Attachment 7.1.3.2 – Impact Assessment of Emissions/Discharges

1.0 INTRODUCTION

AWN Consulting Ltd. (AWN) was appointed by AbbVie Ireland NL B.V. to complete a Receiving Environment Report for their proposed Industrial Emissions (IE) licenced facility in Ballytivnan Sligo. This report is to accompany an application for a new IE licence.

This report was completed in accordance with the *Environmental Protection Agency's (EPA) Licence Application Form Guidance – Industrial Emissions (IE), Integrated Pollution Control (IPC) and Waste.*

1.1 Description of Site

The facility at Ballytivnan is located approximately 1.7 km north east of Sligo town centre. The site is also located approximately 1 km from another AbbVie facility on the Manorhamilton Road established in 2002. The locations of both facilities are shown on Drawing 001.

The purpose of this development is to design a facility to manufacture special medicines 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.

The project will consist of internal demolition of part of the existing redundant manufacturing facility which is located to the west of the new Warehouse to make way for the proposed bio-chemical pharmaceutical suite.

1.2 Limitations of the Report

The conclusions presented in this report are professional opinions based solely on the tasks outlined herein and the information made available to AWN. They are intended for the purpose outlined herein and for the indicated site and project. Furthermore, this report is produced solely for the benefit of AbbVie Ireland NL B.V. to address an Environmental Protection Agency (EPA) requirement for their licence.

This report may not be relied upon by any other party without explicit agreement from AWN. Opinions and recommendations presented herein apply to the site conditions existing at the time of the recently completed field work and subsequent assessment. They cannot apply to changes at the site of which AWN is not aware and has not had the opportunity to evaluate. This report is intended for use in its entirety; no excerpt may be taken to be representative of this baseline assessment. All work carried out in preparing this report has utilized and is based on AWN professional knowledge and understanding of the current relevant Irish and European Community standards, codes and legislation.

2.0 IMPACT TO SURFACE WATER

2.1 Surface Water Environment

The proposed development site is located within the Western River Basin District (WRBD) in Hydrometric Area No. 35 of the Irish River Network. The First Cycle WRBD Management Plan (2009-2015) is to be superseded by Second Cycle River Basin Management Plan (2018-2021) and has recently completed public consultation in August 2017. The new River Basin Management Plan defines a single national river basin district. This has been broken down into 46 catchment management units, which are further sub-divided into 583 sub-catchments. These 583 sub-catchments contain a total of 4,832 water bodies ranging from 3 to 15 water bodies in each sub-catchment. The Western River Management Plan defines that the area of the proposed development is within the Sligo Bay & Drowse catchment and the Bonet sub-catchment.

The Willsborough Stream is located close to the north western boundary of the AbbVie site. The Lisnalurg Stream, a tributary of the Willsborough is 280m to the west. The largely culverted Shannon Eighter Stream is >50m to the south of the site.

The site is not located within a Special Area of Conservation (cSAC) or Specially Protected Area (SPA). The nearest SAC and SPA is Cummeen Strand/Drumcliff Bay (Sligo Bay) located approximately 0.7 km away from the proposed development

There are no natural watercourses occurring within the proposed development site as shown in Figure 1 below. The nearest watercourse is the Willsborough Stream and Shannon Eighter. The Shannon Eighter flows along half of the eastern site boundary and then enters a culvert located at the south-eastern corner of the site which is located less than 50m away from the subject site.

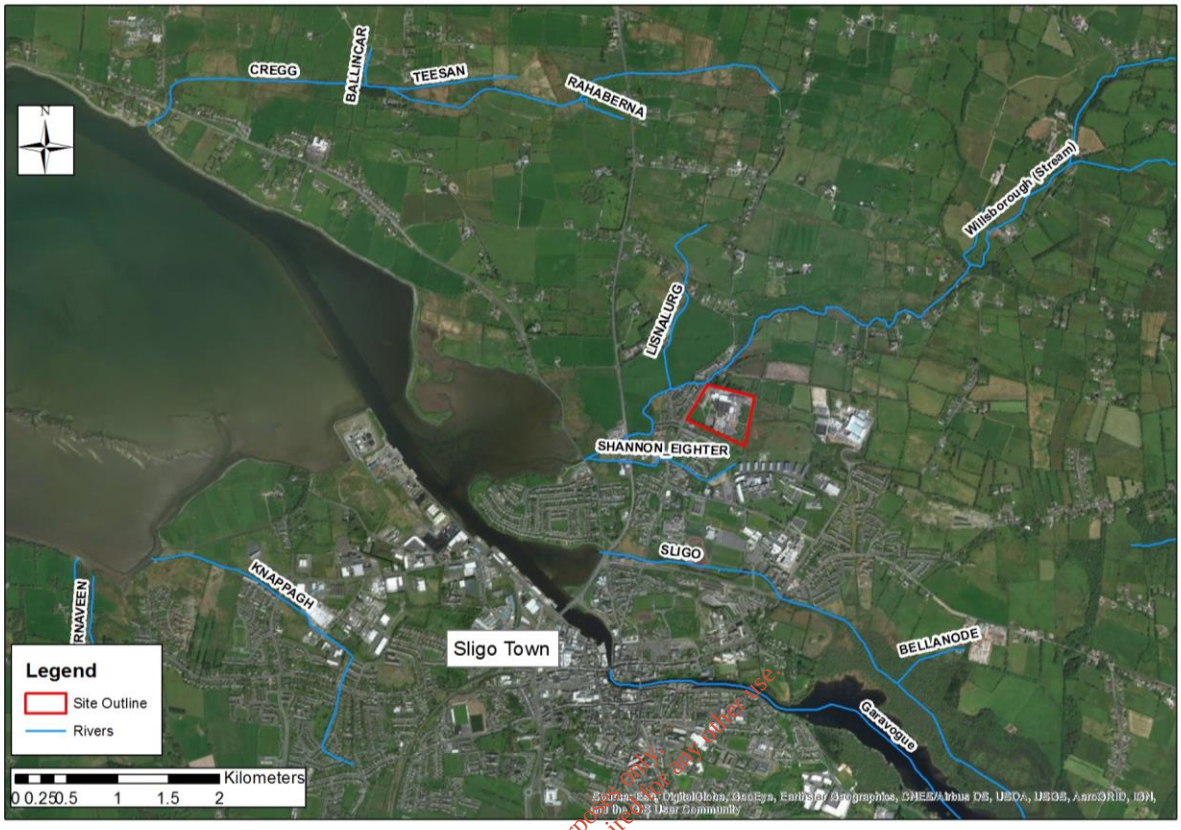

Figure 1 *Hydrological Environment Map (source: www.gsi.ie, 2018)*

2.1.1 Ecologically Designated Sites

The Geological Society of Ireland (GSI) and National Parks and Wildlife Service (NPWS) on-line databases presently list no ecological designated areas within or immediately adjacent to the proposed development site. The Lough Gill (site code: 0001976 SAC & site code: 004035 SPA) SAC (Special Area of Conservation) & SPA (Special Protection Area) is located approx. 1 km to the west and southwest of the proposed development site. This area is also a proposed Natural Heritage Areas (pNHA), with a site code 000627 - Cummeen Strand/Drumcliff Bay (Sligo Bay).

