo WWTP, it is highly unlikely that the environmental quality standards¹⁴ (EQSs) for the Garavoge Estuary will be breached due to the installation's discharges. (The estimated figure of 6.75 mg/l for BOD would be much reduced when taking the treatment process at the MWWTP into account; the Sligo MWWTP typically achieves a 95% BOD reduction.)

The proposed ELVs also include limits for sulphates, chlorides and detergents. There is no BAT-AEL or associated 'Potential BAT' limit for this parameter; rather these limits were specified by the water services authority (Irish Water), and in accordance with section 99E of the EPA Act 1992 as amended, these limits have been transposed in the Recommended Decision (RD).

Table 2: Summary of proposed discharges to sewer

1	2	3	4	5
Parameter	BAT-AEL	S99E consent / Proposed Final ELVs	After on and off site treatment	EQS
Temperature	-	40	-	-
pH	6-9	6-9	-	-
	mg/l	mg/l	mg/l	mg/l
BOD	20	450	<6.75	4.0
COD	250	1,300	<19.5	-
Suspended Solids	35	350	<5.25	-
Ammonia	10	25	0.375	-
Total Phosphorous	2	10	<0.030	0.060 (MRP)
Sulphates	-	1,000	22.5	-
Chlorides	-	1,500	<22.5	-
Detergents (as MBAS)	-	20	<0.30	-
Oils, Fats,	10	10	<0.15	-

¹⁴ EQSs (BOD and orthophosphate) for transitional waters as specified in Schedule 5 of *European Communities Environmental Objectives (Surface Waters) Regulations 2009* as amended.

Grease				
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The ELV's proposed above are, therefore, considered to be in accordance with current BAT for the sector, as well as 'potential BAT' specified in the BREF document for the sector. The limits, as specified, also transpose the consent requirements of Irish Water, and furthermore, ensure that the installation's discharges would not result in the breaching the relevant EQSs for the Garavoge Estuary.

Given the above it is considered that the recommended ELVs for this discharge to sewer are considered to satisfy the requirements of the IED, the WFD, and the EPA Act 1992 as amended.

Additional requirements by Irish Water

As mentioned above, Irish Water specified limits for licensee's discharges to sewer. These limits are the proposed limits in the RD, as detailed in table 2 above (column 3).

In addition to the discharge limits, Irish Water also specified 20 additional requirements relating to the discharges to sewer. Ten of these requirements are provided for in the standard conditions of the RD. However, the remaining ten requirements have been transposed into the RD as new conditions. These are: Conditions 5.4.2, 5.4.3, 5.4.4, 5.4.5 and 5.4.6 *Emissions to Sewer*; Condition 6.6 (Sewer Monitoring); Condition 11.12 (Sewer plans and details); Condition 11.13 (Summary report of daily monitoring); Condition 11.14 (advance notification of discharge alterations) and Condition 12.2.1 (monitoring charges).

7.3 Emissions to Waters

There are no process emissions to surface waters from the installation. The only discharges to surface waters are from surface water run-off. This uncontaminated run-off discharges to a small stream that passes through the grounds of the installation. The stream leaves the installation and eventually joins the Garavoge Estuary approximately 1.5 km downstream.

7.4 Emissions to Ground

There are no emissions to ground or to groundwater from the installation.

The Baseline Report section of this report (see section 10) provides a summary in relation to groundwater monitoring and assessments which have been carried out at the installation. The RD requires biannual monitoring of specified wells for a range of parameters, as well soil monitoring every ten years, thereby fulfilling the monitoring requirements specified in the Industrial Emissions Directive.

7.5 Waste

The main hazardous production wastes are aqueous washing liquids and mother liquors with halogenated and non-halogenated solvents. Waste oils, adhesives, sealants, contaminated packaging, inorganic chemical waste, laboratory waste and other hazardous wastes typical of the sector are also generated on-site. These hazardous wastes are exported for disposal/recovery.

The majority of the other production wastes generated by the current activities are and will be recyclable or recoverable, eg. Scrap metal, plastic packaging, timber, cardboard and glass. Mixed municipal waste from the installation is sent to landfill.

The RD requires that disposal or recovery of waste on-site shall only take place in accordance with the conditions of this licence and in accordance with the appropriate National and European legislation and protocols.

