

PROPOSED CHANGES TO ABBVIE BALLYTIVNAN EMISSION LIMIT VALUES FOR CHLORIDE, SULPHATE AND FOG

EPA LICENCE NUMBER P1087-01

Report Prepared For

Abbvie Ballytivnan

Prepared By



Our Reference

FC/23TA_SO4_FOG_CI

Date Of Issue

14 August 2023

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1.0 INTRODUCTION

Abbvie Ireland NL B.V. operates a manufacturing facility at Ballytivnan in Sligo. The site applied for an IE licence (P1087-01) in 2018 to enable them to operate an integrated biologics manufacturing suite.

This activity has now commenced at the site and now the EPA enforces the licence for the site and it has been noted during compliance monitoring that FOG (Fat Oils Grease) Chloride (Cl) and Sulphate (SO₄) emission limit values listed in the licence need amending. This report has been prepared in support of the technical amendment to change these emission limit values to ones which are more appropriate for the site.

2.0 PROPOSED CHANGES

CURRENT LICENCE EMISSION LIMIT VALUES

Sulphate 15 mg/l

FOG 10 mg/l

Chloride 18 kg/day

PROPOSED CHANGE TO LICENCE EMISSION LIMIT VALUES

Sulphate 400 mg/l

FOG 50 mg/l

Chloride 1080 kg/day

An impact assessment for the proposed amended values is provided in Section 3.0 of this Report.

Irish Water have issued a letter of support for the proposed changes to FOG and Sulphate (see Attachment A) but have not included for the Chloride change, we have requested that they issue an updated letter to cover chloride but have not received a response yet.

An Appropriate Assessment Screening Report is provided as Attachment B of this Report.

3.0 IMPACT ASSESSMENT OF PROPOSED CHANGES

The impact of the proposed changes are assessed below.

3.1 Sulphate

The AER submitted by Irish Water to the EPA for 2020 notes that mean wastewater flow to the Sligo Wastewater Treatment Plant was 25,233 m³/day. The Abbvie Ballytivnan maximum volumetric flow rate is 180 m³/day. This represents a dilution factor of approximately 140, meaning that any wastewater discharged by Abbvie Ballytivnan is diluted by at least a factor of approximately 140 prior to entering the Irish Water WWTP.

Following dilution in the sewer the proposed discharge would lead to a sulphate concentration, assuming the maximum concentration of sulphate of 400 mg/l, of $(400/140) = 2.85$ mg/l SO₄ discharged whereas domestic sewage has a sulphate concentration of 20-50 mg/l (reference Wastewater Engineering: Treatment and Resource Recovery, McGraw Hill, 2013).

Sulphate in sewage does not directly have a significant effect on the activated sludge process, unless present at very high concentrations such as those found in seawater (Activated Sludge Treatment, Handbook of Wastewater Practice, CIWEM, 1997).

Sulphate concentrations in seawater, at 20°C, are around 2,700 mg/l (The Chemistry of Our Environment, R.A.Horne, John Wiley and Sons, New York, 1978). Therefore the requested increase in sulphate concentration limit value is insignificant in terms of impact on the Sligo WWTP or the environment.

3.2 FOG

In his paper:

International evolution of fat, oil and grease (FOG) waste management - A review
Thomas Wallace, David Gibbons, Michael O'Dwyer and Thomas P. Curran
UCD School of Biosystems and Food Engineering, University College Dublin,
Belfield, Dublin 4, Ireland, 2016

Wallace notes on Page 24, Line 400, that:

FOG blockages in Dublin city were reduced from over 1,000 per annum pre-2008 to less than 100 blockages in 2014 (Gibbons et al. 2015) due to a FOG control programme. This contrasts with other urban centres in Ireland where Melia (2016) reported that up to 90% of food businesses had inadequate levels of FOG reduction in place.

*The success in Dublin was achieved through the implementation of the Dublin FOG Programme, which since 2008 has involved over 7,000 annual inspections of the existing 2,300 FSOs. The inspections involve the promotion of best management practices to reduce FOG from entering the sewer and to review the condition of GTSS on site. Wastewater discharged from sites is sampled regularly to confirm that FOG content is under **100 mg/L**, which is the limit required by the discharge licence. Legal action against the FSO is an option for continued failure to comply with the standards of the trade effluent discharge licence. A critical assessment of this programme is currently being carried out.*

It can be seen from the extract above that the limit value for FOG in wastewater is generally 100 mg/l. Abbie are applying for a limit of 50 mg/l, well below the accepted limit value.

3.3 Chloride

The current EPA licence for the site applies a limit of 6000 mg chloride per litre which is acceptable to the site. However it also includes a mass emission limit of 18 kg/day. This is not correct as if one multiplies the permitted maximum volumetric flow rate of 180 m³/day x 6000 mg/l one obtains 1080 kg chloride per day.

We therefore request that the licence be amended to correct this anomaly.

As noted above the mean wastewater flow to the Sligo WWTP was 25,233 m³/day in 2020. If one divides the maximum mass loading of chloride requested (1080 kg/day) by the mean wastewater flow to Sligo WWTP one obtains (1080000000 mg/day)/25233000 litres/day) = 42.8 mg/l which is the predicted chloride concentration in the discharge from the Sligo WWTP into the receiving waters.

Sea water has a chloride concentration of approximately 19,000 mg/l (reference The Physical Chemistry of Seawater, Author: Millero, F. J. , Journal: Annual Review of Earth and Planetary Sciences, Vol. 2, p.101, 1974), a discharge containing 42.8 mg/l is insignificant when being discharged into receiving waters which will have circa 19,000 mg/l of chloride and therefore the requested change has no predicted significant effects on the environment.

3.4 BAT Assessment

BAT for the Organic Fine Chemical Sector, which is the relevant BAT for Abbvie Ballytivnan, is defined as follows (from Table VIII of Integrated Pollution Prevention and Control Reference Document on Best Available Techniques for the Manufacture of Organic Fine Chemicals, published by the European Commission) :

Parameter	Yearly averages*		Comment
	Level	Unit	
COD	12 - 250	mg/l	
Total P	0.2 - 1.5		The upper range results from the production of mainly compounds containing phosphorus
Inorganic N	2 - 20		The upper range results from production of mainly organic compounds containing nitrogen or from, e.g. fermentation processes
AOX	0.1 - 1.7		The upper range results from numerous AOX relevant productions and pretreatment of waste water streams with significant AOX loads
Cu	0.007 - 0.1		The upper ranges result from the deliberate use of heavy metals or heavy metal compounds in numerous processes and the pretreatment of waste water streams from such use
Cr	0.004 - 0.05		
Ni	0.01 - 0.05		
Zn	- 0.1		
Suspended solids	10 - 20		
LID _F	1 - 2		Dilution factor
LID _D	2 - 4		
LID _A	1 - 8		
LID _L	3 - 16		
LID _{EU}	1.5		

* The levels relate to the effluent after biological treatment without dilution, e.g. by mixing with cooling water

