

 <p>Environmental Protection Agency An Ghníomhaireacht um Chaomhnú Comhshaoil</p>	OFFICE OF ENVIRONMENTAL SUSTAINABILITY
INDUSTRIAL AND CARBON EMISSIONS REGULATION PROGRAMME	
TO:	Tom Ryan, Director
FROM:	Guy Price, Inspector, Industrial and Carbon Emissions Regulation Programme
DATE:	2 nd April 2024
RE:	Technical Amendment to Industrial Emissions Licence Register Number: P1087-01 held by AbbVie Ireland NL B.V., for an installation located at Old Bundoran Road, Ballytivnan, Sligo.

The Agency received a request on 18 August 2023 from AbbVie Ireland NL B.V., Licence Reg. No. P1087-01 to technically amend its Licence. The request relates to a proposed amendment to emission limit values (ELV) for emissions to sewer, an increase to the maximum:

- concentration of sulphates (SO₄) and fats, oils and greases (FOGs);
- daily mass emissions for chlorides.

This memo recommends that the change may be accommodated by a Technical Amendment (TA), in accordance with Section 96(1)(c) of Environmental Protection Agency Act 1992 as amended (hereafter referred to as the EPA Act), with the exception of an increase to the maximum:

- daily mass emissions for chlorides.

1. Background

AbbVie Ireland NL B.V. (hereafter referred to as Abbvie), was granted a licence, Reg. No. P1087-01, on 24 April 2020 for an installation located at Old Bundoran Road, Ballytivnan, Sligo. The installation is licenced under Class 5.16¹ of the First Schedule to the EPA Act. There are no previous amendments to the licence.

Abbvie operate an integrated biochemical installation, the main process being the linking of a bio-pharmaceutical molecule to a cytotoxic molecule. There is also a drug delivery devices manufacturing operation within the installation boundary. The installation is located approximately 1.7km north-east of Sligo town centre and operates 7 days per week, 24 hour per day.

2. Technical Amendment Request

On the 18 August 2023, the Agency received a request for a TA of Licence Reg. No. P1087-01, in order to allow for an increase in ELVs for emissions to sewer for the following parameters: SO₄, FOGs and chlorides.

¹The production of pharmaceutical products including intermediates

The licensee has proposed the following changes (to Schedule *B.3 Emissions to Sewer* of the existing licence), an increase to the maximum:

1. concentration of SO₄, from 15 mg/l to 400 mg/l
2. concentration of FOGs, from 10 mg/l to 50 mg/l
3. daily mass emissions of chlorides, from 18 kg/day to 1080 kg/day

The licensee has submitted a letter from Uisce Éireann (UÉ) consenting to the proposed changes to SO₄ and FOGs only, with no consent for the proposed change to chlorides provided.

3. Consultation with the Office of Environmental Enforcement (OEE)

I have consulted with the OEE Inspector, Eimear Kelly in relation to this technical TA request. The OEE confirmed that the proposed increase to ELVs for emissions to sewer for SO₄, FOGs and chlorides cannot be accommodated under the existing licence. OEE has confirmed that there are no legal proceedings in train in respect of this licence.

4. Assessment

The licensee has proposed an increase to the maximum concentration of SO₄ and FOGs, and maximum daily mass emission of chlorides for emissions to sewer (emission point ref. SE1). The Inspector notes that, the Agency's guidance² lists examples of alterations which may be accommodated under a TA including, "*Changes to ELVs for an emission to sewer subject to [UÉ] approval*". As the licensee has provided an approval letter from UÉ for the proposed changes to SO₄ and FOGs only, chlorides have not been considered in the assessment below.

Assessment of SO₄ and FOGs:

Process effluent is discharged to the UE sewer network and treated at the Sligo wastewater treatment plant (WWTP) (discharge licence No. D0014-01). The Sligo WWTP has a design capacity of 50,000 population equivalent and a peak hydraulic capacity of 37,500 m³/day with an average hydraulic capacity of 18,250 m³/day (2022 AER). The proposed increase in the concentration for SO₄ and FOGs is not considered environmentally significant in the context of the volume and buffering capacity provided by the Sligo WWTP. The volume of the installation's discharge will remain unchanged at 180 m³/day and will account for less than 1% of the average hydraulic loading to the sewer network. Therefore, the sewer network has sufficient capacity to accept the proposed discharge from the installation.