7.6 Noise

There is audible plant noise from the external pumps of the tank farms, the process buildings extraction fans and the compressed air lines. Other noise sources include the cooling towers air compressors, boilers and the thermal oxidiser. Baseline noise monitoring was carried out as part of the EIS, which was submitted as part of the original licence application. This baseline report indicates noise levels were generally low, although there was some local traffic and activity noise; i.e. minimal noise prior to initial development at the site.

As part of the current licence, a noise monitoring survey is carried out annually at four individual installation boundary locations, as well as at three noise sensitive receptors outside the boundary. Historical data from these surveys indicate that the installation is consistently compliant with the licence limits.

It is on this basis that the applicant has proposed to conduct a noise survey to incorporate the new TO, and that this would be the final survey if the results were within the licence limits. Discussions held between this inspector and the OEE concluded that, rather than the complete removal of the noise survey requirement, its frequency could be reduced.

Condition 4.3 and Schedule B4: *Noise Emissions* control the noise impact at NSL's; Schedule B.4 also specifies that there shall be no clearly audible tonal component in the noise emissions from the activity at any NSL. In accordance with Agency guidance, noise limits and monitoring requirements in the RD are specified in terms of evening time (as well as day time and night time). Condition 6.16 of the RD provides for a change in the frequency requirement for a noise survey; in light of ongoing compliance at the installation, the RD specifies that the survey should be carried out a frequency to be agreed by the Agency (instead of annually as currently specified.).

8. Use of Resources

The operation of the installation involves the consumption of water, oil and electricity. The estimated quantities used in 2014 are given below.

Resource	Quantity
Electricity	10,737,000 kWhr
Liquified Petroleum Gas	468 m ³
Kerosene	1,134 m ³
Water	83,950 m ³

In addition, over seven tonnes of DCM (R40 - limited evidence of carcinogenic effect) and over nine tonnes of dimethylformamide (R61 may cause harm to unborn child) are used annually on-site. Respective stored amounts of both substances are approximately 28 tonnes and 10 tonnes. 2 tonnes of 2-methoxyethanol is also stored

on-site, as well small amounts of Celpure 1000 filter agent (R48 – Danger of serious damage to health by prolonged exposure). None of the above substances are emitted directly to the environment.

9. Measures to be taken to prevent accidents and limit consequences

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

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

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

10. Measures to be taken upon cessation

A baseline report was submitted with the application. The site has previously been used for agriculture only, with no evidence of other past uses, prior to the construction of the original buildings. The report refers to data from 2015 groundwater analysis as required under the current licence. The groundwater monitoring results indicate elevated levels of conductivity, chloride, chloride, sulphate, iron and manganese. Historically, slightly elevated and/or sporadic levels, of COD, orthophosphate, ammonia and sulphate in the groundwater have been observed. The report concludes that this contamination is due to agricultural activity up-gradient of the installation. The aquifer beneath the site, which is part of the Drumcliffe-Strandhill groundwater body is a locally important bedrock aquifer (The groundwater body is classified as 'good' for the purposes of the WFD, and is classified as 'Possibly at risk' (risk source not specified)).

The report concludes that the risk of contamination of soil/groundwater due to the activity is low; on the basis of the following provisions:

- Impermeable concrete surfaces in all areas associated with the handling and storage of potentially contaminating materials.
- Appropriate bunding for all tank and drum storage areas, with routine integrity testing
- Appropriate drainage incorporating firewater retention facilities.

A Decommissioning Management Plan (DMP) and An Environmental Liabilities Risk assessment (ELRA) have also been submitted with the application (see section 11 below).

In conclusion the site is currently uncontaminated and the risk of contamination from the activities at the installation is low due to the nature of the operation, and the proposed measures as described above.

The RD requires soil monitoring for relevant hazardous substances to be carried out every 10 years, and groundwater monitoring (for relevant hazardous substances) to be carried out every 5 years, in accordance with the requirements of the IED.

11. Fit & Proper Person Assessment

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

Technical Ability

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

Legal Standing

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

Financial Standing

In 2013, under the current licence (P0643-02), the licensee commissioned a DMP and an ELRA for the installation, which were costed at approximately €5,973,000 and €1,866,000 respectively. In 2015 financial provision (parent company guarantee) for €9,162,000 was approved by OEE. A revised DMP and ELRA were submitted as part of this review application and were costed in accordance with the Agency's latest guidance¹⁵. The revised costs were €7,466,000 and €1,866,000 respectively, which would be in line with the current approved financial provision. In any event, a review of both DMP and ELRA, as well as approval of Financial Provision, is required under the RD.