2.1.2 Regional Surface Water Quality

The proposed development is located within the WRBD, as defined under the European Communities Directive 2000/60/EC, establishing a framework for community action in the field of water policy, (commonly known as the Water Framework Directive [WFD]). The WFD requires 'Good Water Status' for all European waters by 2015, to be achieved through a system of river basin management planning and extensive monitoring. 'Good status' means both 'Good Ecological Status' and 'Good Chemical Status'. In 2009, the ERBD River Management Plan (RMP) 2009-2015 was published. In the WRBD RMP, the impacts of a range of pressures were assessed including diffuse and point pollution, water abstraction and morphological pressures (e.g. water regulation

structures). The purpose of this exercise was to identify water bodies at risk of failing to meet the objectives of the WFD by 2015 and include a programme of measures to address and alleviate these pressures by 2015.

The strategies and objectives of the WFD in Ireland have influenced a range of national legislation and regulations. These include the following:

- Statutory Instrument (SI) No. 293 of 1988 European Communities (Quality of Salmonid Waters) Regulations 1988;
- Local Government (Water Pollution) Acts 1977-1990;
- SI No. 258 of 1988 Water Quality Standards for Phosphorus Regulations 1998; and
- SI No. 272 of 2009 European Communities Environmental Objectives (Surface Waters) Regulations 2009.

In accordance with the WFD, each river catchment within the WRBD was assessed and a water management plan detailing the programme of measures was put in place.

Q-Values are used by the EPA to express biological water quality, based on changes in the macro invertebrate communities of riffle areas brought about by organic pollution. Table 1 below summarises an explanation of the ratings; for example, Q1 indicates a seriously polluted water body while Q5 indicates unpolluted water of high quality.

Quality Ratings (Q)	Status	Water Quality	Key
Q5, Q4-5	High	Unpolluted	
Q4	Good	Unpolluted	
Q3-4	Moderate	Slightly Polluted	
Q3, Q2-3	Poor	Moderately Polluted	
Q2, Q1-2, Q1	Bad	Seriously Polluted	

Table 1 *EPA Biological Q Ratings & Key*

Entity Name	Willsborough Stream		
Station Name:	Bridge W of Willsborough	1.5 km W.S.W. of Willsborough	Bridge on Sligo-Bundoran Road
Station ID:	RS35W010150	RS35W010200	RS35W010300
WFD CODE:	IE_EA_35W010150	IE_EA_35W010200	IE_EA_35W010300
Type of water monitored:	River Water	River Water	River Water
River Basin District:	WRBD	WRBD	WRBD
Station Type (WFD):	Operational	Operational	Operational
Easting:	171207.22	169972	169258.31
Northing:	338306.55	337947	337375.33
Last Q Year:	2015	1990	2015
Last Q Value:	4	4	4
Q Legend:	Good	Good	Good
Q Linear Value:	4	4	4

Table 2 *EPA sampling locations for the Willsborough Stream*

Available data for 2015 from the EPA on-line mapping database EPA Maps is presented in Table 2 together with the most recent Q-Value for the watercourse at the locations closest to the site. Figure 2 presents the river catchment map and water quality status (including current EPA monitoring stations).

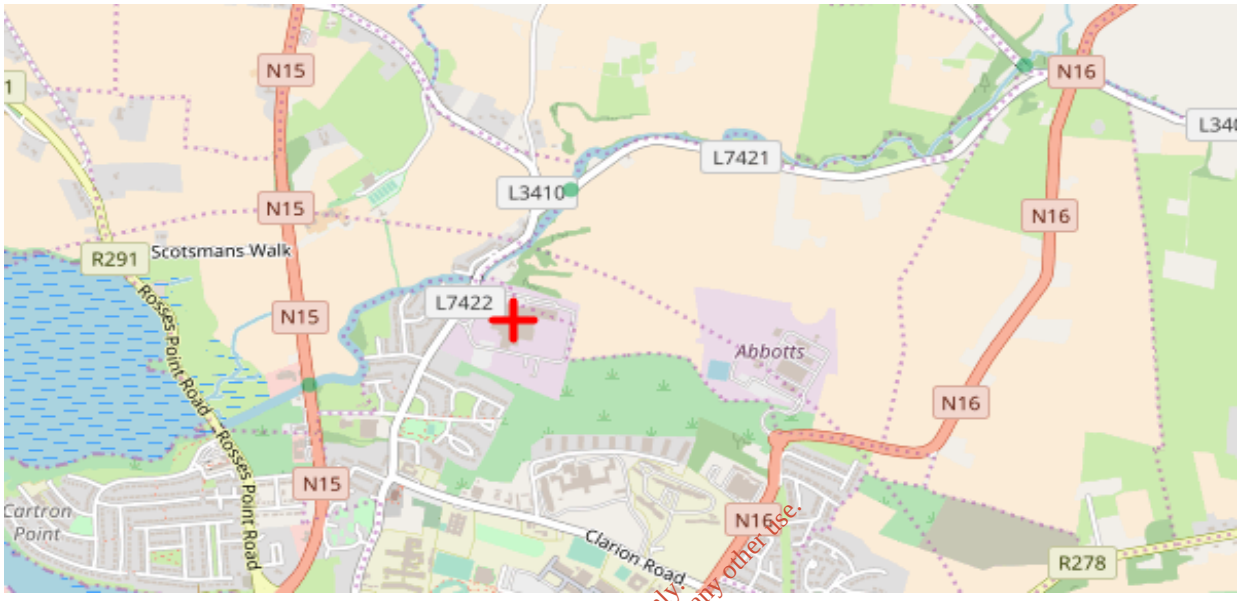

Figure 2 *River Catchment Map & Quality (EPA, 2018) (Site Location Red Cross).*

The values listed above are for monitoring stations located both upstream and downstream of the subject site. The downstream monitoring location (RS35W010300) has a Q Linear Value of 4 (*'Good Status'*), this is similar to the upstream monitoring location (RS35W010150) which also has a Q Linear Value of 4 (*'Good Status'*). The linear value takes into account the current and previous Q-values to determine the expected Q-value for next year. The Willsborough Stream is classified as being 'Not At Risk of Achieving Good Status". The WFD status (2010-2015) is designated as Good.