The inspector notes there are no limits applied within the existing Sligo WWTP discharge licence for SO₄ or FOGs. In determining if the changes to the discharge concentrations from the Abbvie installation would impact on the receiving waters, the Garavoge Estuary (IE_WE_470_0100), the inspector notes there are no environmental quality standards (EQS) for either SO₄ or FOG for Estuarine waters within the "*European Communities Environmental Objectives (Surface Waters) Regulations 2009 as amended*". SO₄ occurs naturally in seawater typically around 2,600 ppm and the setting of ELVs for FOG within the Abbvie licence is due to its association with the creation of blockages within the sewer network itself. Therefore, the proposed changes to emissions of SO₄ and FOG are not considered environmentally significant parameters in this context.

The treatment of the installations discharge must be equivalent to Best Available Techniques (BAT) for the sector, in this case "*Commission Implementing Decision (EU) 2016/902 of 30 May 2016 establishing best available techniques (BAT) under Directive 2010/75/EU of the*

² Guidance on Requests for Alterations to a Licensed Industrial or Waste Activity (published 24 June 2019): <https://www.epa.ie/publications/licensing--permitting/industrial/ied/Licence-Alteration-Guidance-rev-MOC-21-06-19.pdf>

European Parliament and of the Council, for common wastewater and waste gas treatment/management systems in the chemical sector". Taking into account the proposed increase in emission limits for SO₄ and FOG, the operating capacity and discharge limits for the Sligo WWTP, the discharge to sewer from the Abbvie installation will continue to undergo a level of treatment considered at the determination of the existing licence, which is equivalent to BAT.

While the inspector notes there have been individual exceedances of the emission limits for both SO₄ and FOGs over the past two years, the OEE have confirmed there are no ongoing compliance issues, compliance investigations or legal proceedings in place in relation to the installation.

Section 96(1) of the EPA Act:

Section 96(1) of the EPA Act states that:

"The Agency may amend a licence or revised licence for the purposes of -

- (a) correcting any clerical error therein,
- (b) facilitating the doing of anything pursuant to a condition attached to the licence where the doing of that thing may reasonably be regarded as having been contemplated by the terms of the condition or the terms of the licence taken as a whole, but which was not expressly provided for in the condition, or
- (c) otherwise facilitating the operation of the licence and the making of the amendment does not result in the relevant requirements of section 83(5) ceasing to be satisfied".

It is considered that the proposed amendment request may be accommodated under Section 96(1)(c). To amend the licence under this criterion, two parts need to be satisfied, Part (i) otherwise facilitating the operation of the licence and Part (ii) does not result in the relevant requirements of Section 83(5) ceasing to be satisfied. The changes proposed to the concentration limits for SO₄ and FOGs in accordance with the UÉ consent can therefore be considered as otherwise facilitating the operation of the Licence. The changes in concentrations of SO₄ and FOGs in the discharge to sewer will not result in the relevant requirements of Section 83(5) ceasing to be satisfied.

Based on the above assessment, it is recommended that the proposed changes to the licence to increase the concentration limits for SO₄ and FOGs from the installations discharge to sewer be accommodated by Technical Amendment. It is considered that the proposed revisions are in accordance with Agency guidelines for licence amendments. The proposed amendments will satisfy the criteria under Section 96(1)(c) of the EPA Act allowing the Agency to amend a licence or revised licence.

The recommended amendment (RA) provides for the increase in concentration limits for SO₄ and FOGs from the installations discharge to sewer. The specific changes relate to the following schedule of the licence.

- *Schedule B.3 Emissions to Sewer*

5. Appropriate Assessment

Appendix 1 lists the European Sites assessed, their associated qualifying interests and conservation objectives.

A screening for Appropriate Assessment was undertaken to assess, in view of best scientific knowledge and the conservation objectives of the site, if the activity, individually or in combination with other plans or projects is likely to have a significant effect on any European Site. In this context, particular attention was paid to the European Site(s) at Cummeen Strand/Drumcliff Bay (Sligo Bay) SAC (Site Code: 000627), Cummeen Strand SPA (Site Code: 004035), Lough Gill SAC (Site Code: 001976).

The activity is not directly connected with or necessary to the management of any European Site and the Agency considered, for the reasons set out below, that it can be excluded, on the basis of objective information, that the activity, individually or in combination with other plans or projects, will have a significant effect on any European Site and accordingly determined that an Appropriate Assessment of the activity was not required.

