This Report has been cleared for submission to the Board by Programme Manager, Marie O'Connor

Signed: Roisin Kearey ***Date: 19/11/2019***

OFFICE OF ENVIRONMENTAL SUSTAINABILITY

INSPECTOR'S REPORT ON AN INDUSTRIAL EMISSIONS LICENCE APPLICATION, LICENCE REGISTER NUMBER P1087-01

TO: DIRECTORS

FROM: Jennifer Cope	**DATE: 19 November 2019**

Applicant:	AbbVie Ireland NL B.V.
CRO number:	906838 (status: normal)
Location/address:	Located on the outskirts of Sligo Town, Old Bundoran Road, Sligo
Application date:	05/09/2018
Class of activity (under EPA Act 1992 as amended):	5.16 The production of pharmaceutical products including intermediates.
Category of activity under IED (2010/75/EU):	4.5 Production of pharmaceutical products including intermediates.
EPA GMO permit:	Not required
EPA GHG permit:	Not required

European Directives/Regulations (and international legal instruments) relevant to this assessment are listed in the appendix of this report.

CID:	Commission Implementing Decision for common waste water and waste gas treatment/management systems in the chemical sector (2016/902/EU)

Any other relevant BREF documents/ national BAT notes are listed in the appendix of this report

Activity description/background: Biopharmaceutical manufacturing installation.	
Additional information received:	18/01/2019, 23/09/2019, 15/10/2019
No of submissions received:	Three
EIAR submitted: Yes (05/09/2018)	NIS submitted: 18/01/2019
Site visit: 12/09/2019	Site notice check: 4/10/2018

1. Activity description/background

AbbVie Ireland NL B.V. (hereafter referred to as AbbVie) is in the process of constructing an integrated biochemical installation and intends to commence production in January 2020 and will operate 7 days per week, 24 hours per day. The new integrated biochemical manufacturing operation replaces a redundant manufacturing facility at the site. There is also an existing separate Abbvie manufacturing operation within the installation boundary, which is not a licensable activity in its own right, manufacturing drug delivery devices such as auto injector pens. This existing operation uses common utilities and is part of the installation.

The total number of staff expected on site will be approximately 100 individuals once the plant is fully operational. The installation is located at Ballytivnan approximately 1.7 km north east of Sligo town centre. The site is also located approximately 1 km from another AbbVie installation (Register No. P0643-03) on the Manorhamilton Road established in 2002.

2. Process Description

Existing site operation

The existing site operation involves moulding, pad printing and sub-assembly of plastic components for use in combination devices supporting AbbVie medicinal products.

New integrated biochemical installation

The new integrated biochemical manufacturing operation at the installation replaces a redundant manufacturing facility at the site. It has been designed to manufacture special medicine for treating illnesses (like cancer) in a highly controlled and contained environment. The main process includes the linking of a bio-pharmaceutical molecule to a cytotoxic molecule providing effective delivery of the medicine within the patient. At this stage, it is anticipated that there will be 2 no. drug lines produced in the suite.

The main process steps are Buffer Preparation, Thawing, Formulation, and then Vial Filling and Lyophilisation (freeze-drying) followed by semi-automatic inspection and cold storage before shipping. To support these operations additional clean utilities will be required. The main support functions consist of Water for Injection and Clean Steam generation, storage and distribution, as well as raw material and Active Pharmaceutical Ingredients (API) storage.

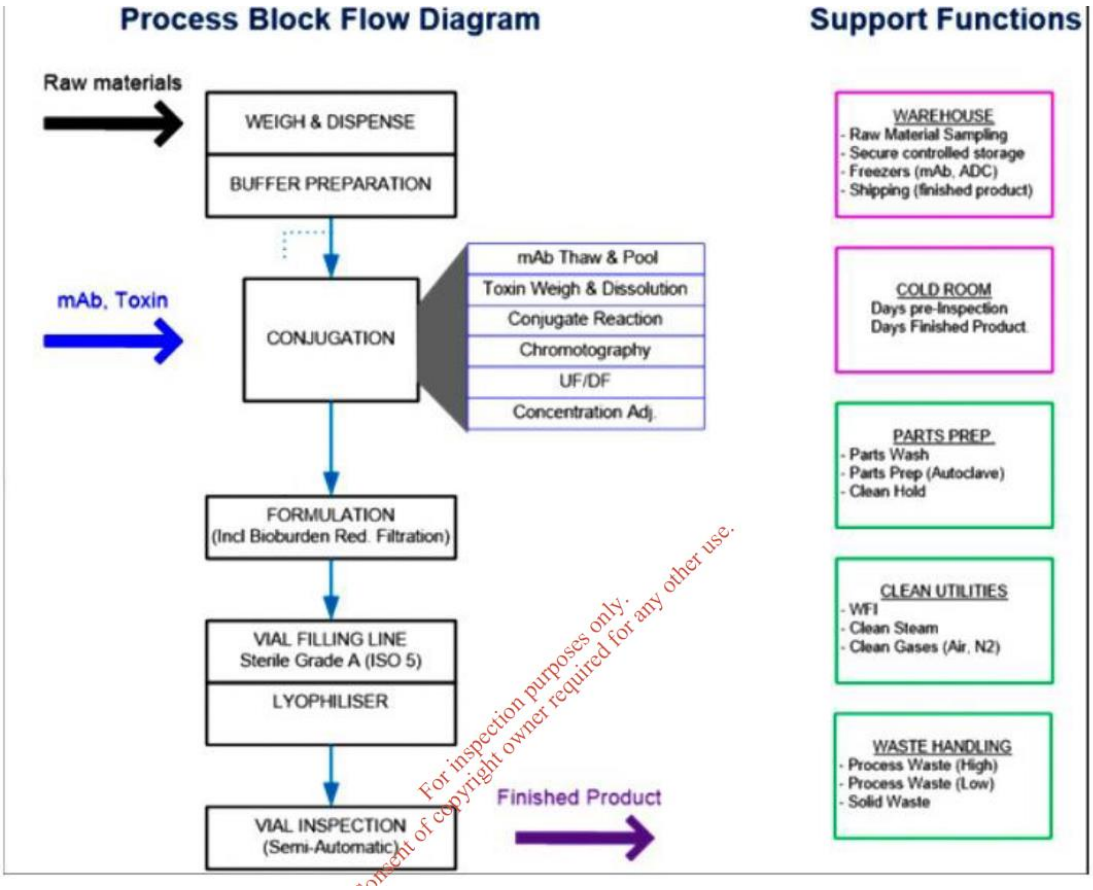


Figure 1: Process Block Flow Diagram for Bio-chemical Pharmaceutical Production.

3. Best Available Techniques

BAT for IE installations

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 an Industrial Emissions Directive (IED) licence. Therefore, BAT for the installation was assessed against the BAT conclusions contained in the relevant Commission Implementing Decision (CID) document specified on page one of this report. Appendix 5 sets out a summary of how the BAT conclusions published in the Common Waste Water CID 2016/192 (CWW CID) have been considered in the licence.

The RD specifies emission limit values in line with BAT associated emission levels (AELs) in the CWW CID, and the BAT Guidance Note for Pharmaceutical and Other Speciality Organic Chemicals, where relevant.

The assessment has demonstrated that the installation will comply with all applicable BAT Conclusion requirements specified in the CID and be in accordance with the guidance specified in the relevant national BAT note (as detailed on page one of this report, and in the appendices).

I consider that the applicable BAT Conclusion requirements are addressed through the technologies and techniques as described in the application, as well as the conditions specified in the RD (see table in Appendix 5).

4. Planning Permission, EIAR and EIA Requirements

4.1 EIA Screening

The licence application was submitted to the Agency after 16 May 2017, the date for transposition of Directive 2014/52/EU amending the 2011 EIA Directive. The Directive has not, however, been fully transposed into Irish legislation to date. In accordance with the advice on administrative provisions in advance of transposition contained in the Department of Housing, Planning Community and Local Government Circular Letter PL1/2017, it is proposed to apply the requirements of Directive 2014/52/EU.

The application was accompanied by an Environmental Impact Assessment Report (EIAR), in accordance with the provisions of Schedule 5 of the Planning and Development Regulations 2001 as amended.

Item 6 (b) of Part 2 of schedule 5 provides that an EIA is required for infrastructure projects comprising:

All installations for production of pesticides and pharmaceutical products, paint and varnishes, elastomers and peroxides using a chemical or biological process.

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

A number of planning applications have been made by the applicant for the area within the installation boundary. Details of the most recent planning permission PL 18/185 has been provided in the application form.

An EIAR relating to planning permission PL 18/185 for an integrated biochemical installation was submitted to the planning authority (Sligo County Council).

4.3 Environmental Impact Assessment Directive

Having specific regard to EIA, this Inspector's report as a whole is intended to identify, describe and assess for the Agency 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 environmental factors: population and human health, biodiversity, land, soil, water, air and climate; the landscape, material assets and cultural heritage.

This Inspector's report addresses the interaction between those effects and the related development forming part of the wider project. The cumulative effects with other developments in the vicinity of the activity have also been considered, as regards the combined effects of emissions. In addition, the vulnerability of the activity to risks of major accidents and/or disasters has been considered. The main mitigation measures proposed to address the range of predicted significant effects arising from the activity have been outlined. This Inspector's report proposes conclusions to the Agency in relation to such effects.

While the environmental factors have been considered throughout my entire assessment, the following table identifies, for ease of reference, the sections of this

report where each environmental factor has been predominantly discussed. See also Section 12 Environmental Impact Assessment of this report.