EPA's *Envision* Database was also consulted to determine if any designated salmonid waters (S.I. 293/1988-European Communities (Quality of Salmonid Waters) Regulations, 1988) existed close to the site or are located so that they may be adversely impacted by the proposed development or operation of the facility. The Willsborough Stream was previously not included in the register of salmonid waters included in those regulations.

2.1.3 Flooding

In accordance with the guidelines produced by the Department of the Environment, Heritage and Local Government (DoEHLG) - The Planning System and Flood Risk Management (FRM) Guidelines for Planning Authorities, November 2009, a Stage 1 assessment has been carried out and is submitted as part of this planning application.

No historic flooding of the site has been identified from the Office of Public Works (OPW) floodmaps.ie website. Soil maps were researched and indicated that the

site was not underlain by alluvium soils therefore indicating that, historically flooding has not occurred onsite. Catchment Flood Risk Assessment and Management Preliminary Flood Risk Assessment (CFRAM PFRA) and Fluvial Flood Extent maps conclusively indicate that the site majority resides within Flood Zone C and is not at risk of flooding from any modelled flood event. A small proportion of the north-eastern and eastern boundary is modelled as having an impact by the 1 in 10 (10% AEP) year flood event which indicates that some of the existing development resides in Flood Zone A. 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 facility has been built in 1970's.

In keeping with the Stage 1 assessment, the review of available information has identified no flood hazards for the proposed works at the proposed development site therefore; in accordance with The Planning System and Flood Risk Management Guidelines for Planning Authorities, there is no requirement to proceed to the Stage 2 or 3 assessments. The proposed redevelopment is found within Flood Zone C, with a small proportion residing within existing development area in Flood Zone A. 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 is primarily within the envelope of the existing development. There is no increase in hardstanding (0%). The proposed development works are located within Flood Zone C and are suitable development for this flood zonation. As a result, there is no expected measurable increase in run-off as a result of this development. During the reworking for the temporary contractor car park, a soil berm will be moved to the southern boundary of the site which is located within Flood Zone C.

The existing drainage systems along with those proposed ensures appropriate drainage for the site. There is inconsequential increase in hardstanding area, therefore no resultant measurable increase in surface run-off.

2.2 Potential Impacts to Surface Water Environment

The proposed development is an internal conversion within the existing AbbVie facility which has been in operation since early 2013 and was previously (1970's) the site of an Abbott Nutrition manufacturing plant. Stormwater discharges via 4 no. hydrocarbon interceptors at 3 no. discharge points into a drainage ditch along the eastern and southern boundary of the site. Each of the discharge points has a manhole to allow for visual inspection on a weekly basis. The locations of these discharge points are shown on Drawing 008.

The existing on-site stormwater drainage network currently covers the entire site (including the proposed location of the development) and collects rainwater runoff from three distinct catchment areas;

- Site roads;
- Car Park areas;
- Building roofs.

Mostly internal modification will be undertaken for the proposed development, so the overall discharge will be similar to the current stormwater discharge in terms of flow and quality.

A Class 1 full retention interceptor will be installed on the stormwater drainage line draining the area around the bulk diesel storage tank as is required.

2.2.1 Management of Fuels, Chemicals and Wastes

A full list of chemicals and their hazard statements is compiled and is presented in Attachment 4-6-2 in Section 4 of this IE licence application.

The majority of the hazardous chemicals that are or will be stored on site are stored in small quantities in drums and bottles. These will be stored in designated areas within the Warehouse or in the existing self-bunded external chemstores.

Table 3 presents the bulk hazardous chemicals to be stored on site which have potential to impact on water quality. Whilst the high high strength wastewater does not carry an H400+ hazard statement it will contain cytotoxins which are highly toxic and mutagenic. As such, the high high strength wastewater has been included in this assessment.

Chemical	Units	Maximum Storage Quantity	Storage Container	Storage Location	Hazard Statements
Diesel	Litres	10,000	Double skinned belly tank	Under Reserve Generator	H351, H304, H332, H315, H373, H226, H411,
High High Strength Waste Water	Litres	60,000	Sunken bunded bulk tank	Beside Main Building	Cyto-toxins (H300, H301, H311, H331, H341, H351, H361)
High High Strength Waste Water	Litres	7,000	Sunken bunded sump tank	Beside Main Building	Cyto-toxins (H300, H301, H311, H331, H341, H351, H361)

Table 3 *Bulk Materials and Corresponding Hazard Statements*

Bulk storage of diesel will be stored within a 10m^3 double skinned belly tank integrated with the back-up generator. The tank will be equipped with leak detection.

The high high strength wastewater will also be stored in a 7m^3 stainless steel, sunken bunded sump tank and a 60m^3 stainless steel, bunded bulk tank located beside the main building. Details of the bunds are provided in Attachment 4.8.1 Operational Report. In the event of a spill into the bund, the wastewater would be tested and pumped out into the appropriate tank.

All process materials, product and chemicals will be delivered to the site in tamper proof and/or lockable containers or tankers, which are approved for transport use.

Trolleys and carts will be used for all material movements within the facility. Separate trolleys/ carts will be used for the general circulation areas as opposed to the individual processing rooms. Each individual processing room will have dedicated trolleys/ carts which will stay within the relevant rooms and will only travel to the individual room material air locks (MAL) to receive materials. Single use mixers (SUM) and totes will also be used for movement of materials and single use components around the process areas.

Diesel fuel oil will be delivered to the site by HGV road tankers approximately every 6 months. A dedicated tanker set-down area will be provided for use during deliveries. All deliveries will be supervised, and any spill will be addressed using designated spill kits by trained personnel.

Bulk chemical storage at the new facility including the external diesel tank and the high and low strength wastewater tanks will be bunded (wastewater tanks) or double lined (diesel belly tank). In the event of a spillage, drainage from bunded areas shall be inspected and diverted for collection and safe disposal if required. Drainage from unloading facility for diesel trucks and for transfer area for wastewater tanker is also diverted for collection and safe disposal.