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

¹⁵ Guidance on Assessing and Costing Environmental Liabilities' (EPA 2014)

12. Compliance with Environmental Impact Assessment Directive (85/337/EEC)

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

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

12(a) Human Beings

Likely significant effect	Description of effect	Assessment addressed in section:
Noise nuisance	Potential noise activity at NSLs from manufacturing process.	12(a)(i)
Air pollution	Air quality impacts on human health as a result of operations e.g. thermal oxidiser	12(a)(ii)
Incident/accident	Potential for direct and indirect impacts on human health from fire/explosion or spillage from on-site solvent usage/storage and any incident leading to from air, water, ground/groundwater contamination.	12(a)(iii)

Assessment of Effects on Human Beings

12(a)(i) Noise Nuisance

As discussed in section 7.6 above, the main sources of noise emissions from the installation are associated with the external pumps of the tank farms, the process buildings extraction fans and the compressed air lines. Other noise sources include the cooling towers air compressors, boilers and the thermal oxidiser. There has been no history of noise complaints in recent years at the installation and results from recent annual noise surveys indicates the operation of the extended plant will not result in a breach of the licence limits.

Mitigation Measures

- Main external noise sources located to the rear of the site in order to maximise the distance to the nearest noise sensitive receptor.
- Condition 4.5 and Schedule B4: Noise Emissions controls the noise impact at NSL's.
- Condition 6.17 of the RD includes a requirement for a routine noise survey.

Conclusion

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

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

12(a)(ii) Air quality

As discussed in section 7.1 above, the main emissions to air arise from the existing and proposed thermal oxidisers, the cryogenic condenser, process scrubber, boilers and from dust exhaust systems. Minor emissions on site are associated with boilers/combustion and smaller vents from the production area. The modelled impact of emissions to air from the installation was assessed.

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

Mitigation Measures

- Significant abatement on all main emissions to air, including a thermal oxidiser, cryogenic condenser and HEPA filters.
- Thermal oxidiser (TO) operates to BAT standards (<1050 deg C, < 2 sec residence time) to ensure the destruction of any dioxins/furans formed in the thermal treatment process.
- Abatement of NO_x emissions from the TO is provided by the selective non-catalytic reduction unit.
- Abatement of HCl emissions from TO is provided by caustic scrubber unit.
- ELVs (Schedule B) have been set with regard to these emission rates modelled by the applicant, as well as the BAT guidance note for the sector and the relevant legislation on emissions.
- Condition 5.2 specifies that no emissions from the installation, including odours, shall result in an impairment of, or an interference with amenities or the environment beyond the installation boundary.

Conclusion

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

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

12(a)(iii) Incident/accident

The aspect of the licensed activity with the most potential for incident/accident is considered to arise from the use and storage of solvents on site. Generally speaking, in any solvent-based manufacturing process there is potential for accidental spillages, leaks and fires with subsequent potential for impact on air, soil, ground/groundwater and personnel. Also process effluent which discharges indirectly via the Sligo MWWTP into the Garavoge Estuary, has the potential to convey liquids from accidental spillages, leaks or fire water.

Mitigation Measures

- Process discharges must comply with licence conditions before discharge to sewer; otherwise discharges are recycled for further on-site treatment.
- The licensable activity is carried out inside the main buildings. These buildings have impermeable concrete floors, with potentially polluting substances stored in designated areas with appropriate secondary containment. The design and construction of the containment is in accordance with Agency guidance.
- Likelihood of groundwater contamination is much reduced, as the all bulk storage tanks are bunded, all process pipework is above ground; the process drain is also double contained.
- A shut-off valve is installed on the outlet of the storm water retention which will be activated in the case of incident/accident to prevent the discharge of contaminated surface water to the onsite stream.
- Condition 3.7 requires bunding and leak detection systems;
- Condition 3.10 requires a Class I full retention interceptor on storm water discharge from yard areas and silt traps on all storm water discharges, other than from roofs;
- Condition 3.11 requires the use of fire-water retention facilities at the installation;
- Condition 6.8 of the RD requires all abatement systems to be calibrated and maintained;
- Condition 6.14 requires trigger levels for TOC to be established such that storm water exceeding these levels will be diverted for retention and suitable disposal;
- Condition 9 requires Accident Prevention and Emergency Response Procedures to be maintained, and;
- Schedule C of the RD requires the licensee to maintain appropriate access to standby and /or spares to ensure the operation of the abatement systems.