Table of Environmental Factors

Environmental Factor	Addressed in the following Sections:
Population and Human Health	Emissions to Air, Discharges to Water and Ground, Noise, Waste, prevention of accidents
Biodiversity	Emissions to Air, Water and Ground, Noise, Waste, prevention of accidents
Land	Discharges to Water and Ground, prevention of accidents
Soil	Discharges to Water and Ground, prevention of accidents
Water	Emissions to Water and Ground, prevention of accidents
Air	Emissions to Air, prevention of accidents
Climate	Emissions to air, prevention of accidents
Landscape	Landscape, material assets & cultural heritage
Material assets	Use of resources, landscape, material assets & cultural heritage
Cultural heritage	Landscape, material assets & cultural heritage

4.4 Consultation with Competent Authorities

Consultation was carried out between Sligo County Council and the Agency under the relevant section of the EPA Act 1992 as amended.

Sligo County Council confirmed that planning permission has been granted under PL 18/185 and that EIA was carried out by the planning authority. Sligo County Council had no further any observations on the licence application and EIAR.

5. Submissions

There were three valid submissions received in relation to the licence application. While the main points raised in the submission are briefly summarised in the table below, the original submission should be referred to at all times for greater detail and expansion of particular points.

The issues raised in the submissions are addressed in this Inspector's report and taken into consideration during the preparation of the Recommended Determination.

<table>
<tr><td colspan="4">Submissions</td></tr>
<tr><td>1</td><td>Name & Position:
Finan Gallagher, Principal Environmental Health Officer</td><td>Organisation:
HSE –, Environmental Health Service Sligo/Leitrim/West Cavan Ardaghowen, Sligo, F91T25N</td><td>Date received:
01 November 2018</td></tr>
<tr><td></td><td colspan="3">Issue raised:
1. Water
In summary, the HSE carried out a site visit on 18 October 2018 and made some observations and recommendations in relation to ground water. The HSE suggests that clarification on the chloride, iron, manganese, aluminium and arsenic exceedances in the groundwater would be beneficial. The HSE recommends that a regime of biannual monitoring at the three existing wells on-site will be continued and regular sewer integrity testing and repair, where necessary, to provide greater clarity on the current groundwater quality and reasons for exceedances.
Response:
The applicant is unclear whether the measurements are accurate. See section 11 of this Inspector's report for further details. The RD specifies groundwater monitoring annually for pH, COD, conductivity, chloride; and quarterly for aluminium, nickel, iron, manganese and arsenic; and every five years for relevant hazardous substances. The RD requires the licensee to integrity test underground pipelines every three years and requires corrective measures where necessary.</td></tr>
<tr><td>2</td><td>Name & Position:
Ms Aisling Donegan, Senior Fisheries Environmental Officer</td><td>Organisation:
Inland Fisheries Ireland, Ardnaree House, Abbey Street, Ballina, Mayo</td><td>Date received:
22 October 2018</td></tr>
<tr><td></td><td colspan="3">Issue raised:
1. Water
In summary, IFI observes that surface water from the installation drains via land drains to the Shannon Eighter, which flows into the Willsborough Stream [also referred to as the Doonally River] and ultimately into the Cummeen Strand/Drumcliff Bay (Sligo Bay) SAC (site code 000627). The IFI asserts that the Willsborough Stream is of good ecological status and provides habitat for brown trout and sea trout and that the Cummeen Strand/Drumcliff Bay (Sligo Bay) SAC is designated for the protection of sea and river lamprey.
IFI recommends the following:
• An emergency response plan must be drawn up with IFI included as a notifiable body in case of a polluting discharge to surface water or ground water.
• A fire water recovery system must be in place to ensure no polluted water can enter the adjacent watercourse via the surface water drainage network.</td></tr>
</table>

Submissions			
	IFI also recommends that Irish Water is satisfied that the process effluent discharge will not have a negative impact on the sewer network or the final effluent discharge from the Sligo Waste Water Treatment Plant. Response: The RD requires the licensee in advance of the commencement of the licensed activity to ensure that a documented Accident Prevention Procedure and Emergency Response procedure is in place that addresses the hazards and emergency situations on-site. The RD specifies that the licensee notify the IFI as soon as practicable after the occurrence of any incident which relates to a discharge to water. A fire detection and alarm system are in place at the installation. The storm water run-off from building and yards will discharge via the proposed Class 1 by-pass interceptors to drainage ditches which ultimately drain into the Shannon Eighter. A Class I full retention interceptor will be in place at the bunded loading bay and discharges from this area will connect to the existing drainage network and discharge off-site at emission point SW-3. The retention sump will be equipped with a built-in level switch and an oil detector which will shut off the pump and cease the discharge to storm water drain should a major fuel spill be detected in the loading bay. Irish Water, under Section 99E of the EPA Act 1992 as amended, gave its consent for the discharge to sewer from the installation, specifying certain ELVs, as well certain other conditions and monitoring requirements. These ELVs have been incorporated into the RD. The discharge from the Irish Water Municipal Waste Water Treatment Plant is controlled by Waste Water Discharge Licence Reg. No. D0014-01.		
3	Name & Position: Peter Sweetman	Organisation: Mr Sweetman & Associates	Date received: 28 January 2019
	Issues raised: The submission refers to CJEU case references C-258/11, C-164/17, C-323/17, C-461/17 and joined cases C-293/17 and C-294/17 and states the following: "Any licence granted by the EPA for the following applications must comply with the Habitats and Birds Directives and must comply with the following judgements of the CJEU." **Response:** The requirements of the EIA Directive (2011/92/EU as amended by 2014/52/EU) and the Habitats Directive (92/43/EC) & Birds Directive (2009/147/EC) are considered as part of the Environmental Impact Assessment and Appropriate Assessment sections of the report. In addition, the rulings from CJEU references C-323/17, C-258/11, C-164/17, C-461/17 & C-293/17 and C-294/17, form part of this assessment, as appropriate. C-461/17: Part of the C-461/17 ruling deals with the 'EIA Directive' 2011/92/EU (as amended by 2014/52/EU) and this is dealt with in the Environmental Impact Assessment section of this report. I have carried out an in-depth examination of the documentation associated with the licence application and concluded that if the activity is carried out in accordance with the licence and the conditions attached, the operation will not cause environmental pollution. I am satisfied that the operation of the activity is not likely to have any unacceptable direct, indirect or cumulative effects in terms of biodiversity. I have carried out an in-depth examination of the documentation associated with the licence application and concluded that for the reasons set out in the Appropriate Assessment section of this report, that the activity, individually or in combination with other plans or projects, will not have a significant effect on any European Site.		

6. Emissions to Air

This section addresses the following:

- channelled emissions to air
- fugitive emissions

6.1 Channelled Emissions to Air

Assessment

There will be two 1.6 MW liquid petroleum gas (LPG) boilers (A1-1 and A1-2) (used for the generation of plant steam) and will have associated emissions of NO_x, SO_2 and CO. The two boilers will operate in a standby/duty mode, with only one boiler in operation at any one time. However, both boilers were modelled as running simultaneously as a conservative approach and to allow for any potential future need to increase capacity.

The emission limit value for NO_x of 200 mg/m^3 and SO_2 of 35 mg/m^3 for new medium combustion plants as set out in the MCP Directive (2105/2193)/ SI595/2017 *European Union (Medium Combustion Plants) Regulations 2017* is achievable. There are three existing Low Pressure Hot Water (LPHW) boilers and four proposed LPHW boilers which individually are <1MW and emit via a common flue. There will be one 2 MW diesel generator for emergency purposes only. The RD limits the operation of the diesel generator to 500hrs in accordance with MCP Regulations.

There are other emission points to air at the installation which, due to their emission characteristics are not considered environmentally significant and therefore are treated as minor emissions to air.

Air Dispersion Model

As part of the application, air dispersion modelling was carried out to predict the ambient pollutant concentrations resulting from the boiler emissions and the LPHW boilers emissions.

The modelling used was in accordance with published Agency guidance and was considered sufficiently detailed and conservative to adequately assess the impact of the boiler emissions to air. All emissions were modelled for NO_x and SO_2, maximum flows and at the proposed ELVs (200 mg/m^3 for NO_2 and 35 mg/m^3 for SO_2) for emission points A1-1 and A1-2. A cumulative assessment including the neighbouring AbbVie (P0643-03) located approximately 1 km from the installation was undertaken.

The effects of building downwash due to on-site buildings, has been included in the model. Emission points were assumed to run continuously, every hour of the day, 365 days per year.

Cumulative Assessment

The table below gives details of the cumulative worst case predicted impact of the pollutants which are considered characteristic of the proposed air emissions.

Parameter	Averaging Period	Background concentration ($\mu g/m^3$)	Process contribution to PEC ($\mu g/m^3$)	PEC ($\mu g/m^3$) Note 1	PEC as % of Air Quality Standard	Air Quality Standards/ Guidelines ($\mu g/m^3$) Note 2
Nitrogen Oxides (as NO_2)	99.8%ile hourly	26	24.1	50.1	25%	200
	Annual	13	2.4	15.4	39%	40
SO_2	99.7%ile hourly	31.6	80.5	89	25%	350
	Daily	14.6	21.1	28.9	23%	125

Note 1: Predicted Environmental Concentration (PEC) was calculated in accordance with EPA, 2010. EPA OEE Air Dispersion Modelling from installations Guidance Note (AG4), Appendix E.

Note 2: Air Quality Standards Regulations, SI180/2011.

The cumulative assessment with the neighbouring AbbVie installation (Register No. P0643-03) shows that the predicted environmental concentrations are well below the relevant air quality standards. The worst-case NO_x PEC is 25% of the hourly air quality standard and 39% of the annual air quality standard. The worst-case SO_2 PEC is 25% of the hourly air quality standard and 23% of the daily air quality standard. The contribution from the installations for NO_x (process contribution 12% and 6% of the hourly and annual air quality standard respectively) and SO_2 (process contribution 23% and 17% of the hourly and daily air quality standard respectively) is not likely to have a significant impact on the environment.