Liquid Nitrogen and LPG will also be stored in bulk tanks external to the buildings however these do not require bunding and will vaporise in the event of a leak.

All proposed tanks, bunded storage and pipelines have been designed for their specific purpose and their contents. As required the structures will be rendered impervious to the materials stored therein. Tanks will be stored in bunds meeting the requirements of Agency guidelines on the “Storage and Transfer of Materials for Scheduled Activities”.

With respect to integrity testing all bulk tanks, bunds and pipelines are new structures. As such no integrity testing of these structures has been carried out to date. It is anticipated that all bunds will be tested in accordance with standard licence requirements (testing is required typically every 3 years). Integrity testing will be completed in accordance with BS8007 “Code of Practice for design of concrete structures for retaining aqueous liquids” i.e. bunds will be demonstrated to be capable of holding 110% of the capacity of the largest tank or drum within the bunded area or 25% of the total volume of substances stored within the bund (whichever the larger).

Individual chemical type storage details are provided in Attachment 4.8.1 Operational Report.

As such, it is very unlikely that any of the chemicals stored onsite will become entrained in the stormwater run-off. Hydrocarbons and sediment from road run-off will be managed through the use of hydrocarbon interceptors as described in Section 2.2.2 below.

2.2.2 Management of Run-off

Stormwater from the site arises from buildings run-off, car-parks, roadways, service yards and other developed areas of the site. There are 3 no. discharge locations which drain to the east (2 no.) and south (1 no.) of the site i.e. SW1, SW2, and SW3. These discharge points drain via hydrocarbon interceptors before combining in the outfall of the plant to the Shannon Eighter watercourse. Drawing no. 008 shows the drainage layout.

The proposed facility will be served by the current stormwater drainage network. There is no increase in hardstanding area (0% change), therefore there is no measurable increase in stormwater run-off.

The existing hydrocarbon interceptors will prevent discharge of oils/fuels which may potentially be present in stormwater run-off from the car park and main building areas. A Class 1 full retention interceptor will be installed on the stormwater drainage line draining the area around the bulk diesel storage tank as is required.

A proposed dedicated fire water system will collect fire water arising within the new biochemical manufacturing area.

2.2.3 Impact to Surface Water Environment

The proposed development will not have a significant impact on the quality of the receiving surface water bodies as further discussed in Attachment 7.1.3.3 Receiving Environment Report. There is a very low risk of Principle Pollution Substances being discharged from the facility via the stormwater network due to the stringent controls and procedures in place to prevent and minimize spills.

3.0 IMPACT TO SEWER

3.1 Emissions to Sewer

The emissions to sewer from the current facility are primarily sanitary, domestic foul and canteen wastewater (32.6m^3/day).

The proposed development will include the addition of Low Strength wastewater to the emissions to sewer. Low Strength wastewater is process specific waste including reject water from water purification systems, boilers and cooling towers blowdown, and wastewater from non-product contact equipment. The anticipated maximum daily volume of low strength wastewater will be 180m^3/day.

The proposed development will also produce high high strength wastewater which is waste from high containment areas or waste which has been identified that may contain some toxin or other harmful substances. This waste is considered hazardous and is not suitable for treatment by conventional WWT (Waste Water Treatment) technology. As such, it will be stored separately in the high high strength wastewater tank and will be tankered offsite for incineration. There will be no discharge of high high strength wastewater to sewer.

Low Strength wastewater will initially be routed, primarily by gravity, to a bunded 10m^3 sump tank, from where it will be pumped to a bunded 30m^3 tank, both within a sunken bund.

The Low Strength wastewater will be sampled and will generally be sent to the foul sewer (municipal waste water treatment). The facility includes for pH and temperature adjustment should there be a need for this before discharge. The waste can also be pumped into the high high strength wastewater tank or to a road tanker if there is ever a concern about the possibility of contamination of the waste. The locations of all low strength and high high strength sumps and tanks are shown on Drawing 007.

The main characteristics of the wastewater are presented in Table 4.

Description	Max values per day (kg unless otherwise noted)	Max Concentration (mg/l unless otherwise stated)
Flow	180 (m^3/day)	-
BOD	61	377
COD	97	599
Total phosphorous	11	68
Total Nitrogen	2	12
Chlorides	18	6000

Table 4. *Wastewater Characteristics*

Due to the nature of the process there will be very infrequent high concentrations of chloride in the wastewater stream. These peaks will occur only during re-generation of the water conditioning skids and the total contribution to the sewer will be minimal.

Small quantities of sulphate, detergents, and oils fats and greases (OFG) may also be present.

It is not anticipated that any significant concentrations of List I or List II substances, as listed in the Annex to European Union (EU) Directive 2006/11/EC (as amended) will be contained in any emission to sewer from the site.

3.1.1 Wastewater Monitoring

Treated wastewater from the low strength wastewater tank will be routed to a wastewater monitoring cabinet. Continuous monitoring of certain wastewater discharge parameters (e.g. pH, temperature) will be performed at this wastewater monitoring station. This station will also be equipped with a composite grab sampler to allow for collection of compliance-related samples.

3.1.2 Shut-off Valve

There is a shutoff valve located downstream from the monitoring cabinet for potential breaches of the licence limits. If the licence limits are breached, the wastewater is recirculated back to the 30m^3 tank. It should be noted that the shut-off valve can recirculate the low strength wastewater only and is located downstream of the monitoring cabinet before the wastewater combines with the domestic sanitary wastewater for discharge to SE1. The location of SE1 is shown on Drawing 006.

3.1.3 Domestic Waste

Wastewater from welfare facilities and the canteen (c. 32.6 m^3/day) will join with the treated low strength wastewater and discharge to the public sewer at SE1. This will be within the prescribed flow velocities range of 0.8 – 3.0 m/s as outlined in the Department of the Environment and Local Government document 'Recommendations for Site Development Works for Housing Areas'.

A grease trap is in place for the kitchen wastewater and grab samples will be taken periodically from an external manhole to ensure the grease trap is working effectively.

3.1.4 Off-site Waste Water Treatment

The existing wastewater treatment works at Sligo Wastewater Treatment Plant (WWTP) at Sligo Harbour has a capacity of 50,000 population equivalent (PE) and is currently receiving and treating a daily load of approximately 28,158 PE according to the 2017 AER. The maximum discharge volumes from the installation represent about 0.96 % of wastewater discharge volumes from the Sligo Wastewater Treatment Plant.