Conclusion

I am satisfied that there will not be significant effects on human beings, receiving waters, air or soil, due to incidents or accidents from the operation of the activity.

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

13(b) Flora & fauna

Likely significant effect	Description of effect	Effect assessed in section:
Air pollution	Air quality impacts impacting flora/fauna during operation. E.g. Emissions from thermal oxidiser	12(a)(ii) and 12(a)(iii)
Water pollution	Water quality impacting flora/fauna and their habitats from operation of the activity e.g. Process water discharge. Contaminated surface water run-off.	12(b)(i) 12(a)(iii)

Assessment of Effects on Flora and Fauna

12(b)(i) Water pollution

As discussed in section 7.2, 7.3 and 7.4 above, there are no direct emissions to water; rather indirect emissions to water arise from the process discharge (as well as from sanitary discharges), which are treated on-site before being discharged to the Irish Water sewer, with subsequent treatment at the Sligo MWWTP before final discharge to the Garavoge Estuary. Natura 2000 sites with hydrological links to the discharge are the Cumeen Strand/Drumcliffe Bay SAC (Site code: 000627) and the Drumcliffe Bay SPA (Site code: 004013), of which Garavoge Estuary forms a part (see also Appropriate Assessment screening in this report). Section 7 of this report goes into considerable detail in the assessment of the proposed discharge's impact on the receiving waters. On foot of this assessment, limits were specified which aim to ensure that the installation's discharges would not result in the breaching the relevant EQSs for the Garavoge Estuary.

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

Mitigation Measures

In addition to the mitigation measure below, the measures listed in section 12 (a)(iii) also apply to mitigation of water pollution.

- ELVs for process discharges (Schedule B) have been set with regard to the EQSs for the receiving waters, as well as the BAT guidance note for the sector and the relevant legislation on emissions.

Conclusion

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

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

12(c) Soil

Likely significant effect	Description of effect	Assessment Addressed in Section
Soil contamination.	Contamination from accidental spillages e.g. tank/bund failure.	12(a)(iii)

Assessment of Effects on Soil

See assessment and conclusion documented in section 12(a)(iii).

12(d) Water

Likely significant effect	Description of effect	Effect assessed in section:
Water Pollution	Impacts on water quality during operation e.g. Process water discharge.	12(b)(i)
	Contaminated surface water run-off.	12(a)(iii)

Assessment of Effects on Water

See assessments and conclusions documented in section 12(b)(i) and 12(a)(iii).

12(e) Air

Likely significant effect	Description of effect	Effect assessed in section:
Air pollution	Air quality impacts during operation e.g. discharges from thermal oxidiser and cryogenic condenser.	12(a)(ii)

Assessment of Effects on Air

See assessment and conclusion documented in section 13(a)(ii).

12(f) Climate

Likely significant effect	Description of effect	Effect assessed in section:
Greenhouse gas production	Emissions of CO ₂ to atmosphere from boilers/combustion at the installation	12(f)(i)

Assessment of Effects on Climate

12(f)(i) Greenhouse gas production

The operation of boilers and combustion processes at any installation will contribute to the accumulation of greenhouse gases CO₂ in the atmosphere, thereby contributing to climate change. As discussed in section 7.1, there are six boilers on-site, fuelled on LPG and kerosene. Two of these boilers have been determined to be main emissions. The operation of the TO is a combustion process, and similarly produces CO₂.

Mitigation Measures

- The RD requires energy efficiency and resource use efficiency to be addressed as part of the Resource Use and Energy Programme (Condition 7)
- Energy audits are carried out annually at the installation; with recommendations incorporated into the EMS.
- New TO more efficient than existing TO; incorporating variable speed drive motors and heat recovery from the exhaust gases.

Conclusion

I am satisfied that there will not be significant effects on climate from the operation of the activity.