Furthermore, the CID published by the European Commission in 2016 (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 (notified under document C(2016) 3127) is also relevant in terms of BAT – the CID states the following:

BAT-AELs for direct emissions of TOC, COD and TSS to a receiving water body

Parameter	BAT-AEL (yearly average)	Conditions
Total organic carbon (TOC) ⁽¹⁾ ⁽²⁾	10-33 mg/l ⁽¹⁾ ⁽⁴⁾ ⁽⁵⁾ ⁽⁶⁾	The BAT-AEL applies if the emission exceeds 3,3 t/yr.
Chemical oxygen demand (COD) ⁽¹⁾ ⁽²⁾	30-100 mg/l ⁽¹⁾ ⁽⁴⁾ ⁽⁵⁾ ⁽⁶⁾	The BAT-AEL applies if the emission exceeds 10 t/yr.
Total suspended solids (TSS)	5,0-35 mg/l ⁽⁷⁾ ⁽⁸⁾	The BAT-AEL applies if the emission exceeds 3,5 t/yr.

Parameter	BAT-AEL (yearly average)	Conditions
Total nitrogen (TN) ⁽¹⁾	5,0-25 mg/l ⁽⁷⁾ ⁽⁸⁾	The BAT-AEL applies if the emission exceeds 2,5 t/yr.
Total inorganic nitrogen (N _{inorg}) ⁽¹⁾	5,0-20 mg/l ⁽⁷⁾ ⁽⁸⁾	The BAT-AEL applies if the emission exceeds 2,0 t/yr.
Total phosphorus (TP)	0,50-3,0 mg/l ⁽⁴⁾	The BAT-AEL applies if the emission exceeds 300 kg/yr.

Parameter	BAT-AEL (yearly average)	Conditions
Adsorbable organically bound halogens (AOX)	0,20-1,0 mg/l ⁽¹⁾ ⁽²⁾	The BAT-AEL applies if the emission exceeds 100 kg/yr.
Chromium (expressed as Cr)	5,0-25 µg/l ⁽¹⁾ ⁽⁴⁾ ⁽⁵⁾ ⁽⁶⁾	The BAT-AEL applies if the emission exceeds 2,5 kg/yr.
Copper (expressed as Cu)	5,0-50 µg/l ⁽¹⁾ ⁽⁴⁾ ⁽⁵⁾ ⁽⁷⁾	The BAT-AEL applies if the emission exceeds 5,0 kg/yr.
Nickel (expressed as Ni)	5,0-50 µg/l ⁽¹⁾ ⁽⁴⁾ ⁽⁵⁾	The BAT-AEL applies if the emission exceeds 5,0 kg/yr.
Zinc (expressed as Zn)	20-300 µg/l ⁽¹⁾ ⁽⁴⁾ ⁽⁵⁾ ⁽⁸⁾	The BAT-AEL applies if the emission exceeds 30 kg/yr.

It can be seen that neither sulphate, chloride or FOG are included in the above tables and are therefore not relevant to BAT.

4.0 CONCLUSIONS

In conclusion the proposed changes to the sulphate and FOG emission limit values are approved by Irish Water, have no environmental or wastewater plant impact and are not restricted by BAT and we therefore request that the EPA approve this TA.

ATTACHMENT A
IRISH WATER LETTER OF APPROVAL



Ms Charlene Rooney,
Abbie Ireland NL.BV,
Ballytivnan,
Co. Sligo

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Reg No: P1087-01

13/Apr/2023

Dear Ms Rooney,

I refer to our telephone correspondence dated 03/04/23 in relation to your proposed and requested amendment to the trade effluent emission limit values (ELV) set out in EPA Licence Reg. No. P1087-01. Uisce Éireann have assessed your proposal and are satisfied to support amendment of Schedule B.3 Emissions to Sewer as outlined below;

Schedule B.3 Emissions to Sewer

Emission Point Reference No.: **SE1**

Discharge Location: SE1 (Grid Reference (169925E, 337335N))

Volume of Trade effluent emitted: Maximum in any one day: 180 m³
 Maximum in any hour: 12.7 m³

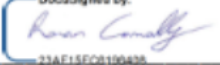
Parameter	Emission Limit Values	
	Concentration (mg/l)	Daily Load (Kg/day)
Temperature	35°C (max)	
pH	6-9 pH Units	
BOD 5 days with inhibition (Carbonaceous BOD)	377	61
COD - Cr	599	97
Suspended Solids	333	54

Stiúrthóir / Directors: Tony Keohane (Chairman), Niall Gleeson (CEO), Christopher Banks, Fred Barry, Gerard Britchfield, Liz Joyce, Patricia King, Eileen Maher, Cathv Mannion, Michael Walsh

Total Nitrogen (as N)	12	2
Chlorides	6000	18
Sulphates (as SO4)	400	-
Fats, Oils & Greases	50	-
Detergents (as MBAS)	20	-

If you have any further queries please do not hesitate to contact Uisce Éireann.

Yours sincerely

DocuSigned by:

23AE15E02100426

Wastewater Source Control and Licensing

ATTACHMENT B
AA SCREENING REPORT

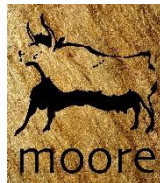
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Report for the purposes of
Appropriate Assessment Screening

Abbvie Ballytivnan IE Licence
Technical Amendment

Prepared by: Moore Group – Environmental Services

14 August 2023



On behalf of Abbvie Ireland NL B.V.

Project Proponent	Abbvie Ireland NL B.V.
Project	AbbVie Ballytivnan IE Licence Technical Amendment
Title	Report for the purposes of Appropriate Assessment Screening AbbVie Ballytivnan IE Licence Technical Amendment

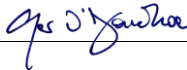
Project Number	22202	Document Ref	22202 Abbvie IE TA AAS1 Rev0	
Revision	Description	Author	Date	
Rev0	Issued to Client	G. O'Donohoe		14 August 2023
Moore Archaeological and Environmental Services Limited				

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Appendix A – Finding of No Significant Effects Report

Abbreviations

AA	Appropriate Assessment
EEC	European Economic Community
EPA	Environmental Protection Agency
EU	European Union
GIS	Geographical Information System
LAP	Local Area Plan
NHA	Natural Heritage Area
NIS	Natura Impact Statement
NPWS	National Parks and Wildlife Service
OSI	Ordnance Survey Ireland
pNHA	proposed Natural Heritage Area
SAC	Special Area of Conservation
SPA	Special Protection Area
SuDS	Sustainable Drainage System
WFD	Water Framework Directive

1. Introduction

1.1. General Introduction

This report for the purposes of Appropriate Assessment (AA) Screening contains information required for the competent authority to undertake screening for Appropriate Assessment (AA) in respect of the proposed Technical Amendment to the existing IE licence for AbbVie Ballytivnan, Co. Sligo (hereafter referred to as the Proposed Development) to determine whether it is likely individually or in combination with other plans and projects to have a significant effect on any European sites, in light of best scientific knowledge.