3.2 Impact to Sewer

Operation of the plant will be according to BAT principles and in compliance with the licence conditions to ensure that inputs to, and subsequent contamination of, soil and water environments does not occur during normal and / or emergency conditions (material spillage or fire event situations).

Wastewater will be discharged after flow balancing and pH neutralisation to ensure no impacts on the sewer network. The main issue at the Sligo WWTP as identified in the 2017 AER for the facility is Total Phosphorus as the facility is not in compliance with the discharge limits for Total Phosphorous. The Total Phosphorous concentration of the wastewater discharge from the AbbVie facility is anticipated to be 68 mg/L which, once diluted with the rest of the hydraulic load of the Sligo WWTP (at a dilution factor of 0.0096) will contribute 0.019 mg /L to the total influent to the facility. Irish Water have advised that the receiving wastewater system will have the capacity to accept the proposed discharge.

S.I. No. 283/2013 - Environmental Protection Agency (Integrated Pollution Control) (Licensing) Regulations 2013, lists a number of Principle Pollution Substance including:

- Substances which contribute to eutrophication (in particular, nitrates and phosphates).

- Substances which have an unfavourable influence on the oxygen balance (and can be measured using parameters such as Biochemical Oxygen Demand (BOD), Chemical Oxygen Demand (COD), etc.).

As such, these parameters will be monitored in accordance with the licence conditions. Mitigation measures were included in the design of the facility to limit the contributions of these parameters as discussed in the BAT Conclusions document for wastewater and waste gas (Attachment 4.7.1).

Other Principle Pollution Substances such as heavy metals are not relevant for this facility as there will be no direct contributions of metals to the wastewater streams. Trace quantities from cleaning of metal equipment may be present in the wastewater only.

Wastewater to be discharged is relatively low strength and has similar characteristics to domestic wastewater. The loading associated with the proposed discharge, as a percentage of Sligo WWTP is insignificant when compared with the overall plant loading. Table 5 shows the percentage of the total influent to the facility based on the 2017 AER.

Description	Proposed Discharge	Quantity of Influent to Sligo (Annual Mean)	Quantity of Influent to Sligo (Annual Max)	Percentage of Sligo Influent
Max wastewater flow per day (m^3 / day)	180	18740.10	51,236	0.96 % (0.35% at Max)

Table 5 *AbbVie wastewater as a % of overall influent to Sligo WWTP*

The impact on the receiving environment is discussed in Attachment 7.1.3.3 Receiving Environment.

4.0 IMPACT TO AIR

4.1 Major and Minor Air Emissions

The primary air emissions from the facility will be from the 2 no. high efficiency LPG fired steam boilers i.e. A1-1 and A1-2. The locations of these boilers are shown on Drawing 004.

The minor air emissions from the facility will include solvent store and pad printing extracts from the existing facility, the new and existing low pressure hot water boilers and domestic hot water boiler, tank and process vents, Lyo vents, autoclave vents, and the Vaporized hydrogen peroxide (VHP) vents (from sterilization).

Potential emissions will include process safety vents emissions and emissions from the new emergency generator (emergency and testing only). The locations of minor and potential emissions are shown on Drawing 005.

4.2 Impact on Air Quality

There is the potential for a number of emissions to the atmosphere during the operational phase of the development. In particular, boiler related air emissions may generate quantities of air pollutants such as NO_2 and SO_2. Oxides of nitrogen are listed as a Principle Pollution Substance (S.I. No. 283/2013) and as such these have been modelled to assess the impact. The manufacturer could not provide maximum emissions values for SO_2, however the manufacturer confirmed that the SO_2 emissions would be negligible. Therefore, the SO_2 concentrations for the boilers have been modelled at the MCP Directive limit value of 35 µg/m^3 for gaseous fuels other than natural gas (all boilers will run on LPG) as this would be the worst case emissions scenario. NO_2 concentrations have been based on maximum emissions as specified by the manufacturer.
The air model report is provided in Appendix A of this attachment.

4.2.1 NO_2 and SO_2 Modelling and Boiler Emissions

The purpose of the modelling study was to determine whether the emissions from the site will lead to ambient concentrations which are in compliance with the relevant ambient air quality standards for NO_2 and SO_2. There is a second AbbVie facility located approximately 1km to the east which holds a valid IE licence (Licence No. P0643-03), emissions from both facilities have been included in a cumulative assessment to ensure compliance with the ambient air quality standards for NO_2 and SO_2.

Air dispersion modelling was carried out using the United States Environmental Protection Agency's regulatory model AERMOD (Version 16216r) and the report is provided as Appendix A to this report. The air dispersion modelling input data consisted of information on the physical environment (including building dimensions and terrain features), design details from all emission points on-site and five full years of appropriate meteorological data. Using this input data, the model predicted ambient ground level concentrations beyond the site boundary for each hour of the modelled meteorological year. The model post-processed the data to identify the location and maximum of the worst-case ground level concentration. This worst-case concentration was then added to the background concentration to give the worst-case predicted environmental concentration (PEC). The PEC was then compared with the relevant ambient air quality standard to assess the significance of the releases from the site.

Throughout this study a worst-case approach was taken. This will most likely lead to an over-estimation of the levels that will arise in practice. The worst-case assumptions are outlined below:

- Maximum predicted concentrations were reported in this study, even if no residential receptors were near the location of this maximum;
- 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.

In order to reduce the risk to health from poor air quality, national and European statutory bodies have set limit values in ambient air for a range of air pollutants. These limit values or "Air Quality Standards" are health- or environmental-based levels for which additional factors may be considered. Air quality significance criteria are assessed on the basis of compliance with the appropriate standards or limit values. The applicable standards in Ireland include the Air Quality Standards Regulations 2011, which incorporate EU Directive 2008/50/EC which combines the previous air quality framework and subsequent daughter directives (see Table 4.1). Although the EU Air Quality Limit Values are the basis of legislation, other thresholds outlined by the EU Directives are used which are triggers for particular actions.

The ambient air quality standards applicable for NO_2 and SO_2 are outlined in Directive 2008/50/EC (see Table 6). These standards have been used in the current assessment to determine the potential impact of NO_2 and SO_2 emissions from the facility on air quality.