No abatement is proposed for boiler emissions or emergency generators. The RD specifies an emission limit value of 200 mg/m^3 for NO_x and 35 mg/m^3 for SO_2 in line with the MCP Regulations.

Control Measures

The RD includes the following requirements for the control of emissions to air:

- Emission limits specified are in accordance with what was modelled. The concentration limits are in compliance with the MCP Regulations (SI595/2017).
- Monitoring parameters for the emission to air points. The frequency of monitoring is in compliance with the MCP Regulations (SI595/2017).

In addition, the RD specifies emission limit values, monitoring requirements and other licence conditions, which will ensure the emissions to air will not negatively impact on air quality and will minimise the potential risk to population and human health, soil and biodiversity. Considering the conservative assumptions in modelling and requirements in the RD, it is unlikely that air emissions from the installation will have a significant impact on the environment. At the emission limit values specified in the RD, the predicted ambient concentrations do not exceed air quality standards.

Accidental air emissions could occur if there was a fire or explosion on site. However, the likelihood of accidental emissions is considered low in light of the measures outlined in the "Prevention of Accidents" section below.

6.2 Fugitive Emissions

Assessment

The primary volatile organic solvent in use on site will be Isopropyl Alcohol (IPA) used as 70% IPA on wet wipes and 70% and 99.7% IPA from spray bottles. IPA will be used for surface cleaning of internal work surfaces. The volume of IPA at the installation is expected to be less than 2 tonnes per annum. The proposed use of dimethylacetamide (DMA), acetic acid and dimethyl sulfoxide (DMSO) solvents is expected to be less than 0.4 tonnes per annum. The solvent use at the installation will not exceed the threshold of 50 tonnes/ year solvent consumption specified in Part 2 of Annex VII of the IED.

Solvents are used as part of the printing process in which ink is printed on medical devices. The expected solvent use is 0.9 tonnes per annum. The use of solvents in printing will not exceed the threshold of 15 tonnes solvent consumption per year specified in Part 2 of Annex VII of the IED.

Therefore, Chapter V requirements will not apply to this installation.

Fugitive emissions at the installation may arise from decontamination of work surface and laboratory activities. Solvents used in cleaning (IPA) will be stored in sealed spray bottles and sealed wipes packaging in the warehouse and in smaller cabinets in the production areas until used. IPA wipes and cloth wipes will be put in flammable waste containers for disposal.

Control Measures

The RD requires the licensee to prepare a programme for the identification and reduction of any fugitive emissions using an appropriate combination of best available techniques. The RD specifies in Schedule A, a limitation in the licence to prevent the exceedance of the threshold specified in Chapter V of the IED.

Accidental fugitive emissions may arise from accidental spills or minor leaks. However, the likelihood of accidental fugitive emissions is considered low in light of the measures outlined above and in light of the proposed conditions relating to fugitive emissions discussed above.

7. Discharges to Water and Ground

7.1 Discharges to Waters

7.1.1 Emissions to Waters and Ground

There are no process emissions to waters or ground/groundwater existing or proposed at the installation. There are no storm water discharges to ground proposed or authorised under the RD.

7.1.2 Storm water discharges

The table below gives details on the installation's storm water discharges to waters.

Storm water discharge point details			
Emission Reference	Proposed / Existing	Monitored parameters (monitoring frequency)	Trigger levels established (Y/N)
SW-1	Proposed	Visual, pH, TOC (weekly)	Required by the RD
SW-2	Proposed	Visual, pH, TOC (weekly)	Required by the RD
SW-3	Proposed	Visual, pH, TOC (weekly)	Required by the RD

Assessment

The storm water run-off from building and yards will discharge via the proposed Class 1 by-pass interceptors to drainage ditches which ultimately drain into the Shannon Eighter. A Class I full retention interceptor will be in place at the bunded loading bay and discharges from this area will connect to the existing drainage network and discharge off-site at emission point SW-3. The retention sump will be equipped with a built-in level switch and an oil detector which will shut off the pump and cease the discharge to storm water drain should a major fuel spill be detected in the loading bay.

Control measures

Below are the control measures specified in the RD.

- The RD requires that the three storm water discharges are visually inspected weekly and monitored for pH and total organic carbon weekly, in accordance with *Schedule C.2.3 Monitoring of Storm Water Emissions.*
- The RD requires the licensee to establish and maintain trigger levels and a response programme to address exceedances.
- Storm water flows via full retention or by-pass oil separators as appropriate prior to discharge.
- The RD contains standard conditions in relation to the storage and management of materials and wastes.

The RD also requires that accident and emergency response procedures are put in place. The controls pertaining to accidents and emergencies are addressed in section 11 below. These measures will help to control any impacts which could occur should any mitigation measures fail. It is therefore considered that direct effects as a result of storm water emissions are considered to be neither likely nor significant.

7.2 Emissions to Sewer

7.2.1 Process emissions to sewer

Assessment

The 'low strength' waste water (including boiler blow down and autoclave waste water) will be discharged to sewer via emission point SE-1.

The table below gives details on installation emissions at the sewer, the processes which contribute to the emissions, the type of on-site treatment, off-site treatment and the proposed maximum daily flows.

On-site treatment				
Emission Reference	Proposed / Existing	Process Description	Abatement	Proposed max. flow (m^3/day)
SE-1	Proposed	'Low strength' waste water from process specific waste water including flashpot condensate drains, utilities blowdowns and waste water from non- toxin/product contact equipment e.g. autoclave and buffer prep equipment is discharged to sewer.	On-site flow balancing and pH neutralisation.	180
Off-site treatment				
Name of sewer network/agglomeration: Sligo County Council Waste Water Treatment Plant				
Annual mean (2017) influent to MWWTP (m^3/day): 18,740 m^3. Network Capacity: 37,500 (from AER 2017)				
Responsible authority for network/agglomeration: Irish Water				
Type of treatment: Preliminary, primary, secondary, nutrient removal and tertiary treatment (ultraviolet treatment)				
Receiving water name (and waterbody type): Garavoge Estuary				
Waste water discharge authorisation: (Y) D0014-01				

The loading associated with the proposed discharge, as a percentage of Sligo WWTP is insignificant when compared with the overall plant loading. I consulted with OEE Inspector Liam O'Suilleabhain in relation to the Sligo MWWTP (D0014-01) who indicated that the MWWTP is in compliance with the emission limit values specified in the WWDL D0014-01.

Irish Water, under Section 99E of the EPA Act 1992 as amended, gave its consent for the discharges from the installation, specifying certain ELVs, as well certain other conditions and monitoring requirements. These ELVs have been incorporated into the RD.

In considering the combination of emission limits set in the RD for the on-site treatment, and for the Irish Water discharge (as well as the accepted percentage reductions achievable for MWWTP) it can be considered that the level of treatment of the installation's discharges is equivalent to BAT.

It has been determined that at the point of discharge from the Irish Water agglomeration it is highly unlikely that the environmental quality standards[1] (EQSs) for the receiving water will be breached due to the installation's emissions.

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.

8. Noise

Assessment

The main sources of noise at the installation include cooling towers, boiler stacks, air handling units, condenser units, and various rooftop mounted fan and exhaust units. The site is situated between the N15 and N16 national roads. The nearest noise sensitive locations (NSLs) are the residential dwellings located approximately 20m south, west, north of the site boundary.

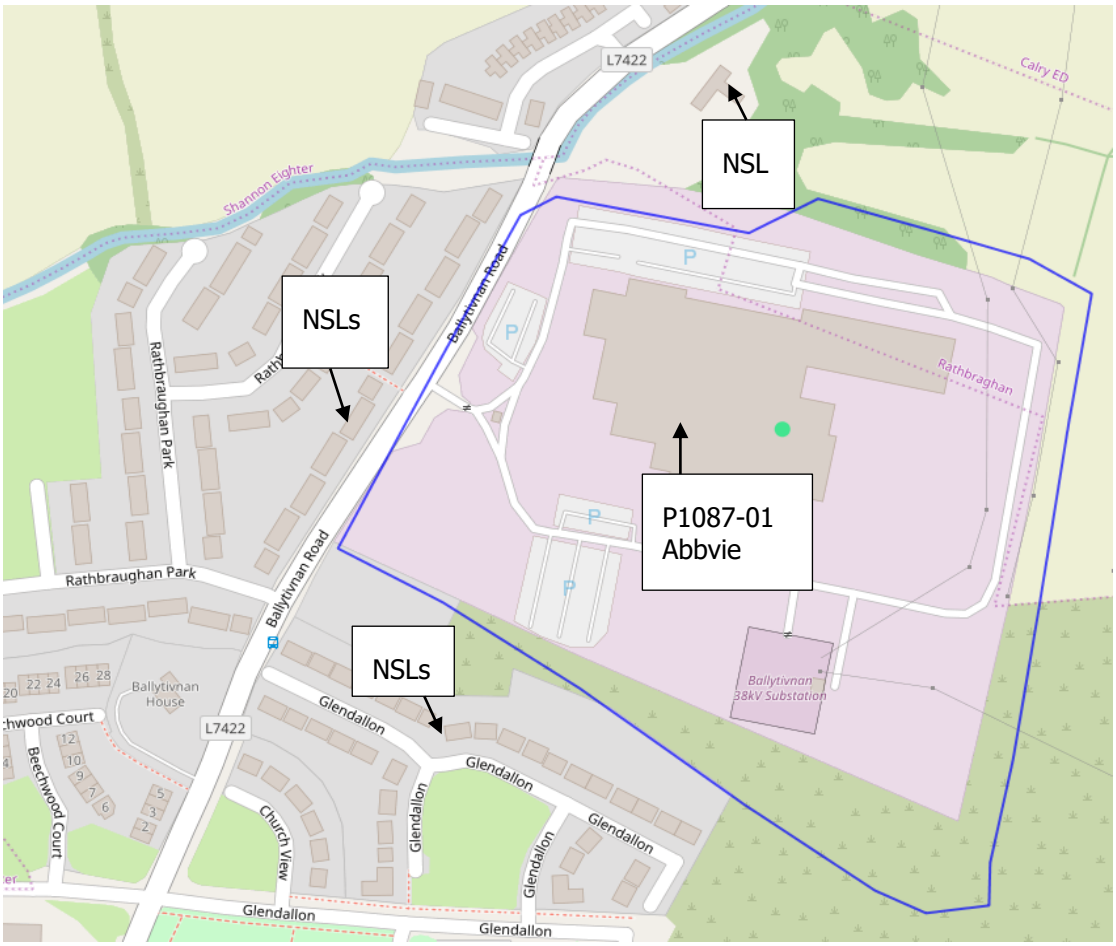


Figure1: Noise sensitive locations (NSLs) in relation to installation.