Having regard to the provisions of the Planning and Development Act 2000 – 2021 (the “Planning Acts”) (section 177U), the purpose of a screening exercise under section 177U of the PDA 2000 is to assess, in view of best scientific knowledge, if the proposed development, individually or in combination with another plan or project is likely to have a significant effect on a European site.

If it cannot be *excluded* on the basis of objective information that the proposed development, individually or in combination with other plans or projects, will have a significant effect on a European site then it is necessary to carry out a Stage 2 appropriate assessment under section 177V of the Planning Acts.

When screening the project, there are two possible outcomes:

- the project poses no potential for a likely significant effect and as such requires no further assessment; and
- the project has potential to have likely significant effect (or this is uncertain) unless mitigation measures are applied, and therefore an AA of the project is necessary.

This report has been prepared by Moore Group - Environmental Services to enable the competent authority to carry out AA screening in relation to the Proposed Development. The report was compiled by Ger O’Donohoe (B.Sc. Applied Aquatic Sciences (GMIT, 1993) & M.Sc. Environmental Sciences (TCD, 1999)) who has 27 years’ experience in environmental impact assessment and has completed numerous Appropriate Assessment Screening Reports and Natura Impact Statements on terrestrial and aquatic habitats for various development types.

1.2. Legislative Background - The Habitats and Birds Directives

Article 6(3) and 6(4) of the Habitats Directive is transposed into Irish Law inter alia by the Part XAB of the Planning Acts (in particular section 177U and 177V) which governs the requirement to carry out appropriate assessment screening and appropriate assessment, where required, per Section 1.1 above.

The Habitats Directive (Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora) is the main legislative instrument for the protection and conservation of biodiversity in the European Union (EU). Under the Habitats Directive, Member States are obliged to designate Special Areas of Conservation (SACs) which contain habitats or species considered important for protection and conservation in a EU context.

The Birds Directive (Council Directive 2009/147/EC on the conservation of wild birds), transposed into Irish law by the Bird and Natural Habitats Regulations 2011 as amended, and the Wildlife Act 1976, as amended, is concerned with the long-term protection and management of all wild bird species and their habitats in the EU. Among other things, the Birds Directive requires that Special Protection Areas (SPAs) be established to protect migratory species and species which are rare, vulnerable, in danger of extinction, or otherwise require special attention.

SACs designated under the Habitats Directive and SPAs, designated under the Birds Directive, form a pan-European network of protected sites known as Natura 2000. The Habitats Directive sets out a unified system for the protection and management of SACs and SPAs. These sites are also referred to as European sites.

Articles 6(3) and 6(4) of the Habitats Directive set out the requirement for an assessment of proposed plans and projects likely to have a significant effect on Natura 2000 sites.

Article 6(3) establishes the requirement to screen all plans and projects and to carry out an appropriate assessment if required (Appropriate Assessment (AA)). Article 6(4) establishes requirements in cases of imperative reasons of overriding public interest:

Article 6(3): *“Any plan or project not directly connected with or necessary to the management of the site but likely to have a significant effect thereon, either individually or in combination with other plans or projects, shall be subjected to an appropriate assessment of its implications for the site in view of the site’s conservation objectives. In light of the conclusions of the assessment of the implications for the site and subject to the provisions of paragraph 4, the competent national authorities shall agree to the plan or project only after having ascertained that it will not adversely affect the integrity of the site concerned and, if appropriate, after having obtained the opinion of the general public.”*

2. Methodology

The Commission’s methodological guidance (EC, 2002, 2018, 2021 see Section 2.1 below) promotes a four-stage process to complete the AA and outlines the issues and tests at each stage. An important aspect of the process is that the outcome at each successive stage determines whether a further stage in the process is required.

Stages 1 and 2 deal with the main requirements for assessment under Article 6(3). Stage 3 may be part of Article 6(3) or may be a necessary precursor to Stage 4. Stage 4 is the main derogation step of Article 6(4).

Stage 1 Screening: This stage examines the likely effects of a project either alone or in combination with other projects upon a Natura 2000 site and considers whether it can be objectively concluded that these effects will not be significant. In order to screen out a project, it must be excluded, on the basis of objective information, that the Proposed Development, individually or in combination with other plans or projects, will have a significant effect on a European site.

Stage 2 Appropriate Assessment: In this stage, there is a consideration of the impact of the project with a view to ascertain whether there will be any adverse effect on the integrity of the Natura 2000 site either alone or in combination with other projects or plans, with respect to the site's structure and function and its conservation objectives. Additionally, where there are predicted impacts, an assessment of the potential mitigation of those impacts is considered.

Stage 3 Assessment of Alternative Solutions: This stage examines alternative ways of implementing the project that, where possible, avoid any adverse impacts on the integrity of the Natura 2000 site.

Stage 4 Assessment where no alternative solutions exist and where adverse impacts remain: Where imperative reasons of overriding public interest (IROPI) exist, an assessment to consider whether compensatory measures will or will not effectively offset the damage to the sites will be necessary.

To ensure that the Proposed Development complies fully with the requirements of Article 6 of the Habitats Directive and all relevant Irish transposing legislation, Moore Group compiled this report to enable Sligo County Council to carry out AA screening in relation to the Proposed Development to determine whether the Proposed Development, individually or in combination with another plan or project will have a significant effect on a Natura 2000 site.

2.1. Guidance

This report has been compiled in accordance with guidance contained in the following documents:

- Appropriate Assessment of Plans and Projects in Ireland - Guidance for Planning Authorities. (Department of Environment, Heritage and Local Government, 2010 rev.)(soon to be superseded by EC Guidance in prep.).
- Appropriate Assessment under Article 6 of the Habitats Directive: Guidance for Planning Authorities. Circular NPWS 1/10 & PSSP 2/10.
- Managing Natura 2000 Sites: The Provisions of Article 6 of the Habitat's Directive 92/43/EEC (EC, 2018).
- Guidance document on the strict protection of animal species of Community interest under the Habitats Directive (EC, 2021).
- Assessment of plans and projects in relation to Natura 2000 sites - Methodological guidance on Article 6(3) and (4) of the Habitats Directive 92/43/EEC (EC, 2021).

- Office of the Planning Regulator (OPR) Practice Note PN01 Appropriate Assessment Screening for Development Management (OPR, 2021).