Pollutant	Regulation Note 1	Limit Type	Value
Nitrogen Dioxide (NO_2)	2008/50/EC	Hourly limit for protection of human health - not to be exceeded more than 18 times/year	200 µg/m^3 NO_2
		Annual limit for protection of human health	40 µg/m^3 NO_2
		Critical level for the protection of vegetation	30 µg/m^3 NO + NO_2
Sulphur Dioxide (SO_2)	2008/50/EC	Hourly limit for protection of human health - not to be exceeded more than 24 times/year	350 µg/m^3
		Daily limit for protection of human health - not to be exceeded more than 3 times/year	125 µg/m^3
		Critical limit for the protection of ecosystems	20 µg/m^3

Note 1 EU 2008/50/EC – Clean Air For Europe (CAFÉ) Directive replaces the previous Air Framework Directive (1996/30/EC) and daughter directives 1999/30/EC and 2000/69/EC

Table 6 Air Quality Standards Regulations 2011 (Based on Directive 2008/50/EC and S.I. 180 of 2011)

The results indicate that the ambient ground level concentrations of nitrogen oxides (as NO_2) are below the annual and 1-hour ambient air quality standards. Emissions from the facility lead to an ambient NO_2 concentration (including background) which is 24% of the maximum 1-hour limit and 38% of the annual limit at the worst-case off-site location for the worst-case years modelled (2014 and 2015).

The results also indicate that the ambient ground level concentrations of sulphur dioxide (as SO_2) are below the 1-hour and 24-hour ambient air quality standards. Emissions from the facility lead to an ambient SO_2 concentration (including background) that is 21% of the maximum ambient 1-hour limit value (measured as a 99.7th%ile) and 23% of the 24-hour limit value (measured as a 99.2nd%ile) at the worst-case location off-site for the worst case years modelled (2013 and 2014).

The cumulative assessment with the neighbouring AbbVie facility also found results to be in compliance with the relevant ambient air quality limit values. Emissions from both facilities lead to an ambient NO_2 concentration (including background) which is 25% of the maximum ambient 1-hour limit value and 39% of the annual mean limit value at the worst-case off-site receptor for the worst-case years modelled (2014 and 2016). Emissions from both facilities lead to an ambient SO_2 concentration (including background) that is 25% of the maximum ambient 1-hour limit value (measured as a 99.7th%ile) and 23% of the 24-hour limit value (measured as a 99.2nd%ile) at the worst-case location off-site for the worst case years modelled (2013 and 2014).

Ambient levels of nitrogen oxides (as NO_2) and sulphur dioxides (SO_2) from the facility are well below the air quality limit values for the protection of human health and it is predicted that air emissions from the installation will not have a significant impact on the local environment.

No abatement is proposed for boiler emissions or emergency generators. The proposed boiler and emergency generator technology have been selected with minimisation of environmental emissions as a key criterion. The boilers will run on liquid petroleum gas (during normal operations) which will minimise pollutant concentrations in comparison to oil/diesel fired alternatives.

4.2.2 *Impact from Minor Process Emissions*

New minor emissions from preparatory and production vessels, emissions from fume hoods, autoclave vents, Lyo vents, production room vents, and low pressure hot water boilers are not considered to be significant and appropriate abatement (i.e. HEPA filters and 2 um filters as appropriate) will be employed to remove trace contaminants. Dual catalytic converters in series will be in place on the Isolator lines to convert H_2O2 to H_20 and O_2.

Existing process emissions include extracts from the pad printer and the solvent store. These contain small amounts of Volatile Organic Compounds (VOCs); however, the quantities of emissions are not considered significant and abatement systems are not required.

4.2.3 *Impact from Potential Emissions – Emergency Generators*

A diesel generator will provide emergency power to critical and essential manufacturing and utility equipment and systems. Emissions of NO_x, SO_x and particulate matter from the emergency generator will be inconsequential as the generator is small in size and will normally only be used during very short duration operability test every month.

4.2.4 Fugitive Emissions

Fugitive emissions are defined as low level diffuse emissions, mainly of volatile organic compounds, that occur when either gaseous or liquid process fluids escape from plant equipment. There are very minor fugitive emissions anticipated from the use of Isopropyl Alcohol (IPA) impregnated wipes and spray for cleaning internal work surfaces. Losses due to displacement of vapour and dilution are anticipated internally within the production areas only.

5.0 NOISE IMPACTS

5.1 Noise Emissions

The primary sources of outward noise in the operational context are deemed long term and will involve:

- Building Services and Process Plant including provision of Emergency Diesel Generators and;
- Additional vehicular traffic on public roads.

The main operational noise sources associated with building services and factory process plant will include cooling towers, air handling units (AHU's), condenser units and various rooftop mounted fan and exhaust units. For the purposes of this assessment we have assumed that all items of plant will operate continuously 24/7.
In addition to the factory process plant, it is proposed to install 1 no. emergency diesel generator on site. It is expected that this generator will only run occasionally for example, when grid power fails and intermittently during daytime hours for testing purposes.

5.2 Impact on Noise Environment

An environmental noise survey was conducted to quantify the existing noise environment in the vicinity of the nearest noise sensitive locations (NSL's) around the site. The surveys were conducted in accordance with guidance contained within the EPA NG4 publication and ISO 1996: 2007: *Acoustics – Description, measurement and assessment of environmental noise*. Further details of the baseline noise survey are provided in Appendix B to this report.

The results of the baseline noise survey were then used in a noise model to assess whether the addition of the development would cause noise levels at the nearest sensitive receptors to exceed the following restrictions:

- Daytime (07:00 to 19:00hrs) 55dB $L_{Ar,15min}$
- Evening (19:00 to 23:00hrs) 50dB $L_{Ar,15min}$
- Night time (23:00 to 07:00hrs) 45dB $L_{Aeq,15min}$

5.2.1 Noise Modelling

To assess the potential noise impact of the proposed plant items an industrial noise prediction model incorporating the new plant items associated with the proposed development has been prepared.

Noise levels were predicted at the three nearest Noise Sensitive Locations (NSL), the locations of which are shown in the modelling report. Please see Appendix B of this attachment.

A noise survey was undertaken in April 2018 to assess the level of the existing noise emissions. The existing AbbVie facility was operational during the noise survey. Plant noise emissions that were measured during the survey were then used to determine the expected cumulative noise emissions at the nearest noise sensitive locations for both the existing and new mechanical plant items.

Some of the noise sources at the existing facility at the time of the surveys were from operational Abbott equipment including the Steriliser installation. These were decommissioned between January 2018 and May 2018 and as such the existing operational noise levels are anticipated to be lower than those measured.

There are several items of noise generating equipment proposed for the new development. The plant items identified as major or minor noise sources with the potential to emit noise beyond the site boundary were considered, and the details and location of all noise emission points and associated noise source data were provided by Jacobs Engineering.