[1] EQSs as specified in Schedule 5 of *European Communities Environmental Objectives (Surface Waters) Regulations 2009* as amended.

A detailed noise survey has been completed at three noise sensitive locations surrounding the site to establish the existing noise environment. This work has demonstrated that the existing noise environment is dictated by the existing Abbvie installation at Ballytivnan. A noise impact assessment has been completed using information obtained from the design team for significant items of plant. Noise propagation modelling (incorporating baseline noise conditions) has been used to predict worst-case impacts of noise sources from the proposed installation at nearby sensitive locations. This report indicates predicted noise levels are below the day, evening and night-time noise criteria. For assessment purposes, limits specified in the Agency guidance[2] were used as ambient standards. The results indicate that the impact is low, and well within the standard noise emission limit values in the RD.

Control Measures

As part of the design process, to minimise potential noise impact at noise sensitive locations the applicant proposes to implement noise reduction measures such as:

- Barrier screening of on-site buildings.
- Selection of low noise generating plant items e.g. attenuated cooling towers.
- Noisy plant items to be located within buildings.

Due to the proximity of the noise sensitive locations to the installation, the RD proposes that a noise survey of the site operations is carried out annually. Standard noise conditions and emission limit values, which apply at the noise sensitive locations, have been included in the RD.

9. Waste Generation

The operation of the installation will result in the generation of a range of hazardous and non-hazardous wastes which will be segregated at source.

Assessment

The installation will not generate significant quantities of waste. Non-hazardous waste includes paper and cardboard, plastic, glass, timber, metal, compostable food waste, empty toner cartridges, mixed non-recyclables, which are sent off-site for recovery or disposal. Hazardous process waste will consist of both liquid and solid waste streams. 'High High Strength' waste water is liquid waste from high containment areas or liquid waste which has been identified as potentially containing some toxin or other harmful substances. This liquid waste is considered hazardous and is not suitable for treatment by conventional waste water treatment technology. 'High High Strength' waste water will therefore be tankered offsite for disposal by incineration.

Solid hazardous process waste will consist of storage bags, drum liners, tubes and hoses, filter cartridges and support implements such as spatulas, probes and funnels. Typical non-process hazardous waste generated consists of lead batteries, WEEE and fluorescent tubes.

Control Measures

Waste materials will be segregated on-site into appropriate categories and stored appropriately.

[2] NG4 Guidance Note for Noise: Licence Applications, Surveys and Assessments in Relation to Scheduled Activities (EPA, 2016)

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.

If dealt with in accordance with the conditions of the RD, the management of waste generated at the installation will be in accordance with the requirements of Article 11(e) of the Industrial Emissions Directive.

A waste management plan is required as part of the EMS in the RD. There are standard conditions in the RD pertaining to the storage and management of waste generated by the activity.

10. Use of Resources

The applicant has provided a comprehensive list of resources consumed at the installation; these are listed in the application form.

The operation of the installation will involve the consumption of electricity, water, liquid petroleum gas and oil. The estimated quantities to be used in a calendar year are given below.

Resource	**Quantity per annum**
Electricity	15,000 MWh
Water (public supply)	90,500 m^3
Liquid petroleum gas (LPG)	2,000 m^3
Gas Oil	6 m^3

Hazardous Materials

Diesel will be stored on-site for use in the emergency diesel generator. No bulk chemicals will be stored on-site. Small quantities of chemicals in sealed bottles and drums will be stored within the warehouse and in the two self-bunded and lockable external chemstores. The proposed use of IPA (solvent) for cleaning (decontamination of work surfaces) is less than 2 tonnes per annum. The proposed use of diemethylacetamide (DMA), acetic acid and dimethyl sulfoxide (DMSO) for preparation of the solutions for biochemical production is to be approximately 0.4 tonnes per annum. Fuel and chemical storage tanks will be bunded.

The main substance of concern related to the activity is diesel (Hazard statement H351, H411).

The amount of hazardous materials to be consumed for the proposed activity is considered low, especially when compared to traditional pharmaceutical manufacture. The likelihood of accidental releases of these substances to the environment, as a result of the licensable activity, is low. Furthermore, as part of the Environmental Management System (Condition 2 and Condition 7 of the RD) the licensee must annually review of all operations and processes with respect to cleaner production and the efficient use of raw materials.

Control Measures

- Condition 7 of the licence requires an energy audit to be carried out and repeated at intervals as required by the Agency.

- The RD provides for the inclusion of Energy Efficient Management as part of the EMS, which is in accordance with the BREF on Energy Efficiency.
- The RD specifies that the EMS Schedule of Environmental Objectives and Targets shall include an evaluation of options for the use of cleaner technology and cleaner production.

11. Accidents and Cessation

This section addresses any likelihood of accidents at the installation, as well as the measures required to protect the environment in the event of the closure of the activity.

11.1 Prevention of Accidents

The operation of any activity involves a certain amount of risk to the environment and human health. The table below specifies the risks and associated safety measures relevant to this installation.

Potential accidents & measures for prevention/limitation of consequences	
Potential for an accident or hazardous/ emergency situation to arise from activities at the installation	• Fire leading to emissions to air, water and/or soil. • Spillages/leaks due to accidents on-site. • Spillage of chemicals, raw materials and diesel during delivery and unloading operations.
Preventative/Mitigation measures to reduce the likelihood of accidents and mitigate the effects of the consequences of an accident at the installation	• Provision and maintenance of adequate bunding. • Drainage from the diesel loading bay will be via a Class 1 full retention interceptor. • Fire detection and alarm system in place. • Automatic sprinkler system.
Additional measures provided for in the RD	• Accident prevention and emergency response requirements (Condition 9). • Integrity of tanks to be assessed every 3 years and maintenance carried out as required (Condition 6). • Storm water discharge points to be visually monitored (Schedule C).

Assessment

The risk of accidents and their consequences, and the preventative and mitigation measures listed in the table above, have been considered in full in the assessments carried out throughout this report. The RD requires the licensee to carry out a risk assessment to determine if the activity should have a fire-water retention facility.

It should be noted that the quantities of Dangerous Substances used are below the thresholds which would make the installation subject to the additional controls for major accident prevention and emergency response, specified in the Seveso III Directive (2012/18/EU).

Control Measures

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.

11.2 Cessation of activity

The application details a range of measures to be employed upon cessation of the activity. These include:

- Cancellation of incoming raw materials and cessation of all production activities.
- Full decontamination and decommissioning of all production equipment and building surfaces.
- All storage areas fully emptied and stored material transported off-site or disposed of and decontamination, decommissioning and verification of all site utility services.
- Disposal or recovery of all waste materials in a manner that complies with regulatory requirements.

Condition 10 of the RD requires the proper closure of the activity with the aim of protecting the environment.

Assessment

Baseline Report

Article 22(2) of the IED requires that where the activity involves the use, production or release of relevant hazardous substances and having regard to the possibility of soil and groundwater contamination at the site of the installation, the operator shall prepare and submit to the competent authority a baseline report before commencement of the licensable activity.

The baseline report is a tool that permits, as far as possible, a quantified comparison between the state of the site described in that report and the state of the site upon definitive cessation of activities, in order to ascertain whether a significant increase in pollution of soil or groundwater has taken place.

A baseline report (ref: Attachment 4.8.3 of the licence application, dated: 3/09/2018) was submitted with the application. The site was used for industrial purposes from circa 1972 until present. Prior to its development into industrial land use the site had previously been used for agriculture purposes. The baseline report submitted states that chloride was detected above the groundwater threshold value of 24 mg/l, which is an indication of the presence of saline or other intrusions, at MW1 (63.5 mg/l) and MW2 (25.8 mg/l). The overall groundwater threshold value range for chloride specified in the Groundwater Regulations 2010 as amended (SI9/2010 and SI366/2016)) is 24 – 187.5 mg/l. The report states that the difference between the upgradient of the site (MW3) and downgradient of the site (MW1 and MW2) may be a result of a discharge to ground on site (e.g. leaky sewer line). I note that the levels of chloride are within the overall threshold value range. Elevated levels of aluminium, nickel, iron, manganese and arsenic was detected in the groundwater samples at concentrations above the groundwater threshold values. The applicant is unclear whether the measurements are accurate and suspect that any pollution is down to a leaky sewer line. The RD requires the licensee to arrange for the carrying out, by an appropriately qualified consultant/professional, of a comprehensive hydrogeological investigation of the site. The RD specifies groundwater monitoring annually for pH, COD, conductivity, chloride; and quarterly for aluminium, nickel, iron, manganese and arsenic; and every

five years for relevant hazardous substances. The RD requires the licensee to integrity test underground pipelines within three months of the date of the grant of the licence and requires corrective measures where necessary.