2.2. Data Sources

Sources of information that were used to collect data on the Natura 2000 network of sites, and the environment within which they are located, are listed below:

- The following mapping and Geographical Information Systems (GIS) data sources, as required:
 - National Parks & Wildlife (NPWS) protected site boundary data;
 - Ordnance Survey of Ireland (OSI) mapping and aerial photography;
 - OSI/Environmental Protection Agency (EPA) rivers and streams, and catchments;
 - Open Street Maps;
 - Digital Elevation Model over Europe (EU-DEM);
 - Google Earth and Bing aerial photography 1995-2022;
- Online data available on Natura 2000 sites as held by the National Parks and Wildlife Service (NPWS) from www.npws.ie including:
 - Natura 2000 - Standard Data Form;
 - Conservation Objectives;
 - Site Synopses;
- National Biodiversity Data Centre records;
 - Online database of rare, threatened and protected species;
 - Publicly accessible biodiversity datasets.
- Status of EU Protected Habitats in Ireland. (National Parks & Wildlife Service, 2019); and
- Relevant Development Plans;
 - Sligo County Development Plan 2017-2023

3. Description of the Proposed Development

A Technical Amendment (TA) is requested from the EPA for the AbbVie Ballytivnan IE Licence P1087-01.

There will be no direct discharges to surface waters as a result of the proposed change and there is no connectivity to European sites.

The Screening process is effectivity on the Technical Amendment to the Licence only.

Figure 1 shows the Proposed Development location and Figure 2 shows a detailed view of the Proposed Development boundary on recent aerial photography.

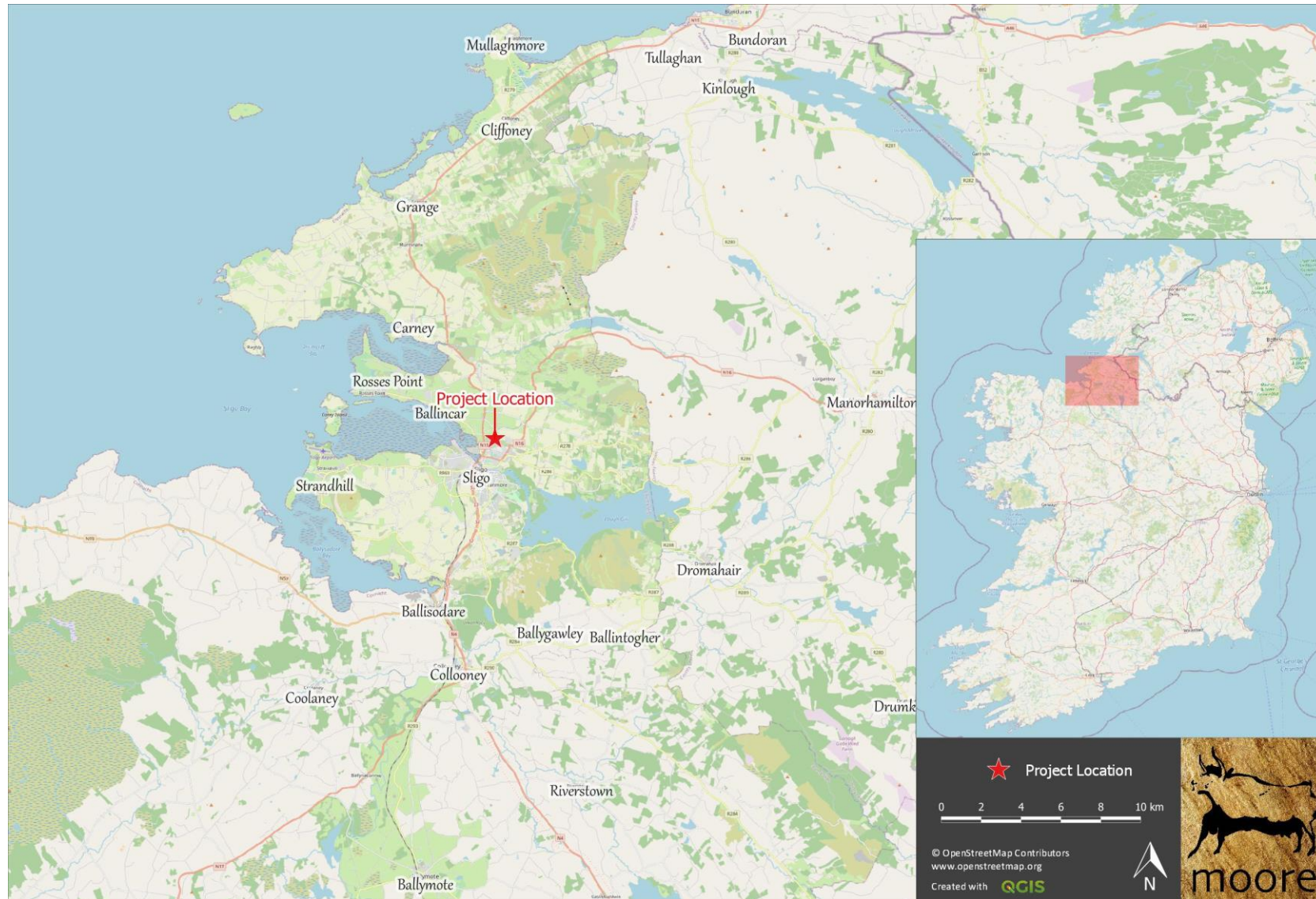


Figure 1. Showing the Proposed Development location at Ballytivnan, Co. Sligo.



Figure 2. Showing the Proposed Development boundary on recent aerial photography.

4. Identification of Natura 2000 Sites

4.1. Description of Natura Sites Potentially Significantly Affected

A Zone of Influence (Zoi) of a proposed development is the geographical area over which it could affect the receiving environment in a way that could have significant effects on the Qualifying Interests of a European site. In accordance with the OPR Practice Note, PN01, the Zoi should be established on a case-by-case basis using the Source- Pathway-Receptor framework.

The European Commission's "Assessment of plans and projects in relation to Natura 2000 sites guidance on Article 6(3) and (4) of the Methodological Habitats Directive 92/43/EEC" published 28 September 2021 states at section 3.1.3:

Identifying the Natura 2000 sites that may be affected should be done by taking into consideration all aspects of the plan or project that could have potential effects on any Natura 2000 sites located within the zone of influence of the plan or project. This should take into account all of the designating features (species, habitat types) that are significantly present on the sites and their conservation objectives. In particular, it should identify:

- *any Natura 2000 sites geographically overlapping with any of the actions or aspects of the plan or project in any of its phases, or adjacent to them;*
- *any Natura 2000 sites within the likely zone of influence of the plan or project Natura 2000 sites located in the surroundings of the plan or project (or at some distance) that could still be indirectly affected by aspects of the project, including as regards the use of natural resources (e.g. water) and various types of waste, discharge or emissions of substances or energy;*
- *Natura 2000 sites in the surroundings of the plan or project (or at some distance) which host fauna that can move to the project area and then suffer mortality or other impacts (e.g. loss of feeding areas, reduction of home range);*
- *Natura 2000 sites whose connectivity or ecological continuity can be affected by the plan or project.*

The range of Natura 2000 sites to be assessed, i.e. the zone in which impacts from the plan or project may arise, will depend on the nature of the plan or project and the distance at which effects may occur. For Natura 2000 sites located downstream along rivers or wetlands fed by aquifers, it may be that a plan or project can affect water flows, fish migration and so forth, even at a great distance. Emissions of pollutants may also have effects over a long distance. Some projects or plans that do not directly affect Natura 2000 sites may still have a significant impact on them if they cause a barrier effect or prevent ecological linkages. This may happen, for example, when plans affect features of the landscape that connect Natura 2000 sites or that may obstruct the

movements of species or disrupt the continuity of a fluvial or woodland ecosystem. To determine the possible effects of the plan or project on Natura 2000 sites, it is necessary to identify not only the relevant sites but also the habitats and species that are significantly present within them, as well as the site objectives.