This determination is based on the following reasons:

- The installation is not located within any European site; and
- Wastewater from the installation discharges to sewer and undergoes treatment at Sligo WWTP (licensed under WWDL D0014-01). Considering both the nature of the discharges from the installation and the capacity of the receiving WWTP it is considered that the changes will not indirectly have a significant effect on European Sites in the vicinity of the WWTP discharge to the Garavoge Estuary (IE_WE_470_0100).

6. Recommendation

This memo recommends that the requested changes, as detailed above, be accommodated by a Technical Amendment of Licence P1087-01 (held by AbbVie Ireland NL B.V.), in accordance with Section 96(1)(c) of the EPA Act 1992 as amended.

I recommend that the licence amendment be approved as set out in the attached recommended Technical Amendment. The making of the amendment will not result in the relevant requirements of Section 83(5) of the EPA Act 1992 as amended, ceasing to be satisfied.

Signed,



Guy Price
Inspector
Industrial and Carbon Emissions Regulation Programme

Appendix 1: List of European Sites assessed, their associated qualifying interests and conservation objectives.

	European Site (Site Code)	Distance/Direction from Installation	Qualifying Interests (* denotes a priority habitat)	Conservation Objectives
1	Cummeen Strand/Drumcliff Bay (Sligo Bay) SAC (000627)	0.85 km south and west of the installation.	<p>Habitats: 1130 Estuaries 1140 Mudflats and sandflats not covered by seawater at low tide 2110 Embryonic shifting dunes 2120 Shifting dunes along the shoreline with <i>Ammophila arenaria</i> (white dunes) 2130 Fixed coastal dunes with herbaceous vegetation (grey dunes)* 5130 <i>Juniperus communis</i> formations on heaths or calcareous grasslands 6210 Semi-natural dry grasslands and scrubland facies on calcareous substrates (<i>Festuco-Brometalia</i>) (* important orchid sites) 7220 Petrifying springs with tufa formation (Cratoneurion)*</p> <p>Species 1014 Marsh Snail (<i>Vertigo angustior</i>) 1095 Sea Lamprey (<i>Petromyzon marinus</i>) 1099 River Lamprey (<i>Lampetra fluviatilis</i>) 1365 Harbour seal (<i>Phoca vitulina</i>)</p>	NPWS (2013) Conservation Objectives: Cummeen Strand/Drumcliff Bay (Sligo Bay) SAC 000627. Version 1. National Parks and Wildlife Service, Department of Arts, Heritage and the Gaeltacht.
2	Lough Gill SAC (001976)	1.05 km south-east of the installation.	<p>Habitats: 3150 Natural eutrophic lakes with Magnopotamion or Hydrocharition - type vegetation 6210 Semi-natural dry grasslands and scrubland facies on calcareous substrates (<i>Festuco-Brometalia</i>) (* important orchid sites)</p>	NPWS (2021) Conservation Objectives: Lough Gill SAC 001976. Version 1. National Parks and Wildlife Service,

			<p>91A0 Old sessile oak woods with Ilex and Blechnum in the British Isles 91E0 Alluvial forests with Alnus glutinosa and Fraxinus excelsior (Alno-Padion, Alnion incanae, Salicion albae)*</p> <p>Species 1092 White-clawed Crayfish (<i>Austropotamobius pallipes</i>) 1095 Sea Lamprey (<i>Petromyzon marinus</i>) 1096 Brook Lamprey (<i>Lampetra planeri</i>) 1099 River Lamprey (<i>Lampetra fluviatilis</i>) 1106 Salmon (<i>Salmo salar</i>) 1355 Otter (<i>Lutra lutra</i>)</p>	Department of Housing, Local Government and Heritage.
3	Cummeen Strand SPA (004035)	1.45 km west of the installation.	<p>Habitats: A999 Wetlands</p> <p>Species A046 Brent Goose <i>Branta bernicla hrota</i> A130 Oystercatcher <i>Haematopus ostralegus</i> A162 Redshank <i>Tringa totanus</i></p>	NPWS (2013) Conservation Objectives: Cummeen Strand SPA 004035. Version 1. National Parks and Wildlife Service, Department of Arts, Heritage and the Gaeltacht.