Control Measures

Condition 10 of the RD requires the licensee to affect the proper closure of the activity to the satisfaction of the Agency by decommissioning, rendering safe or removing for disposal/recovery, buildings, plant or equipment, or any waste, materials or substances that may result in environmental pollution.

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

12. Environmental Impact Assessment

12.1 Statutory Provisions

This EIA has had regard to the information provided by the applicant, received through consultation, written submission, as well as considering any supplementary information where appropriate and includes the licence assessment completed in this Inspector's Report.

I have carried out an examination, analysis and evaluation of the information provided by the applicant, including the EIAR, received through consultation, written submission, as well as considering any supplementary information, where appropriate. A summary of the submission made by the planning authority is provided in Section 4 of this report. A summary of the submissions made by third parties has been set out at Section 5 of this report.

Having regards to the requirements of the EIA Directive 2014/52/EU, I am satisfied that:

(i) the likely significant environmental effects arising as a consequence of the proposed activity have been satisfactorily identified, described and assessed in accordance with the requirements of Article 3;
(ii) the information contained in the EIAR has been prepared by competent experts and complies with the provisions of Article 5;
(iii) the EIAR contains a non-technical summary in accordance with the requirements of Article 5;
(iv) the public have been given early and effective opportunity to participate in the environmental decision-making procedure.

12.2 Alternatives

Article 5(1)(d) of the Directive 2014/52/EU requires:

(d) a description of the reasonable alternatives studied by the developer, which are relevant to the project and its specific characteristics, and an indication of the main reasons for the option chosen, taking into account the effects of the project on the environment;

Annex IV of the Directive (Information for the EIAR) provides more detail on 'reasonable alternatives':

2. A description of the reasonable alternatives (for example in terms of project design, technology, location, size and scale) studied by the developer, which are relevant to

the proposed project and its specific characteristics, and an indication of the main reasons for selecting the chosen option, including a comparison of the environmental effects.

The matter of alternatives is addressed in Chapter 3 of the EIAR. The site for the installation was considered most favourable for several reasons including the brownfield site with the existing building shell being the most advantageous solution in terms of operations and logistics. The front of the site is used for parking and laboratories. The existing building is preferable to an extension and the re-use of the building forms a logical pattern of manufacturing islands within the existing installation. The preferred site arrangements maximise the available floor space on-site. The utility buildings are placed to the north so that the manufacturing floor can be developed easily.

In this regard, I consider that the matter of the examination of alternatives has been satisfactorily addressed.

12.3 Likely Significant Direct and Indirect Effects

The likely significant direct and indirect effects of the development are considered in this Inspector's Report under the following headings, after those set out in Article 3 of the EIA Directive 2014/52/EU:

(a) population and human health;

(b) biodiversity, with particular attention to species and habitats protected under Directive 92/43/EEC and Directive 2009/147/EC;

(c) land, soil, water, air and climate;

(d) material assets, cultural heritage and the landscape;

(e) the interaction between the factors referred to in points (a) to (d).

12.3.1 Population & human health

Population and human health are addressed in Chapter 5 of the EIAR. The EIAR evaluates potential impacts from the proposed development on economic activity, land-use, employment, settlement patterns, social patterns and human health. The impacts associated with the proposed development are considered positive in terms of employment and the associated economic and social benefit. No signicant negative impacts are anticipated in relation to land-use, human health or tourism.

The likely significant direct, indirect and cumulative effects of the development on population and human health have been identified, described and assessed, in sections 6, 7, 8, 9, 11 and 13 of this report.

Conclusions

I have examined all the information on population and human health, provided by the applicant, received through consultations, written submissions, as well as considering any supplementary information, where appropriate. I am satisfied that the potential effects identified will be avoided, managed and mitigated by the measures identified and through the proposed conditions of the Recommended Determination. I am, therefore, satisfied that the operation of the activity is not likely to have any unacceptable direct, indirect or cumulative effects in terms of population and human health.

12.3.2 Biodiversity (including Flora and Fauna)

Biodiversity (including Flora and Fauna) is addressed in Chapter 6 of the EIAR. Note that in addition to the Biodiversity Chapter of the EIAR, a separate determination of Appropriate Assessment (AA) under Article 6 of EU Habitats Directive was also required to support this application. The applicant has provided the following AA documentation as part of the application:

- Natura Impact Statement (NIS received by the Agency on 18 January 2019)

As outlined in Section 14 of this Inspector's report an Inspector's Appropriate Assessment has been completed and has determined, based on best scientific knowledge in the field and in accordance with the European Communities (Birds and Natural Habitats) Regulations 2011 as amended, pursuant to Article 6(3) of the Habitats Directive, that the activities, individually or in combination with other plans or projects, will not adversely affect the integrity of any European Site, in particular those site specified in Appendix 2, having regard to their conservation objectives and will not affect the preservation of these sites at favourable conservation status if carried out in accordance with this Recommended Determination and the conditions attached hereto.

The baseline ecological data indicates that the proposed site can be considered to have a low ecological value. The potential impacts to biodiversity are predominantly associated with the construction phase works which are temporary. The operational phase of the project is considered to have negligible impacts given the low ecological value of the habitats.

Potential impacts to biodiversity (including flora and fauna) have been addressed in sections 6, 7, 8, 9, 10, 11, 13 and 14 of this Inspector's report. The likely significant direct, indirect and cumulative effects of the development on biodiversity have been identified, described and assessed in Sections 6, 7, 8, 9, 10, 11, 13 and 14 of this Inspector's report.

Conclusions
I have examined all the information on biodiversity provided by the applicant, received through consultation, written submission, as well as considering any supplementary information, where appropriate. I am satisfied that the potential effects identified will be avoided, managed and mitigated by the measures identified and through the proposed conditions of the Recommended Determination. I am, therefore, satisfied that the operation of the activity is not likely to have any unacceptable direct, indirect or cumulative effects in terms of biodiversity, flora and fauna.

12.3.3 Land and soil (including geology, emissions to ground and groundwater)

Chapter 7 of the EIAR addresses Land, Soil, Geology and Hydrogeology. The environmental factors potentially affected by discharges to ground and groundwaters include: groundwater quality, soil, biodiversity, and population & human health.

The potential impacts to ground, groundwater and land and soil are addressed in Section 7, 9, 11 and 13 of this Inspector's report. The installation's emissions to ground and groundwater are assessed in Section 7 of this Inspector's report. There are no proposed process emissions to ground/groundwater at the installation and there are no storm water discharges to ground proposed or authorised in the RD. There will be no increase in hardstanding, all the proposed development is within the footprint of the building and within hardstanding areas. Elevated levels of aluminium, nickel, iron, manganese and arsenic were detected in the groundwater samples at concentrations

above the groundwater threshold values. (see section 11 of this report for further details).

The likely significant direct, indirect and cumulative effects of the development on land and soil have been identified, described and assessed in Sections 7, 9, 11 and 13 of this Inspector's report and are detailed below.

Direct and indirect effects

Should any accidental emission occur, such a chemical spill because of bund failure, it has the potential to discharge to ground and/or groundwater. This could have the potential to affect groundwater quality, soil, biodiversity and population & human health.

Cumulative effects

It is considered that there will be no significant cumulative effect from any accidental emissions to ground and groundwater and other activities/developments in the area.

Conclusions

I have examined all the information on land, soil, geology emissions to ground and groundwater provided by the applicant, received through consultations, written submissions, as well as considering any supplementary information, where appropriate. I am satisfied that the potential effects identified will be avoided, managed and mitigated by the measures identified and through the proposed conditions of the Recommended Determination. I am, therefore, satisfied that the operation of the activity is not likely to have any unacceptable direct, indirect or cumulative effects in terms of on land, soil or geology.

12.3.4 Water (including emissions to sewer, storm water)

Chapter 7 of the EIAR addresses Water and hydrology. The potential impacts to water include water quality, soil, biodiversity and population & human health and are addressed in Sections 7, 11 and 13 of this Inspector's report. The likely significant direct, indirect and cumulative effects of the development on water have been identified, described and assessed in Sections 7, 11 & 13 of this Inspector's report.

Direct and indirect effects

Should any accidental emission occur, e.g. a chemical spill because of bund failure, it has the potential to discharge through the storm water emission point. This could have the potential to affect surface water quality downstream, as well as aquatic habitats within the surface water. Should emission levels in the emission to sewer cause an exceedance of Water Quality Standards at the discharge point of Sligo municipal waste water treatment plant, this could have implications for aquatic biodiversity and species habitats at that discharge point. I consider that no indirect effects are likely as a result of these storm water emissions or emissions to sewer from the activity.

Cumulative effects

The storm water emissions consist of rain water run-off from roofs and non-process areas.

The assessment carried out above takes account of total flow in the sewer network from all discharges into the agglomeration and that the MWWTP is controlled by its own Wastewater Discharge Licence.

It is considered that there will be no significant cumulative effect from storm water emissions and emissions to sewer from the proposed activity and other activities/developments in the area.

Conclusions

I have examined all the information on water (including emissions to water, storm water) provided by the applicant, received through consultations, written submissions, as well as considering any supplementary information, where appropriate. I am satisfied that the potential effects identified will be avoided, managed and mitigated by the measures identified and through the proposed conditions of the Recommended Determination. I am, therefore, satisfied that the operation of the activity is not likely to have any unacceptable direct, indirect or cumulative effects on water (including Emissions to sewer, storm water).