The Zone of Influence may be determined by considering the Proposed Development's potential connectivity with European sites, in terms of:

- Nature, scale, timing and duration of all aspects of the proposed works and possible impacts, including the nature and size of excavations, storage of materials, flat/sloping sites;
- Distance and nature of potential pathways (dilution and dispersion; intervening 'buffer' lands, roads etc.); and
- Location of ecological features and their sensitivity to the possible impacts.

The potential for source pathway receptor connectivity is firstly identified through GIS interrogation and detailed information is then provided on sites with connectivity. European sites that are located within a potential Zone of Influence of the Proposed Development are listed in Table 1 and presented in Figures 3 and 4 below. Spatial boundary data on the Natura 2000 network was extracted from the NPWS website (www.npws.ie) on 26 September 2022. This data was interrogated using GIS analysis to provide mapping, distances, locations and pathways to all sites of conservation concern including pNHAs, NHA and European sites.

Table 1 European Sites located within the potential Zone of Influence¹ of the Proposed Development.

Site Code	Site name	Distance (km) ²
000627	Cummeen Strand/Drumcliff Bay (Sligo Bay) SAC	0.79
001976	Lough Gill SAC	1.28
004013	Drumcliff Bay SPA	4.18
004035	Cummeen Strand SPA	0.80

The nearest European sites to the facility to which the licence relates, the Abbvie Campus at Ballytivnan, are the Cummeen Strand SPA (Site Code 004035), and the Cummeen Strand/Drumcliff Bay (Sligo Bay) SAC (Site Code 000627), both approximately 800m to the west.

The facility is located in the northern outskirts of Sligo. A review of aerial photography, Ordnance Survey Ireland (OSI) mapping and OSI Geographical Information System (GIS) data for rivers and streams indicates that there are no notable surface water features onsite and no direct hydrological pathways to offsite surface water bodies. There is no direct connectivity to any European sites within or outside the zone of influence

¹ All European sites potentially connected irrespective of the nature or scale of the Proposed Development.

² Distances indicated are the closest geographical distance between the Proposed Development and the European site boundary, as made available by the NPWS.

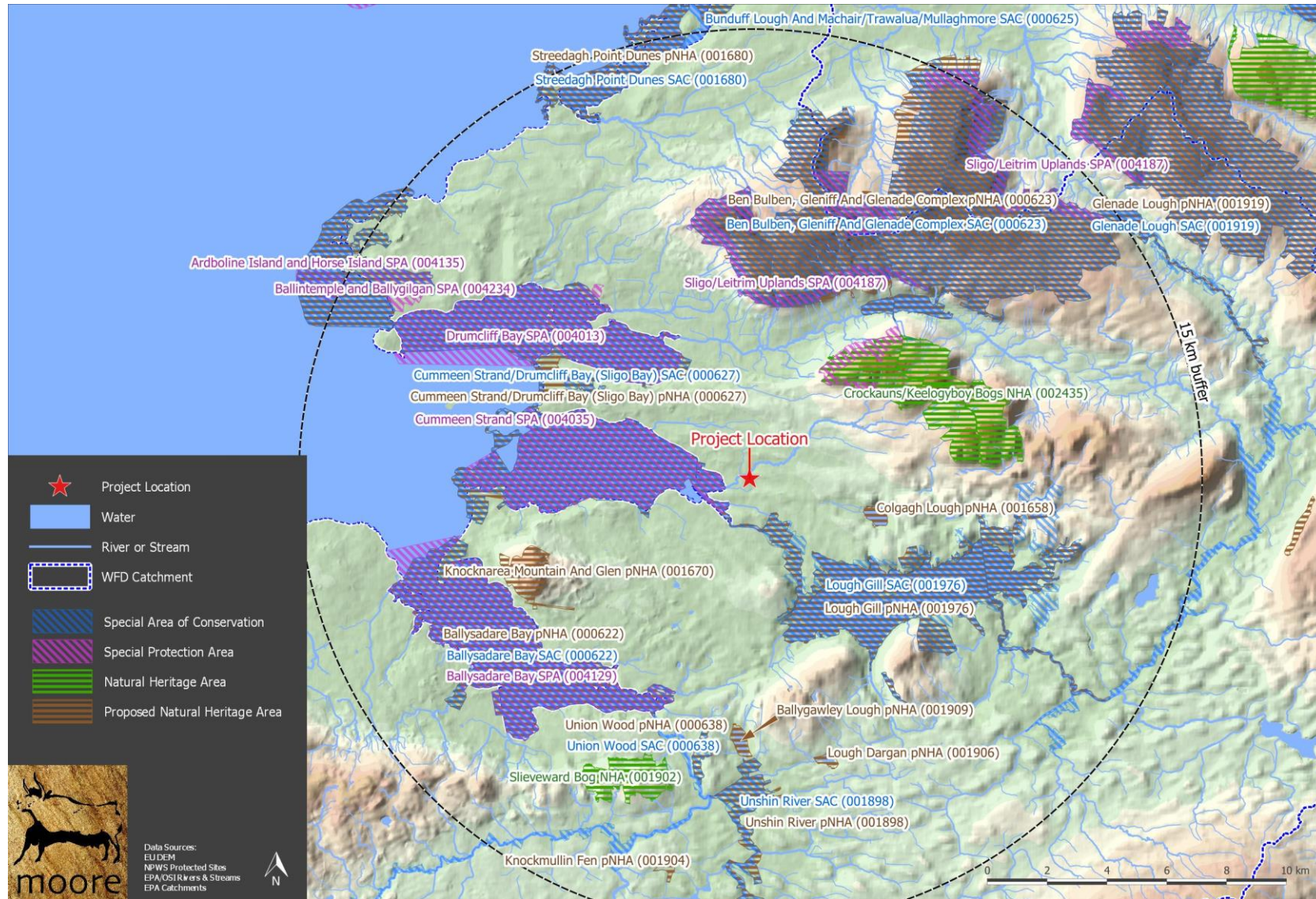


Figure 3. Showing European sites and NHAs/pNHAs within the wider Potential Zone of Influence of the Proposed Development.