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

12(g) Landscape, Material Assets & Cultural Heritage

Likely significant effect	Description of effect	Assessment Addressed in Section
Archaeology and architecture.	Disturbance or damage of archaeology and architecture from activity at the installation.	12(g)(i)
Landscape and visual impact.	The potential for the operation of the activity to negatively impact the landscape and have a visual impact.	12(g)(ii)
Use of natural resources and generation of wastes	Water, oil, and electricity will be used in the operation of the activity. Hazardous materials will be used on site. Quantities of other wastes will also be produced as part of the licensable activity, such as WWTP sludge	12(g)(iii)

Assessment of effects on landscape, material assets and cultural heritage

12(g)(i) Disturbance of archaeology and architecture.

The EIS noted that there were three features¹⁶ of archaeological or cultural significance within the installation boundary. These features were protected during the original construction phase of the installation. The EIS stated that current and proposed emissions from the operation of the activity are unlikely to impact on any such features.

Mitigation Measures

No particular mitigation measures are proposed in the RD.

Conclusion

I am satisfied that there will not be significant effects on archaeology and architecture from the operation of the activity, including the operation of the new TO.

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

12(g)(ii) Landscape and visual impact.

The installation is located in a semi-rural area at the outskirts of Sligo town. The site and immediate surrounding area are a type of landscape which is common in the area and visually robust on account of the number of small visually self-contained valleys. The operation of the activity is unlikely to impact on the landscape of the area.

Mitigation Measures

¹⁶ Ringfort SMR No: 014:025, Ringfort SMR No:014:024, Mill SMR No: 014:023

- From the public roadside viewpoint the buildings profile does not impinge on distant mountain skyline.
- Planting and retained existing mature vegetation screens much of the buildings from the roadside viewpoint.

Conclusion

I am satisfied that there will not be significant effects on landscape from the operation of the activity.

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

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

Section 8 above outlines the resources and other materials (including hazardous substances used by this activity.

As described in section 7.5, the production wastes generated by the current and proposed activities are mainly recyclable material such as scrap metal, plastic packaging, timber pallets, cardboard, waste paints and thinners.

Mitigation Measures

- Any waste generated on-site that cannot be recycled at the installation is otherwise recovered off site;
- The RD requires that waste is appropriately segregated and stored while on site and that all waste sent off site is transported and recovered/disposed in accordance with National and European Legislation and that waste records are maintained;
- The RD (e.g. Condition 2.2.2.7) requires the prevention, reduction and minimisation of waste;
- The RD (Condition 8) requires waste to be stored in designated areas, protected against spillage and leachate run-off;
- The RD requires energy efficiency and resource use efficiency to be addressed as part of the Resource Use and Energy Programme.

Conclusion

I am satisfied that there will not be significant use of natural resources, other resources or significant generation of wastes from the operation of the activity.

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

12(i) Interaction of effects

I have considered the interaction between the factors referred to in Tables (a) to (h) above and the interaction of the likely effects identified.

The interaction between factors as a result of the operation of the installation are summarised below:

	Climate	Traffic	Soils & Geology	Water	Ecology	Air	Noise	Land-scape	Human Beings	Cultural Heritage	Materials Assets
Climate		x									
Traffic									x		
Soils & Geology				x							
Water			x						x		
Ecology							x				x
Air		x							x		
Noise		x							x		
Landscape				x		x			x		x
Human Beings	x	x			x	x	x	x			x
Cultural Heritage									x		
Material Assets									x		

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

12.2 Reasoned Conclusion on Environmental Impact Assessment

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

13. Compliance with other EU Directives

Industrial Emissions Directive (IED) (2010/75/EU)

The IED requires that the competent authority take account of the general principles set out in Article 11 when determining the conditions of the licence. The installation falls within the scope of Annex 1 of Council Directive 2010/75/EU concerning industrial emissions. The RD as drafted takes account of all of the relevant requirements of Article 11

The use of solvents at this installation falls within the scope of Chapter V Annex VII of Council Directive 2010/75/EU. The RD as drafted takes account of all of the relevant requirements of Chapter II (Provisions for activities listed in Annex I) and Chapter V (special provisions for installations and activities using organic solvents).