12.3.5 Climatic Factors and Air Quality (including Noise)

Chapter 9 of the EIAR addresses climate and air quality and Chapter 10 addresses noise. The environmental factors potentially affected by emissions to air and noise include population and human health, biodiversity, air and climate. The potential impacts to climate and air are addressed in Sections 6, 8 and 12 of this Inspector's report. The likely significant direct, indirect and cumulative effects of the development from emissions to air have been identified, described and assessed in Sections 6, 8 and 12 of this Inspector's report.

Climate

Climate change is a significant global issue which affects weather and environmental conditions (air, water and soil) which consequently affects population and human health, material assets and cultural heritage and biodiversity. Climate change is caused by warming of the climate system by enhanced levels of atmospheric greenhouse gases (GHG) due to human activities.

Assessment
The main source of emissions of climate altering substances will be the LPG boilers (1.6 MW) on site. There are also three existing Low Pressure Hot Water (LPHW) boilers and four proposed LPHW boilers. There will be one 2 MW diesel generator for emergency purposes only. The combustion plants at the installation are below the threshold for requiring a Greenhouse Gas emissions permit.

The carbon dioxide emissions from the installation will not be significant in relation to Ireland's national annual carbon dioxide emissions.

Mitigation

Regarding reducing the climate impact of the installation under IED, the RD requires energy efficiency and use of cleaner production to be addressed as part of the Environmental Management System. It also requires an energy efficiency audit and an assessment of resource use efficiency to be undertaken in accordance with Condition 7.

It is considered that the likelihood of accidental emissions occurring which could affect climate is low in light of the measures outlined in the "Prevention of Accidents" section below and the proposed conditions in the RD.

Direct and indirect effects

The installation under normal operation is not likely to cause a significant direct effect on the above environmental factors due to emissions of carbon dioxide. It is also

considered that no secondary or indirect effects are likely as a result of these air emissions from the activity.

Cumulative effects

Any combustion process will inevitably produce quantities of GHG gases, any discussion of GHG emissions must be extended to national and global climate impact. It cannot be concluded that the combined emissions from all industrial combustion processes will not have a significant cumulative impact on climate change. However, the total thermal input at this installation is two 1.6 MW boilers, with only one boiler in operation at any one time, which is relatively small and its contribution to the national output would be insignificant. Given the small quantity of climate altering substances that could be released from the activity, in a national context, I consider that the impact of any emissions from the installation on climatic considerations should be minimal.

Air quality

An assessment of Emissions to Air was carried out in Section 6 of this Inspector's report. Should emission levels cause an exceedance of Air Quality Standards (AQS), this could have implications for population & human health, air quality and the health status of biodiversity beyond the installation boundary.

Direct and indirect effects

The above assessment of the installation's air dispersion model indicates that air emissions from the installation under normal operation are not likely to cause a significant direct effect on the above environmental factors. It is also considered that no secondary or indirect effects are likely as a result of these air emissions from the activity.

In relation to the fugitive air emissions, the above assessment would indicate that the fugitive emissions are not likely to have a significant effect on the environment when the installation is operating in accordance with the conditions of the Recommended Determination.

Cumulative effects

Air modelling has taken account of the background levels and it is considered that there is not likely to be a significant cumulative effect from air emissions from the installation and other emissions generated by other activities/developments in the area. In this assessment, it has already been determined that NO_x emissions from the installation will not significantly affect local air quality, individually or cumulatively.

Noise

An assessment of noise was carried out in Section 8 of this Inspector's report. Noise arising from installation could have the potential to cause nuisance for those living in the vicinity of the activity or on noise sensitive species.

Direct and Indirect effects

The likelihood of accidental noise emissions occurring is considered low considering the measures outlined and the conditions discussed above.

I consider that direct significant effects and indirect effects as a result of noise from the activities are unlikely.

Cumulative effects

The site is situated between the N15 and N16 national roads. The existing noise environment is dictated by the existing Abbvie installation at Ballytivnan and road traffic noise. Noise propagation modelling (incorporating baseline noise conditions) has been used to predict worst-case impacts of noise sources from the proposed installation at nearby sensitive locations. This report indicates predicted noise levels are below the day, evening and night-time noise criteria.

Therefore, it is considered that there would not likely be a significant cumulative effect from noise emissions from the activities and other noise emissions generated by other activities/developments in the area.

Conclusions

I have examined all the information on air and climatic factors (including noise) provided by the applicant, received through consultations, written submissions, as well as considering any supplementary information, where appropriate. I am satisfied that the potential effects identified will be avoided, managed and mitigated by the measures identified and through the proposed conditions of the Recommended Determination. I am, therefore, satisfied that the operation of the activity is not likely to have any unacceptable direct, indirect or cumulative effects in terms of climate and air (including noise).

12.3.6 Material Assets (including resource use and waste generation), Cultural Heritage and the Landscape (Including Architectural and Archaeological Heritage as appropriate)

Material Assets and resource use

Chapter 12 of the EIAR addresses material assets. Section 10 of this Inspector's report addresses the use of resources at the installation. The environmental factors potentially affected by resource use include material assets, biodiversity, soil, land and water.

Based on the above assessment of the installation's use of resources, the direct, indirect and cumulative effects have been identified, described and assessed, and are detailed below.

Direct and indirect effects

The likelihood of accidental releases of these substances to the environment is low in light of the measures outlined in this report and in Section 11 Prevention of Accidents and the conditions of the RD discussed above. There will be no additional land take required for the proposed development. According to the EIAR the ESB networks confirm there is adequate capacity in the local network for the increase in demand. The propane gas tank will increase in size as part of the development. The planning authority have not identified any direct or indirect effects in relation to material assets aspects dealt with as part of their assessment.

Cumulative effects

It is considered that significant cumulative effects on the environment from the use of water and hazardous substances by this installation and other developments in the area are not likely. The planning authority did not identify any cumulative effects as part of its assessment.

Waste generation

Chapter 14 of the EIAR addresses waste management. Section 9 of this Inspector's report addresses waste generation at the installation. The environmental factors

potentially affected by waste generated by the activity include: population and human health, air, water, material assets and biodiversity.

Based on the above assessment of waste generated by the activity, the direct, indirect and cumulative effects have been identified, described and assessed, and are detailed below.

Direct and indirect effects

Accidental emissions could occur if waste is not managed or stored correctly. The controls in the RD in relation to waste will prevent the occurrence of possible direct and indirect negative effects on the environment.

Cumulative effects

The controls in the RD in relation to waste will prevent the occurrence of possible negative effects. Significant cumulative effects on the environment from the generation of wastes by this installation and other developments are not likely. I am satisfied that there will be no significant cumulative effects on the environment from the generation of waste by this installation and other developments.

Landscape and visual impact

Chapter 11 of the EIAR addresses landscape and visual impact. The likely significant direct, indirect and cumulative effects of the development on landscape and visual impact have been identified, described and assessed below.

Any disturbance of the landscape of an area has the potential to impact on population and human health and their enjoyment of the surrounding area.

Direct and indirect effects

The planning authority have not identified any direct or indirect effects in relation to landscape and visual impact dealt with as part of their assessment.

Cumulative effect

The planning authority have not identified any cumulative effects in relation to landscape and visual impact dealt with as part of their assessment.

Cultural effects including archaeology and architecture

Chapter 15 of the EIAR addresses Cultural Heritage. The likely significant direct, indirect and cumulative effects of the development on cultural heritage have been identified, described and assessed below.

There are no buildings or features of architectural significance and no known archaeological features at the installation. The nearest site of archaeological interest is located at approximately 94m to the northwest of the installation. Any loss of archaeological or architectural heritage could impact negatively on human beings.

Direct and indirect effects

It is very difficult to envisage any pathway by which emissions from the operation of the activity could impact any feature which may be present.

The planning authority has not identified any direct or indirect effects in relation to cultural effects including archaeology and architecture dealt with as part of their assessment.

Cumulative effect

The planning authority has not identified any cumulative effects in relation to cultural effects including archaeology and architecture dealt with as part of their assessment.

Conclusions

I have examined all the information on material assets (including resource use and waste generation), cultural heritage and the landscape provided by the applicant, received through consultations, written submissions, as well as considering any supplementary information, where appropriate. I am satisfied that the potential effects identified will be avoided, managed and mitigated by the measures identified. I am, therefore, satisfied that the operation of the activity is not likely to have any unacceptable direct, indirect or cumulative effects in terms of material assets (including resource use and waste generation), cultural heritage and the landscape.

12.3.7 Interactions between the factors

Chapter 16 of the EIAR addresses Interaction between the factors.

The most significant interactions between the factors as a result of the activity are summarised below:

Population and human health, air, water and biodiversity

Negative impacts on air quality could affect human health and biodiversity through emissions to air from the boilers and fugitive emissions. Noise arising from the installation could have the potential to cause nuisance for those living in the vicinity of the activity or on noise sensitive species near the site. Emissions to sewer and storm water discharges have the potential to affect the surface water quality and the aquatic habitats and species within these surface waters. As demonstrated in earlier parts of this Inspector's report such effects are considered not to be likely or significant.

Water, soil, biodiversity and population & human health

Accidental discharges or spills may directly and indirectly effect soil, ground water quality, surface water quality downstream, aquatic habitats and aquatic flora and fauna. As demonstrated above, in earlier parts of this Inspector's report such effects are considered not to be likely or significant.