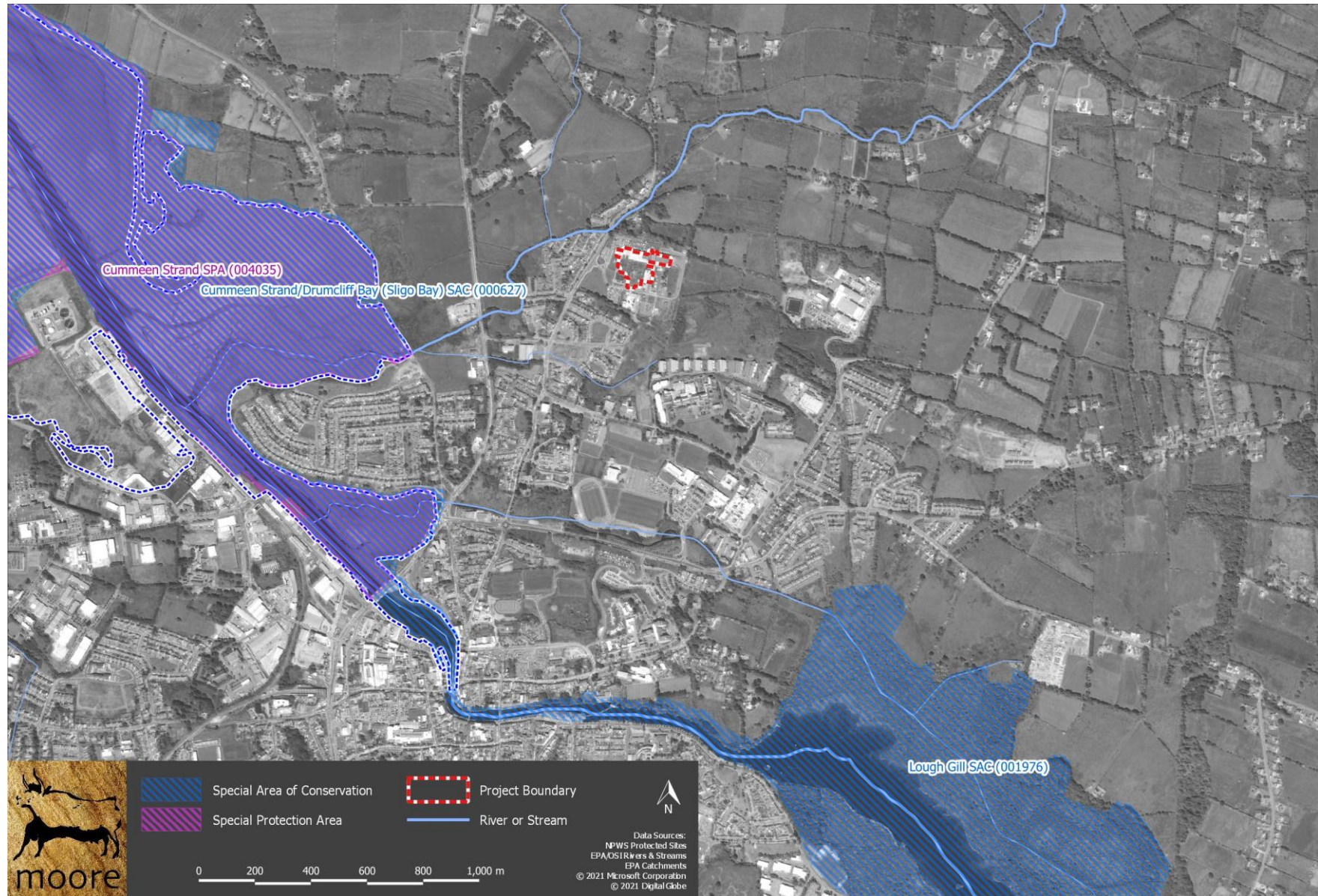


Figure 4. Detailed view of European sites in the nearer Potential Zone of Influence of the Proposed Development.

4.2. Ecological Network Supporting Natura 2000 Sites

A concurrent GIS analysis of the proposed Natural Heritage Areas (pNHA) and designated Natural Heritage Areas (NHA) in terms of their role in supporting the species using Natura 2000 sites was undertaken along with GIS investigation of European sites. It was assumed that these supporting roles mainly related to mobile fauna such as mammals and birds which may use pNHAs and NHAs as ecological corridors or “stepping stones” between Natura 2000 sites.

Article 10 of the Habitats Directive and the Habitats Regulations 2011 place a high degree of importance on such non-Natura 2000 areas as features that connect the Natura 2000 network. Features such as ponds, woodlands and important hedgerows were taken into account in the decision process and during the preparation of this AA Screening report.

The NHAs and pNHAs identified in Figure 4 are located outside the Zone of Influence.

5. Identification of Potential Impacts & Assessment of Significance

The Proposed Development is not directly connected with or necessary to the management of the sites considered in the assessment and therefore potential impacts must be identified and considered.

5.1. Assessment of Likely Significant Effects

The facility is located in the northern outskirts of Sligo. A review of aerial photography, Ordnance Survey Ireland (OSI) mapping and OSI Geographical Information System (GIS) data for rivers and streams indicates that there are no notable surface water features onsite and no direct hydrological pathways to offsite surface water bodies. There is no connectivity to any European sites within or outside the zone of influence

The consideration of all potential direct and indirect impacts that may result in significant effects on the conservation objectives of a European site, taking into account the size and scale of the Proposed Development are presented in Table 3.

Table 2 Assessment of Likely Significant Effects.

Identification of all potential direct and indirect impacts that may result in significant effects on the conservation objectives of a European site, taking into account the size and scale of the project.	
Impacts:	Significance of Impacts:
<p>Construction phase e.g.</p> <p>Vegetation clearance</p> <p>Demolition</p> <p>Surface water runoff from soil excavation/infill/landscaping (including borrow pits)</p> <p>Dust, noise, vibration</p> <p>Lighting disturbance</p> <p>Impact on groundwater/dewatering</p> <p>Storage of excavated/construction materials</p> <p>Access to site</p> <p>Pests</p>	<p>None</p> <p>The Proposed Project consists of a Technical Amendment to an existing IE Licence on an existing facility.</p>
<p>Operational phase e.g.</p> <p>Direct emission to air and water</p> <p>Surface water runoff containing contaminant or sediment</p> <p>Lighting disturbance</p> <p>Noise/vibration</p> <p>Changes to water/groundwater due to drainage or abstraction</p> <p>Presence of people, vehicles and activities</p> <p>Physical presence of structures (e.g. collision risks)</p> <p>Potential for accidents or incidents</p>	<p>All foul and surface water runoff will continue be contained on site and discharged to urban drainage systems.</p> <p>There is no real likelihood of any significant effects on European Sites in the wider catchment area.</p> <p>The facility is located at a distance of removal such that there will be no disturbance to qualifying interest species in any European sites.</p>
Describe any likely changes to the European site:	
<p>Examples of the type of changes to give consideration to include:</p>	<p>None.</p>

<p>Reduction or fragmentation of habitat area</p> <p>Disturbance to QI species</p> <p>Habitat or species fragmentation</p> <p>Reduction or fragmentation in species density</p> <p>Changes in key indicators of conservation status value (water quality etc.)</p> <p>Changes to areas of sensitivity or threats to QI</p> <p>Interference with the key relationships that define the structure or ecological function of the site</p> <p>Climate change</p>	<p>The Proposed Project consists of a Technical Amendment to an existing IE Licence on an existing facility.</p>
<p>Are 'mitigation' measures necessary to reach a conclusion that likely significant effects can be ruled out at screening?</p>	
<p>No</p>	<p>N/A</p>

On the basis of the information supplied, which is considered adequate to undertake a screening determination and having regard to:

- the nature and scale of the proposed development,
- the intervening land uses and distance from European sites,
- the lack of direct connections with regard to the Source-Pathway-Receptor model,

It may be concluded that the proposed development, individually or in-combination with other plans or projects, would not be likely to have a significant effect on the above listed European sites or any other European site, in view of the said sites' conservation objectives.