Seveso Directive (2012/18/EU)

The applicant made an assessment of the status of the installation in relation to the Seveso III Directive which has been implemented in Ireland via the Chemicals Act (Control of Major Accident Hazards involving Dangerous Substances) Regulations, SI 209/ 2015. The assessment concluded that there are no named substances or categories of Seveso III dangerous substances present in quantities that exceed lower tier thresholds. The Health and Safety Authority (HSA) is the competent authority responsible for administration and enforcement of these regulations.

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

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

Environmental Liability Directive (2004/35/EC)

The Environmental Liabilities Directive has been transposed into national legislation by European Communities (Environmental Liability) Regulations 2008 (SI 547/ 2008). An Environmental Liabilities Risk Assessment (ELRA) and a Decommissioning Management Plan (DMP) have been provided by the applicant and these are discussed above.

The RD includes conditions and schedules, which require the licensee to control operation of the activity and meet the specified ELVs. The RD includes, under Condition 9, measures to be taken in the case of an incident. Conditions 10 and Condition 12 require the DMP and ELRA to be reviewed and approved, as required by the Agency. Condition 12 of the RD as drafted, satisfies all the requirements of the Environmental Liabilities Directive in particular those requirements outlined in Article 3(1) and Annex III of 2004/35/EC.

Water Framework Directive [2000/60/EC]

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

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

The installation is in semi-rural location on the outskirts of Sligo town. The main emissions to air arise from the existing and proposed thermal oxidisers, the cryogenic condenser, process scrubber, boilers and from dust exhaust systems. There are no direct discharges to waters. The installation discharges indirectly to Garavoge Estuary (Sligo Harbour) via the Sligo municipal WWTP.

There are several Natura 2000 sites located in the vicinity (within 15 km) of the activity: Lough Gill SAC (Site code: 001976), Cumeen Strand/Drumcliffe Bay SAC (Site code: 000627), Ben Bulbin, Gleniff and Glenade Complex SAC (Site code: 000623), Ballysadare Bay SAC (Site code: 000622), Union Wood SAC (Site code: 000638), Unshin River SAC (Site code: 001898), Streedagh Point Dunes SAC (Site code: 001680), Cumeen Strand SPA (Site code: 004035), Drumcliffe Bay SPA (Site code: 004013), Sligo/Uplands SPA (Site code: 004187) However, it is considered that

only the European sites at Sligo Harbour and Lough Gill are considered within the zone of influence of the installation's emissions (see appendix). This zone of influence was determined on the basis that, as determined in section 7 above, air emissions will have minimal impact beyond the boundary of the installation, and that furthermore there are no direct discharges to water/groundwater other than uncontaminated surface water. (All process emissions to water are treated at the Sligo MWWTP which discharges to the Garavoge Estuary in Sligo Harbour.)

A screening for Appropriate Assessment was undertaken to assess, in view of best scientific knowledge and the conservation objectives of the site, if the activity, individually or in combination with other plans or projects is likely to have a significant effect on any European Site. In this context, particular attention was paid to the European sites at Sligo Harbour and Lough Gill.

The Agency considered, for the reasons set out below, that the activity is not directly connected with or necessary to the management of those sites as European Sites and that it can be excluded, on the basis of objective scientific information following screening under this Regulation, that the activity, individually or in combination with other plans or projects, will have a significant effect on any European site and accordingly determined that an Appropriate Assessment of the activity is not required.

This determination was made in light of the scale and nature of emissions to the environment; in particular scale and nature of the emissions to air from the installation, and their distance to terrestrial habitats. Air dispersion modelling demonstrates that emissions from the proposed activity will not result in ground level concentrations which exceed the relevant air quality standards for the protection of vegetation and the environment. With regards to hydrologically linked sites, it has been determined that the Sligo municipal WWTP has the capacity to sufficiently treat the effluent discharges from the activity; and that furthermore, there are no direct emissions to surface water or emissions groundwater from the installation. Specific precautionary infrastructural and procedural measures are in place at the installation to prevent significant impacts occurring due to chemical spills or fire.

Cross Office Liaison

I consulted OEE Inspectors, Helen Boyce and John Gibbons in relation to this site, as well as to OEE Inspector Niamh O'Donoghue in relation to individual licence conditions, Denise O'Riordan in relation to financial provision, and Senior Inspector Ian Marnane in relation to air modelling. In general, the OEE have no significant concerns regarding the proposed changes to the licensable activity.