Conclusions

I have considered the interaction between population and human health, biodiversity, land, soil, water, air, climate, landscape, material assets, cultural heritage and the interaction of the likely effects identified throughout this Inspector's report. I am satisfied that the potential effects identified will be avoided, managed and mitigated by the measures identified and through the proposed conditions of the Recommended Determination. I am, therefore, satisfied that the operation of the activity is not likely to have any unacceptable direct or indirect effects in terms of the interaction between the foregoing environmental factors.

12.4 Vulnerability of the Project to Risks of Major Accidents and or Disasters

The EIAR describes the expected effects deriving from the vulnerability of the activity to risks of major accidents and/or disasters that are relevant to the project concerned. This is dealt with in Chapters 6, 7 and 8 of the EIAR. The vulnerability of the project to risks of major accidents and/or disasters has been identified, described and assessed below.

The Seveso Directive and Regulations are not applicable at the installation. The risks of accidents associated with the activity are dealt with in Section 11 of this Inspector's report.

The vulnerability of the installation to natural disasters has been examined. Flooding was considered to be the only natural disaster possibly impacting the installation. There has been no historic flooding of the site identified from the OPW floods map website. A stage 1 Flood Risk Assessment concluded that most of the installation resides in Flood Zone C (where the probability of flooding is low (less than 0.1% Annual Exceedance Probability (AEP) or 1 in 1000 for both river and coastal flooding)). A small proportion of the north eastern and eastern boundary resides in Flood Zone A and is modelled as having an impact as a result of a 1 in 10 (10% AEP) year flood event. This is due to the partly culverted Shannon Eighter watercourse located at the south-eastern boundary. The Shannon Eighter is susceptible to flooding due to the capacity of the culvert during periods of heavy rainfall and high tides. No flooding has been recorded on the site since the development was built in 1970's. The development is considered a "Less Vulnerable Development" due to the nature of the development, e.g. buildings used for industrial and non-residential institutions. The proposed development works are located within Flood Zone C and are suitable development for this flood zone. As a result, there is no expected measurable increase in run-off as a result of this development. Therefore, the site is considered not to be vulnerable to flooding.

The Planning Authority has assessed and considered the effect to be acceptable. No mitigation measures have been proposed in the RD.

The environmental factors potentially affected by accidents at the installation, or the cessation of activity, include: material assets, population and human health, biodiversity, air, soil and water.

Based on the above assessment of accidents the direct, indirect and cumulative effects have been identified, described and assessed, and are detailed below.

Direct and indirect effects

Accidental emissions are addressed in this Inspector's report (sections on air, water, noise, waste generation, use of resources, prevention of accidents). It is considered that the conditions of the RD and the mitigation measures proposed will significantly reduce the likelihood of accidental emissions occurring and limit the environmental consequences of an accidental emission should one occur.

Cumulative effect

It is considered very unlikely that accidents would occur concurrently in the area that would give rise to significant effects on the environment.

Conclusions

I have examined all the information on major accidents and/or disasters provided by the applicant, received through consultations, written submissions, as well as considering any supplementary information, where appropriate. I am satisfied that the potential effects identified will be avoided, managed and mitigated by the measures identified and through the proposed conditions of the Recommended Determination. I am, therefore, satisfied that the operation of the activity is not likely to have any unacceptable direct, indirect or cumulative effects in terms of major accidents and/or disasters.

12.5 Reasoned Conclusion on the significant effects

Having regard to the examination of environmental information contained above, and in particular to the content of the EIAR and supplementary information provided by the applicant, and the submissions from the planning authority, and third parties in the course of the application, it is considered that the potential significant direct and indirect effects of the activities on the environment are as follows:

- Generation of effluent and discharge to sewer.
- Emissions to air.
- Noise emissions.
- Accidental leakages or spills.

Having assessed those potential effects, the Agency has concluded as follows:

- Generation of effluent and discharge to sewer will be mitigated through: imposing emission limit values and implementing monitoring and control measures. Sligo MWWTP has the capacity for the loading associated with the proposed discharge from the installation;
- Emissions to air will be mitigated through: imposing emission limit values to ensure compliance with ambient air quality standards; and implementing monitoring, maintenance and control measures;
- Noise emissions will be mitigated through: imposing daytime, evening-time and night-time noise limits at noise sensitive locations; and implementing monitoring, maintenance and control measures;
- Accidental leakages or spills will be mitigated through inspection and maintenance of bunds and tanks and accident and emergency requirements specified in the RD.

Having regard to the effects (and interactions) identified, described and assessed throughout this Inspector's report, I consider that the monitoring, mitigation and preventative measures proposed will enable the activity to operate without causing environmental pollution, subject to compliance with the licence.

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

13. Appropriate Assessment

Appendix 2 lists the European Sites assessed, their associated qualifying interests and conservation objectives along with the assessment of the effects of the activity on the European Sites.

A screening for Appropriate Assessment was undertaken to assess, in view of best scientific knowledge and the conservation objectives of the site, if the proposed 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 specified in Appendix 2.

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

Site and accordingly determined that an Appropriate Assessment of the activities was required, and for this reason determined to require the applicant to submit a Natura Impact Statement.

This determination has been made based on the project's hydrological connectivity with, and the distance to, European sites.

An Inspector's Appropriate Assessment has been completed and has determined, based on best scientific knowledge in the field and in accordance with the European Communities (Birds and Natural Habitats) Regulations 2011 as amended, pursuant to Article 6(3) of the Habitats Directive, that the activities, individually or in combination with other plans or projects, will not adversely affect the integrity of any European Site, in particular those sites specified in Appendix 2, having regard to their conservation objectives and will not affect the preservation of these sites at favourable conservation status if carried out in accordance with this Recommended Determination and the conditions attached hereto for the following reasons:

- Air dispersion modelling has demonstrated that the impact of air emissions from the installation on qualifying interests of any European site is low;
- All process effluent from the installation is discharged to sewer and ultimately treated in Sligo WWTP in accordance with an EPA waste water discharge licence.
- The licence specifies noise emission limit values at any noise sensitive locations, and the noise modelling assessment demonstrated that these limits can be complied with to avoid disturbance of qualifying interest species.
- While there is potential for accidents and unplanned releases from the installation, it is considered that the conditions of the licence in relation to bunding and the protection of surface water and groundwater, are sufficient to ensure that accidental emissions from the activity will not impact on the qualifying interests of any of the European sites identified above, particularly in light of the nature of the potential accidental emissions.

In light of the foregoing reasons no reasonable scientific doubt remains as to the absence of adverse effects on the integrity of those European Sites: Cummeen Strand /Drumcliff bay (Sligo Bay) SAC (000627) and Cummeen Strand SPA (004035).

14. Fit & Proper Person Assessment

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

Technical Ability

The applicant 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 applicant has demonstrated the technical knowledge required.

Legal Standing

Neither the applicant nor any relevant person has relevant convictions under the Environmental Protection Agency Act 1992, as amended, or under any other relevant environmental legislation.

Financial Provision/Strength

ELRA, CRAMP & FP

The licence category and proposed installation was assessed for the requirements of Environmental Liabilities Risk Assessment (ELRA), Closure, Restoration and Aftercare Management Plan (CRAMP) and Financial Provision (FP), in accordance with Agency guidance. Under this assessment it has been determined that ELRA, CRAMP and FP were not required.

Fit & Proper Conclusion

It is my view, and having regard to the Conditions of the RD, that the applicant can be deemed a Fit & Proper Person for the purpose of this application.

15. Charges

The annual enforcement charge recommended in the RD is €13,773, which reflects the anticipated enforcement effort required and the cost of monitoring.

16. Recommendation

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

I recommend that a Proposed Determination be issued subject to the conditions and for the reasons as drafted in the RD.

Signed

Jennifer Cope

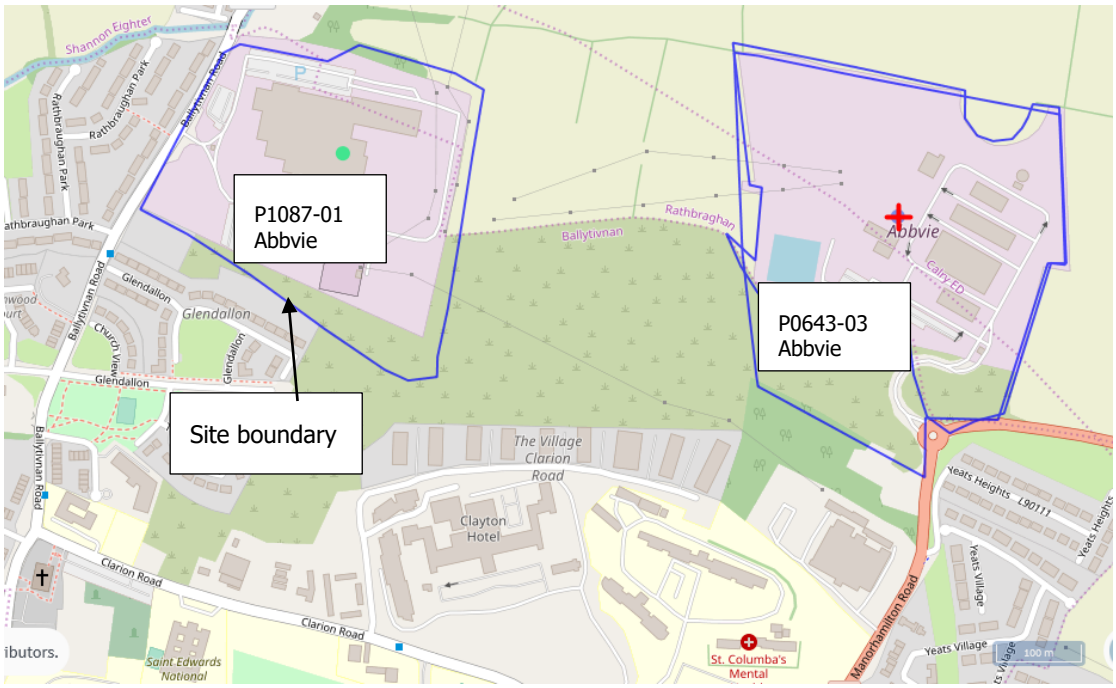
Jennifer Cope

Procedural Note

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

Appendices

Appendix 1: Map showing site boundary of installation (P1087-01) and location of neighbouring Abbvie installation (P0643-03)



Appendix 2: List of European Sites assessed, their associated qualifying interests and conservation objectives.