The computer-based noise model was prepared using a proprietary noise modelling software package, *iNoise V2017 Enterprise*. All noise prediction calculations were carried out in accordance with ISO 9613-2:1996 *Acoustics -- Attenuation of sound during propagation outdoors -- Part 2: General method of calculation*. This is the preferred calculation methodology as stated in the NG4 Guidance and in this instance, due to the number of noise sources and distances to the nearest NSL's, it is considered the most appropriate assessment method. This method has the scope to consider a range of factors affecting sound propagation, including:

- the magnitude of the noise source in terms of sound power;
- the distance between the source and receiver;
- the presence of obstacles such as screens or barriers in the propagation path;
- the presence of reflecting surfaces;
- the hardness of the ground between the source and receiver;
- attenuation due to atmospheric absorption, and;
- meteorological effects such as wind gradient, temperature gradient, humidity (these can have significant impact at distances greater than approximately 400m).

Control of noise has been considered as part of the design of the new facility. Where practical, external plant layout has utilised barrier screening of on-site

buildings, low noise generating plant items such as attenuated cooling towers have been selected and noisy plant items have been located within buildings.

As a worst case it was assumed that the plant (except emergency items) are operating continuously during daytime, evening and night periods. From the modelled values, the predicted noise levels at all NSL's are below the day, evening and night-time noise criteria that are applicable to the site operations (see the noise modelling report in Appendix 2).

In the event of a failure in electricity supply from the national grid, the standby generator will operate in order to maintain the sites key operations. Otherwise, testing of emergency plant is likely to be scheduled on an agreed frequency and would typically involve operation of plant consecutively over a short time during a scheduled daytime period. The predicted operational and emergency noise levels at the nearest modelled locations were also within both the relevant emergency operations limits, as well as and normal operational limits.

A follow up noise survey will be undertaken in 2019 following installation of the new plant to confirm compliance with the relevant limits.

6.0 IMPACTS TO GROUND

6.1 Soil and Groundwater Environment

The current condition of the AbbVie Ireland NL B.V. facility located at Ballytivnan, Co. Sligo is covered in Sections 6.0 *Stage 5 – Environmental Setting* an 8.0 *Stage 7 – Site Investigation and Baseline Soil & Water Quality Assessment* of the Screening & Baseline report submitted as part of this application.

Soil Type and Quality

Reference to the GSI (2018) on-line mapping indicates the predominant subsoil type in the general area at the AbbVie site is Made Ground and limestone tills. The Teagasc subsoil map of Ireland illustrates the natural soil covering the site to be predominantly Tills derived chiefly from limestone rocks (TNSSs). The soils distribution across the study area is provided on the EPA/Teagasc Soils Map. The map identified podzolics, gleys and alluvium as the distinct soil types that exist in the general area.

Results of baseline soil testing carried out in July 2018 can be seen in Section 8.2 *Baseline Soil Analysis* of the Soil & Water Baseline Report. Overall, this indicated that the soil is relatively clean and there is no contamination present on site.

Groundwater Characteristics

The GSI (2018) currently classifies the bedrock aquifer underlying the site as a (Ll) Locally Important Aquifer - Bedrock which is Moderately Productive only in Local Zones. According to the GSI National Draft Gravel Aquifer Map for the region, the subject site is not underlain by a gravel aquifer.

The GSI well search for the area surrounding the site does not identify any groundwater abstraction wells within 1.5 km of the subject site. It should be noted that the area is serviced by public water supply however agricultural wells may be present.

During the site investigation carried out in 2018, groundwater was only encountered at one out of four boreholes at 4.70 metres below ground level (mbgl) and at one out of three trial pits at 2.05mbgl in a thin layer of gravel.

The underlying bedrock of interbedded limestone and shale by nature has a low fracture index with little connectivity and therefore there is no likely hydrogeological connectivity with Lough Gill SAC located 1 km from the proposed development site or Cummeen Strand/Drumcliff Bay (Sligo Bay) pNHA.

As part of a groundwater monitoring round carried out by TMS Environment on behalf of AbbVie Ireland NL B.V., it was concluded that the water table in the limestone beneath the site is shallow and the groundwater flow direction is not uniform across the site. It is likely that a groundwater divide exists across the site, where groundwater in the west of the site flows to the west/southwest and groundwater in the east flows to the southeast, with some local groundwater drainage along the southern site boundary into the drainage ditch.

Groundwater Quality

The European Communities Directive 2000/60/EC established a framework for community action in the field of water policy, (commonly known as the Water Framework Directive [WFD]). The WFD required *'Good Water Status'* for all European waters by December 2015, to be achieved through a system of river basin management planning and extensive monitoring. 'Good status' means both *'Good Ecological Status'* and *'Good Chemical Status'.*

The Groundwater Body (GWB) regionally underlying the site is the Drumcliff Strandhill GWB (EU Groundwater Body Code: IE_WE_0044). Currently, the EPA (2018) on-line mapping classifies the GWB as "under review" meaning it may or may not achieve good status.

Results of baseline groundwater sampling and comparison with Groundwater Regulations 2010, S.I. No. 9 of 2010 are included in Section 8 *Stage 7 – Site investigation, Baseline Soil & Water Quality Assessment* of the Baseline Report. The results are compared with Drinking Water Parametric Values (PVs) provided in the European Union (Drinking Water) Regulations 2014 (S.I. No. 122 of 2014), and Groundwater Threshold Values (GTVs) from the European Union Environmental Objectives (Groundwater) (Amendment) Regulations 2016 (S.I. No. 366 of 2016). GTVs are trigger values ('threshold' values) which warn of potential breaches of water quality standards, but not water quality standards themselves.

Overall, the groundwater quality is good with no major noticeable contamination across the AbbVie site apart from minor exceedances of some inorganics. Volatile Organic Compounds (VOCs), Semi Volatile Organic Compounds (SVOCs), Polycyclic Aromatic Hydrocarbons (PAHs) and most inorganic parameters were not detected above statutory or guideline levels during groundwater monitoring.

Levels of chloride were elevated compared to the GTVs however not compared to the Drinking Water PVs and may have been related to a leaking sewer in the vicinity. Integrity testing of the AbbVie sewer lines was last undertaken in April 2017.

Elevated aluminium, iron, arsenic and manganese was detected in groundwater samples at concentrations above the GTVs. However, these levels are considered to be a reflection of filtering practices in the laboratory.