Recommended Determination (RD)

The recommended determination specifies the necessary measures to provide that the installation shall be operated in accordance with the requirements of Section 83(5) of the EPA Act 1992 as amended, and having regard to the AA screening and EIA.

The recommended determination specifies ELVs that have been determined on the basis of BAT and relevant EQS's, as well as the requirements of Irish Water. Monitoring requirements specified in the RD are set with regard to BAT.

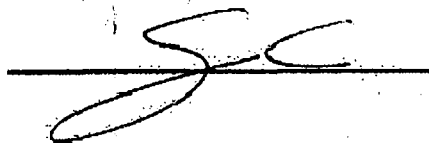
Charges

The annual charge included in the Recommended Determination is the 2015 annual enforcement charge of €10,842.96 to cover the anticipated enforcement effort for the site.

Recommendation

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

Signed

A handwritten signature in black ink, appearing to be 'G. Clabby', written over a horizontal line.

Gavin Clabby

Office of Climate Licensing & Resource Use

Procedural Note

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

Appendix

European Site (site code)	Distance/ Direction from installation	Qualifying interests (* denotes a priority habitat)	Conservation objectives
Lough Gill SAC (Site code: 001976),	1 km south	<p>Habitats:</p> <p>Natural eutrophic lakes with Magnopotamion or Hydrocharition - type vegetation</p> <p>Old sessile oak woods with <i>Ilex</i> and <i>Blechnum</i> in the British Isles</p> <p>Alluvial forests with <i>Alnus glutinosa</i> and <i>Fraxinus excelsior</i> (Alno-Padion, Alnion incanae, Salicion albae)*</p> <p>Species:</p> <p>White-clawed crayfish (<i>Austropotamobius pallipes</i>)</p> <p>Sea Lamprey (<i>Petromyzon marinus</i>)</p> <p>Brook Lamprey (<i>Lampetra planeri</i>)</p> <p>River Lamprey (<i>Lampetra fluviatilis</i>)</p> <p>Salmon (<i>Salmo salar</i>)</p> <p>Otter (<i>Lutra lutra</i>)</p>	As per NPWS (2015) Conservation objectives for Lough Gill SAC [001976]. Generic Version 4.0 Department of Arts, Heritage and the Gaeltacht (dated 13/02/2015).
Cumeen Strand/Drum cliffe Bay SAC (Site code: 000627),	1.3 km west	<p>Habitats:</p> <p>Estauries</p> <p>Mudflats and sandflats not covered by seawater at low tide</p> <p>Embryonic shifting dunes</p> <p>Shifting dunes along the shoreline with <i>Ammophila arenaria</i> (white dunes)</p> <p>Fixed coastal dunes with herbaceous vegetation (grey dunes)*</p> <p><i>Juniperus communis</i> formations on heaths or calcareous grasslands</p> <p>Petrifying springs with tufa formation (Cratoneuria)*</p>	As per NPWS (2013) Conservation objectives for Cumeen Strand/Drumcliffe Bay (Sligo Bay) SAC [000627]. Version 1 Department of Arts, Heritage and the Gaeltacht (dated 18/09/2013).

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		<p>Species:</p> <p>Marsh Snail (<i>Vertigo angustior</i>)</p> <p>Sea Lamprey (<i>Petromyzon marinus</i>)</p> <p>River Lamprey (<i>Lampetra fluviatilis</i>)</p> <p>Harbour Seal (<i>Phoca Vitulina</i>)</p>	
<p>Cumeen Strand SPA (Site code: 004035),</p>	<p>1.3 km west</p>	<p>Habitats:</p> <p>Wetland habitat</p> <p>Species:</p> <p>Light-bellied Brent Goose (<i>Branta bernicla hrota</i>)</p> <p>Oystercatcher (<i>Haematopus ostralegus</i>)</p> <p>Redshank (<i>Tringa tetanus</i>)</p>	<p>As per NPWS (2013) Conservation objectives for Cumeen Strand SPA [004035]. Version 1 Department of Arts, Heritage and the Gaeltacht.</p>

1. The first part of the document
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of the country and the
state of the economy.

2. The second part of the document
describes the state of the
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