Site Name	**Cummeen Strand/Drumcliff Bay (Sligo Bay) SAC (000627)**
Distance To (km)	Approximately 0.85 km south and west of the installation
Conservation Objectives	NPWS (2013) Conservation objectives for Cummeen Strand/Drumcliff Bay (Sligo Bay) SAC (000627). Generic Version 1.0. Department of Arts, Heritage and the Gaeltacht.
Qualifying Interests (* denotes a priority habitat)	**Assessment**
Habitats 1130 Estuaries 1140 Mudflats and sandflats not covered by seawater at low tide 2110 Embryonic shifting dunes 2120 Shifting dunes along the shoreline with Ammophila arenaria (white dunes) 2130 Fixed coastal dunes with herbaceous vegetation (grey dunes)* 5130 Juniperus communis formations on heaths or calcareous grasslands 6210 Semi-natural dry grasslands and scrubland facies on calcareous substrates (Festuco-Brometalia) (* important orchid sites) 7220 Petrifying springs with tufa formation (Cratoneurion)* **Species** 1365 Harbour Seal *(Phoca vitulina)* 1014 Narrow-mouthed Whorl Snail *(Vertigo angustior)* 1095 Sea Lamprey *(Petromyzon*	**<u>Emissions to sewer</u>** Emissions to sewer ultimately discharge to Cummen Strand/Drumcliff Bay following treatment in the Sligo WWTP. The main potential for impact would arise from changes in water quality which could affect the habitats and species directly or could affect the water dependent prey on which the qualifying species depend. Refer to Section 7 of this Inspector's report. Mitigation The RD, as proposed, requires that the following controls are in place to protect the qualifying interests of the SAC: • Emissions may be made from specified emission points set out in *Schedule B: Emission Limits*, subject to compliance with the Emission Limit Values specified in that Schedule. • The licensee shall install and maintain oil separators at the installation. • The licensee shall install and maintain suitable trigger levels for storm water discharges. **<u>Emissions to Air</u>** There are two main emission points to air (A1-1 and A1-2). There is potential for fugitive emissions during operational phases of the activities. The main potential for impact would arise from changes in air quality which could affect the habitats and species directly or could affect the prey on which the qualifying species depend. Refer to section 6 of this Inspector's report.

marinus) 1099 River Lamprey *(Lampetra fluviatilis)*	Air dispersion modelling demonstrates that the impact of emissions from the installation will be significantly below the relevant air quality standards and standards for protection of vegetation (refer to section 6). Noise modelling demonstrates that the activities can comply with the limits specified in the licence to avoid any disturbance of qualifying interests (refer to section 8). *Mitigation* The RD, as proposed, requires that the following controls are in place to protect the qualifying interests of the SAC: • Emissions may be made from specified emission points set out in *Schedule B: Emission Limits*, subject to compliance with the Emission Limit Values specified in that Schedule. • The licence requires the licensee to prepare a programme for the identification and reduction of fugitive emissions using a combination of best available techniques. • The licence specifies noise emission limit values at any noise sensitive locations. The licensee shall carry out an annual noise survey. **<u>Potential for Accidents to Arise</u>** There is the potential for accident/hazardous and emergency situations arising from the operation of this installation which could affect the habitats and species. Refer to section 11 of this Inspector's report. *Mitigation* The RD, as proposed, requires that the following controls are in place to protect the qualifying interests of the SAC: • A documented Accident Prevention Procedure is in place that addresses that hazards on-site, particularly in relation to the prevention of accidents with a possible impact on the environment. • A documented Emergency Response Procedure in place that addresses any emergency situation on-site which should include provision for minimising the effects of any emergency on the environment. • All tank, container and drum storage areas shall be rendered impervious to the materials stored therein. Bunds shall be designed having regard to Agency guidelines '*Storage and Transfer of Materials for Scheduled Activities*' (2004), which will minimise the potential for contamination of soil/groundwater.
Site Name	**Cummeen Strand SPA (004035)**
Distance To (km)	Approximately 1.45 km west of the installation.

Conservation Objectives	NPWS (2013) Conservation Objectives: Cummeen Strand SPA [004035] Version 1. Department of Arts, Heritage and the Gaeltacht.
Qualifying Interests (* denotes a priority habitat)	**Assessment**
Birds A130 Oystercatcher *(Haematopus ostralegus)* A046 Light-bellied Brent Goose *(Branta bernicla hrota)* A162 Redshank *(Tringa totanus)* **Habitats** Wetlands	**<u>Emissions to sewer</u>** Emissions to sewer ultimately discharge to Cummen Strand/Drumcliff Bay following treatment in the Sligo WWTP. The main potential for impact would arise from changes in water quality which could affect the habitats and species directly or could affect the water dependent prey on which the qualifying species depend. Refer to Section 7 of this Inspector's report. Mitigation The RD, as proposed, requires that the following controls are in place to protect the qualifying interests of the SAC: • Emissions may be made from specified emission points set out in *Schedule B: Emission Limits*, subject to compliance with the Emission Limit Values specified in that Schedule. • The licensee shall install and maintain oil separators at the installation. • The licensee shall install and maintain suitable trigger levels for storm water discharges. **<u>Emissions to Air</u>** There are two main emission points to air (A1-1 and A1-2). There is potential for fugitive emissions during operational phases of the activities. The main potential for impact would arise from changes in air quality which could affect the habitats and species directly or could affect the prey on which the qualifying species depend. Refer to section 6 of this Inspector's report. Air dispersion modelling demonstrates that the impact of emissions from the installation will be significantly below the relevant air quality standards and standards for protection of vegetation (refer to section 6 of this Inspector's report). Noise modelling demonstrates that the activities can comply with the limits specified in the licence to avoid any disturbance of qualifying interests (refer to section 8 of this Inspector's report).

	Mitigation The RD, as proposed, requires that the following controls are in place to protect the qualifying interests of the SAC: • Emissions may be made from specified emission points set out in *Schedule B: Emission Limits*, subject to compliance with the Emission Limit Values specified in that Schedule. • The licence requires the licensee to prepare a programme for the identification and reduction of fugitive emissions using a combination of best available techniques. • The licence specifies noise emission limit values at any noise sensitive locations. The licensee shall carry out an annual noise survey. **<u>Potential for Accidents to Arise</u>** There is the potential for accident/hazardous and emergency situations arising from the operation of this installation which could affect the habitats and species. Refer to section 11. *Mitigation* The RD, as proposed, requires that the following controls are in place to protect the qualifying interests of the SAC: • A documented Accident Prevention Procedure is in place that addresses that hazards on-site, particularly in relation to the prevention of accidents with a possible impact on the environment. • A documented Emergency Response Procedure in place that addresses any emergency situation on-site which should include provision for minimising the effects of any emergency on the environment. • All tank, container and drum storage areas shall be rendered impervious to the materials stored therein. Bunds shall be designed having regard to Agency guidelines '*Storage and Transfer of Materials for Scheduled Activities*' (2004), which will minimise the potential for contamination of soil/groundwater.

Appendix 3. Relevant European (and international) legal instruments

The following Irish and European and international legal instruments are regarded as relevant to this application assessment and have been considered in the drafting of the Recommended Determination.
Industrial Emissions Directive (IED) (2010/75/EU)
Environmental Impact Assessment (EIA) Directive (85/337/EEC, as amended)
Habitats Directive (92/43/EEC) & Birds Directive (79/409/EC)
Water Framework Directive [2000/60/EC]
Waste Framework Directive (2008/98/EC)
Air Quality Directives (2008/50/EC and 2004/107/EC)
Environmental Liability Directive (2004/35/CE)
Medium Combustion Plant Directive (EU) 2015/2193

Appendix 4: Other BREF documents and National BAT notes relevant to this assessment

Commission Implementing Decision	Publication date
COMMISSION IMPLEMENTING DECISION (EU) 2016/902 of 30 May 2016 establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for common waste water and waste gas treatment/ management systems in the chemical sector ((EU) 2016/902)	June 2016
Sectoral BREF	Publication date
Reference Document on the Best Available Techniques for the Production of Pharmaceutical and Other Specialty Inorganic Chemicals	August 2007
Horizontal BREF	Publication date
Common Waste water and Waste Gas Treatment/Management Systems in the Chemical Sector	2016
Reference Document on the Best Available Techniques on Emissions from Storage	July 2006
Reference Document on the Best Available Techniques for Energy Efficiency	February 2009
National BAT notes	Publication date
BAT Guidance Note for the Pharmaceutical and Other Speciality Organic Chemicals Sector	2008

Appendix 5: BAT compliance conditions

BAT Reference Document (BREFs/BAT)	BREF/BAT Reference No.	BAT employed/to be employed at this installation	Condition/ Schedule
Common Waste Water	BAT 13 Waste	Waste management plan as part of EMS	Condition 2 (EMS)
	BAT 19 Diffuse VOC's	Diffuse VOCs are reduced through plant design.	Condition 3.19 and 6.8
	BAT 22	Noise Management Plan	Condition 2 (EMS)