5.2. Assessment of Potential In-Combination Effects

In-combination effects are changes in the environment that result from numerous human-induced, small-scale alterations. In-combination effects can be thought of as occurring through two main pathways: first, through persistent additions or losses of the same materials or resource, and second, through the compounding effects as a result of the coming together of two or more effects.

As part of the Screening for an Appropriate Assessment, in addition to the Proposed Development, other relevant plans and projects in the area must also be considered at this stage. This step aims to identify at this early stage any possible significant in-combination effects of the Proposed Development with other such plans and projects on European sites.

A review of the National Planning Application Database was undertaken. The first stage of this review confirmed that there were no data gaps in the area where the Proposed Development is located. The database was then queried for developments granted planning permission within 500m of the Proposed Development within the last three years, these are presented in Table 3 below.

Table 3. Planning applications granted permission in the vicinity of the Proposed Development.

Planning Ref.	Description of development	Comments
19227	development consisting of provision of a new private service road to connect the Abbvie facilities in Ballytivnan and Manorhamilton Road. The proposed service road will be 6.5m wide, with a 1m wide pedestrian path and 2.4m high security fencing on either side. The road will be approximately 560 m long with ancillary site works including controlled access at both ends and lighting which will only be enabled during use. the development is subject to a Natura Impact Statement.	No potential for in-combination effects given the scale and location of the project.
19346	development consisting of the demolition and removal of an existing chain link fence and gates to the north, south, east and western boundaries and replacement with 2.4m high weld mesh fence and gates, installation of circa. 80 linear metres of 2.4m high architectural slatted metal fence to the southern boundary, installation of weld mesh fence to match the existing security gates adjacent the existing security hut on the southern boundary, provision of 2m wide gravel walkway adjacent to the east, north and western site boundaries, erection of 13 no. circa 4m high CCTV camera poles and all associated site services	No potential for in-combination effects given the scale and location of the project.
20382	PR - development consisting of a Prefabricated Communications building with a floor area of 39 square metres and 3.46 metres in height installed to the east of the existing buildings with associated site works. The building is clad in insulated metal cladding	No potential for in-combination effects given the scale and location of the project.
2074	development consisting of a temporary classroom	No potential for in-combination effects given the scale and location of the project.
2085	Development consisting of the following; construction of dwelling house with connection to public services and all associated site works on site	No potential for in-combination effects given the scale and location of the project.
2091	Development consisting of construction of site security fencing around the perimeter of the Abbvie Ballytivnan site boundaries (approximately 1304m long). The fencing will be 2.4m high galvanised welded steel mesh panels and posts with powder coated finish. The new security fence will include vehicular access gates and pedestrian gates at locations around the boundary.	No potential for in-combination effects given the scale and location of the project.

The Sligo County Development Plan in complying with the requirements of the Habitats Directive requires that all Projects and Plans that could affect the Natura 2000 sites in the same potential Zone of Influence of the Proposed Development site would be initially screened for Appropriate Assessment and if requiring Stage 2 AA, that appropriate employable mitigation measures would be put in place to avoid, reduce or ameliorate negative impacts. In this way any, in-combination impacts with Plans or Projects for the proposed development area and surrounding townlands in which the proposed development site is located, would be avoided.

The listed developments have been granted permission in most cases with conditions relating to sustainable development by the consenting authority in compliance with the relevant Local Authority Development Plan and in compliance with the Local Authority requirement with regard to the Habitats Directive. The development cannot have received planning permission without having met the consenting authority requirement in this regard.

There are no predicted in-combination effects given that it is predicted that the Proposed Development will have no effect on any European site.

Any new applications for the Proposed Development area will be assessed on a case by case basis *initially* by Sligo County Council which will determine the requirement for AA Screening as per the requirements of Article 6(3) of the Habitats Directive.

6. Conclusion

There are no predicted effects on any European sites given:

- There are no predicted emissions to air, water or the environment as a result of the Technical Amendment to the IE Licence that would result in significant effects.

It has been objectively concluded by Moore Group Environmental Services that:

1. The Proposed Development is not directly connected with, or necessary to the conservation management of the European sites considered in this assessment.
2. The Proposed Development is unlikely to either directly or indirectly significantly affect the Qualifying interests or Conservation Objectives of the European sites considered in this assessment.
3. The Proposed Development, alone or in combination with other projects, is not likely to have significant effects on the European sites considered in this assessment in view of their conservation objectives.
4. It is possible to conclude that significant effects can be excluded at the screening stage.

It can be *excluded*, on the basis of objective information, that the Proposed Development, individually or in combination with other plans or projects, will have a significant effect on a European site.

An appropriate assessment is not, therefore, required.

A finding of no significant effects report is presented in Appendix A in accordance with the EU Commission's methodological guidance (European Commission, 2002).

7. References

Department of the Environment, Heritage and Local Government (2010) Guidance on Appropriate Assessment of Plans and Projects in Ireland (as amended February 2010).

European Commission (2000) Managing Natura 2000 sites: the provisions of Article 6 of the 'Habitats' Directive 92/43/EEC.

European Commission (2007) Guidance document on Article 6(4) of the 'Habitats Directive' 92/43/EEC: Clarification of the concepts of: alternative solutions, imperative reasons of overriding public interests, compensatory measures, overall coherence and opinion of the Commission. European Commission, Brussels.

European Commission (2018) Managing Natura 2000 sites: the provisions of Article 6 of the 'Habitats' Directive 92/43/EEC.

European Commission (2021) Assessment of plans and projects in relation to Natura 2000 sites - Methodological guidance on Article 6(3) and (4) of the Habitats Directive 92/43/EEC, Brussels 28.9.21.

European Commission (2021) Guidance document on the strict protection of animal species of Community interest under the Habitats Directive, Brussels 12.10.21.

NPWS (2019) The Status of EU Protected Habitats and Species in Ireland. National Parks and Wildlife Service, Department of the Environment, Heritage and Local Government, Dublin.