6.2 Impact to Ground and Groundwater

There will be no direct discharges of contaminated water to groundwater or soil environment during operation. As such, the only impact that could only occur is due to accidental emissions such as localised accidental leakages from cars/vehicles in the car park areas/ on site or accidental leakage from the bunded diesel storage tank and/ or chemical releases during refueling or transport.

During operation, an environmental management plan (EMP) will be in place to ensure compliance with licencing requirements. This will include full and adequate containment and management of potential contaminants. Site-specific

emergency response measures will be in place and all relevant personnel will be trained accordingly.

Fuel and Chemical Handling

In order to minimise any impact on the underlying sunken strata from material spillages, chemical storage tanks will be fully bunded in designated areas with an impervious loading area. Bunding will be to a volume in compliance with EPA standards.

Drainage from the diesel storage area will be to a Class 1 full retention interceptor which will be inspected and properly managed. All tanks, bunding and transfer pipelines will be tested regularly to confirm integrity as per the site EMP and licencing requirements.

As such, it is considered that other than those parameters that are natural elevated in the local groundwater body, there will be no impact on the quality of the groundwater. As such, it is anticipated that there will be no additional exceedances of the European Communities Environmental Objectives (Groundwater) Regulations 2010 (S.I. No. 9 of 2010) and the EPA (2003) Interim guidelines.

Groundwater Recharge

As there will be no increase in hardstanding, the proposed development will not have a significant impact on the recharge of the groundwater body. The aquifer is classified as Moderately Productive only in Local Zones, with the site naturally underlain by natural gravelly and sandy firm Clays ranging in thickness from 5 m to 10 mbgl.

Groundwater Monitoring

Operation of the plant will be according to BAT (Best Available Technology) principles and in compliance with the licence for the site to ensure that inputs to, and any subsequent contamination of, soil and water environments does not occur during normal and/ or emergency conditions (material spillage or fire event situations).

Groundwater monitoring will be undertaken at the following points: MW1, MW2 and MW3. The locations of these wells are shown on Drawing 009. It is proposed that monitoring results are compared with current regulatory limits and guidelines, including the European Communities Environmental Objectives (Groundwater) Regulations 2010 (S.I. No. 9 of 2010) and the EPA (2003) Interim guidelines.

7.0 COMPLIANCE WITH BEST AVAILABLE TECHNIQUES

The proposed facility is intended to replicate successful and proven technologies and processes already developed and in manufacture and use in existing facilities in the USA. With that in mind and with Good Management Practice (GMP) requirements and other bio-pharmaceutical manufacturing constraints, much of the proposed technology and techniques to be applied at the facility had already been pre-determined from the outset of this project.

Nevertheless, as part of the detailed design currently being completed, the design team have assessed BAT and ensured compliance with the relevant BAT as a minimum requirement.

In terms of the document referred to regarding Economic and Cross-Media Effects, it is our understanding that the process described in the document facilitates applicants in determining whether an alternative technique or techniques that might be implemented under IPPC (replaced by IE) offers the highest level of protection for the environment as a whole. This is achieved by following a methodology for balancing the trade-offs that may have to be made in determining which is the best environmental option.

It is anticipated that in many cases, the technique that offers the highest level of protection to the environment will be BAT, but the Directive also requires that the likely costs and benefits of implementing a technique are considered.

7.1 Relevant Decisions on BAT

The following documents are considered potentially relevant in terms of BAT conclusions, BREF and BAT guidance:

- EU Conclusions on Best Available Techniques in Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector, June 2016;
- BREF document on Best Available Techniques for the Manufacture of Organic Fine Chemicals, August 2006;
- BREF document on Best Available Techniques for Energy Efficiency, February 2009;
- BREF document on Best Available Techniques for Emissions from Storage, July 2006.

Please refer to Attachments 4-7-1 to 4-7-4 for detailed assessments of compliance with BAT for each of the above listed BAT Reference (BREF) and BAT guidance documents. It is concluded from this assessment that the facility when completed will comply with the required best available techniques.

7.2 Emerging Techniques

An ‘Emerging technique’ is defined as a novel technique for an industrial emissions directive activity that, if commercially developed, could provide either a higher general level of protection of the environment or at least the same level of protection of the environment and higher cost savings than existing best available techniques.

It is concluded that the proposed technology, based on successful and proven technologies and processes already developed and in manufacture and use in existing facilities in the USA, is not novel and no specific aspect is considered to represent an “Emerging technique”.

7.3 Cleaner Technologies, Waste Minimization and Raw Material Substitution

Please refer to Section 8 of the application for details regarding Waste Minimization.

There are limited opportunities for the substitution of raw materials in the proposed process. The raw materials used have been developed carefully, with due respect to minimizing potential environmental nuisances or other consequences of their use**.**

Cleaner technologies are addressed in Section 9 under Energy Efficiency.

7.4 General Environmental Measures

Unlike traditional chemical based pharmaceutical facilities, the proposed facility will be a lower risk, cleaner, water-based bio-chemical manufacturing process using limited quantities of solvents or hazardous substances.

The facility will be managed by an experienced team of bio-chemical specialists. All operatives will be trained for their specific duties and work will be carried out in line with standard operating procedures. In the event of an accident or other malfunction staff will be trained to address the accident as efficiently and effectively as possible thereby minimizing pollution arising therefrom.

Following grant of the revised licence, AbbVie will be required to comply with the conditions of its licence. All emissions from the facility will be abated and monitored to ensure compliance. For further details of the controls in place, including accident prevention and management of liabilities, see Section 9.

8.0 CONCLUSIONS

From an assessment of both the direct and indirect emission sources, the proposed development is unlikely to have a significant impact on the air, noise, water and ground environments within the vicinity of the site. Monitoring of the emissions will be in accordance with the licence requirements. Diffuse discharges will be controlled through the use of sealed systems and standard operating procedures for control and maintenance.

A further discussion on the impact from the direct emissions (i.e. air, sewer and stormwater emissions) to their respective receiving environment is provided in Attachment 7.1.3.3.

9.0 REFERENCES

EIAR (2018) Environmental Impact Assessment Report for Internal Works & Change in Activity at AbbVie Ireland, NL B.V., Ballytivnan, Sligo. Environmental Impact Services; May 2018.

Annual Environmental Report (2017), D0014-01, Sligo (Sligo Wastewater Treatment Plant).

Appendix 7.1.3.2-A

Air Dispersion Modelling

Appendix 7.1.3.2-B

Noise Modelling Report