NPWS (2022) National Parks and Wildlife Service Metadata available online at <https://www.npws.ie/maps-and-data>

Office-of-the-Planning-Regulator (2021) Appropriate Assessment Screening for Development Management OPR Practice Note PN01. March 2021

Appendix A

FINDING OF NO SIGNIFICANT EFFECTS REPORT

Finding no significant effects report matrix

Name of project or plan

Abbvie Ballytivnan IEL Technical Amendment

Name and location of the Natura 2000 site(s)

The nearest European sites to the facility to which the licence relates, the Abbvie Campus at Ballytivnan, are the Cummeen Strand SPA (Site Code 004035), and the Cummeen Strand/Drumcliff Bay (Sligo Bay) SAC (Site Code 000627), both approximately 800m to the west.

The facility is located in the northern outskirts of Sligo. A review of aerial photography, Ordnance Survey Ireland (OSI) mapping and OSI Geographical Information System (GIS) data for rivers and streams indicates that there are no notable surface water features onsite and no direct hydrological pathways to offsite surface water bodies.

Description of the project or plan

A Technical Amendment (TA) is requested from the EPA for the AbbVie Ballytivnan IE Licence P1087-01

There will be no discharges to surface waters as a result of the proposed change and there is no connectivity to European sites.

The Screening process is effectivity on the Technical Amendment to the Licence only.

Is the project or plan directly connected with or necessary to the management of the site(s)

No

Are there other projects or plans that together with the projects or plan being assessed could affect the site

A review of the National Planning Application Database was undertaken. The first stage of this review confirmed that there were no data gaps in the area where the Proposed Development is located. The database was then queried for developments granted planning permission within 500m of the Proposed Development within the last three years, these are presented in the Table below.

Planning applications granted permission in the vicinity of the Proposed Development.

Planning Ref.	Description of development	Comments
19227	development consisting of provision of a new private service road to connect the Abbvie facilities in Ballytivnan and Manorhamilton Road. The proposed service road will be 6.5m wide, with a 1m wide pedestrian path and 2.4m high security fencing on either side. The road will be approximately 560 m long with ancillary site works including controlled access at both ends and lighting which will only be enabled during use. the development is subject to a Natura Impact Statement.	No potential for in-combination effects given the scale and location of the project.
19346	development consisting of the demolition and removal of an existing chain link fence and gates to the north, south, east and western boundaries and replacement with 2.4m high weld mesh fence and gates, installation of circa. 80 linear metres of 2.4m high architectural slatted metal fence to the southern boundary, installation of weld mesh fence to match the existing security gates adjacent the	No potential for in-combination effects given the scale and location of the project.

Planning Ref.	Description of development	Comments
	existing security hut on the southern boundary, provision of 2m wide gravel walkway adjacent to the east, north and western site boundaries, erection of 13 no. circa 4m high CCTV camera poles and all associated site services	
20382	PR - development consisting of a Prefabricated Communications building with a floor area of 39 square metres and 3.46 metres in height installed to the east of the existing buildings with associated site works. The building is clad in insulated metal cladding	No potential for in-combination effects given the scale and location of the project.
2074	development consisting of a temporary classroom	No potential for in-combination effects given the scale and location of the project.
2085	Development consisting of the following; construction of dwelling house with connection to public services and all associated site works on site	No potential for in-combination effects given the scale and location of the project.
2091	Development consisting of construction of site security fencing around the perimeter of the Abbie Ballytivnan site boundaries (approximately 1304m long). The fencing will be 2.4m high galvanised welded steel mesh panels and posts with powder coated finish. The new security fence will include vehicular access gates and pedestrian gates at locations around the boundary.	No potential for in-combination effects given the scale and location of the project.

The Sligo County Development Plan in complying with the requirements of the Habitats Directive requires that all Projects and Plans that could affect the Natura 2000 sites in the same potential Zone of Influence of the Proposed Development site would be initially screened for Appropriate Assessment and if requiring Stage 2 AA, that appropriate employable mitigation measures would be put in place to avoid, reduce or ameliorate negative impacts. In this way any, in-combination impacts with Plans or Projects for the proposed development area and surrounding townlands in which the proposed development site is located, would be avoided.

The listed developments have been granted permission in most cases with conditions relating to sustainable development by the consenting authority in compliance with the relevant Local Authority Development Plan and in compliance with the Local Authority requirement for regard to the Habitats Directive. The development cannot have received planning permission without having met the consenting authority requirement in this regard. There are no predicted in-combination effects given that it is predicted that the Proposed Development will have no effect on any European site.

There are no predicted in-combination effects given that the reasons discussed in the 'Comments' column of the Table above and given that the Proposed Development is unlikely to have any adverse effects on any European sites.

Any new applications for the Proposed Development area will be assessed on a case by case basis *initially* by Sligo County Council which will determine the requirement for AA Screening as per the requirements of Article 6(3) of the Habitats Directive.

THE ASSESSMENT OF SIGNIFICANCE OF EFFECTS

Describe how the project or plan (alone or in combination) is likely to affect the Natura 2000 site.

The facility is located in the northern outskirts of Sligo. A review of aerial photography, Ordnance Survey Ireland (OSI) mapping and OSI Geographical Information System (GIS) data for rivers and streams indicates that there are no notable surface water features onsite and no direct hydrological pathways to offsite surface water bodies. There is no connectivity to any European sites within or outside the zone of influence

Explain why these effects are not considered significant.

There are no predicted effects on any European sites given:

- There are no predicted emissions to air, water or the environment as a result of the Technical Amendment to the IE Licence that would result in significant effects.

List of agencies consulted: provide contact name and telephone or e-mail address

The requirement for Appropriate Assessment Screening was determined during pre-planning discussion with Sligo County Council.

Response to consultation

N/A.

DATA COLLECTED TO CARRY OUT THE ASSESSMENT

Who carried out the assessment

Moore Group Environmental Services.

Sources of data

NPWS database of designated sites at www.npws.ie

National Biodiversity Data Centre database <http://maps.biodiversityireland.ie>

Level of assessment completed

Desktop Assessment. Fieldwork was carried out as part of the EIA process.

Where can the full results of the assessment be accessed and viewed

Sligo County Council Planning web portal.

OVERALL CONCLUSIONS

There are no predicted effects on any European sites given:

- There are no predicted emissions to air, water or the environment as a result of the Technical Amendment to the IE Licence that would result in significant effects.

It has been objectively concluded by Moore Group Environmental Services that:

1. The Proposed Development is not directly connected with, or necessary to the conservation management of the European sites considered in this assessment.
2. The Proposed Development is unlikely to either directly or indirectly significantly affect the Qualifying interests or Conservation Objectives of the European sites considered in this assessment.
3. The Proposed Development, alone or in combination with other projects, is not likely to have significant effects on the European sites considered in this assessment in view of their conservation objectives.
4. It is possible to conclude that significant effects can be excluded at the screening stage.

It can be *excluded*, on the basis of objective information, that the Proposed Development, individually or in combination with other plans or projects, will have a significant effect on a European site.

An appropriate assessment is not, therefore, required.