

 <p>Environmental Protection Agency An Ghníomhaireacht um Chaomhnú Comhshaoil</p>	OFFICE OF ENVIRONMENTAL SUSTAINABILITY
ENVIRONMENTAL LICENSING PROGRAMME	
TO:	Gerard O'Leary, Director
FROM:	Jennifer Cope, Inspector, Environmental Licensing Programme
DATE:	15 June 2021
RE:	Technical Amendment to Industrial Emissions Licence Register Number: P1087-01, held by AbbVie Ireland NL B.V., Manorhamilton Road, Sligo.

The Agency received a request on 26 March 2021 from AbbVie Ireland NL B.V., Licence Reg. No. P1087-01 to technically amend its licence. The request relates to an increase in mass emissions from the installation and a reduction in stack heights for two boilers.

This memo recommends that the change is not accommodated by a Technical Amendment of IE Licence Register Number P1087-01.

1. Background

AbbVie Ireland NL B.V. 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 5.16 The production of pharmaceutical products including intermediates* of the First Schedule to the EPA Act 1992 as amended and is an IE activity. AbbVie Ireland NL B.V are licenced to operate an integrated biochemical installation and the main process includes linking of a bio-pharmaceutical molecule to a cytotoxic molecule providing effective delivery of the medicine within the patient. There is also an existing separate Abbvie manufacturing operation within the installation boundary, which is not a licensable activity in its own right, manufacturing drug delivery devices such as auto injector pens. This existing operation uses common utilities and is part of the installation.

2. Technical Amendment request

On 26 March 2021, the Agency received a request for a Technical Amendment of IE Licence Reg. No. P1087-01, to reduce the stack heights and increase the volumetric flows for the two 1.6 MW liquid petroleum gas boilers (emission points A1-1 and A1-2) installed on-site which will increase the mass emissions from the installation. The licensee confirmed that the information provided for the two boilers as part of the licence application is different to the actual boiler specification installed at the installation. The licensee has planning permission for an integrated biochemical installation (planning permission PL18/185) and the development consisting of 4 no. new boiler flues, 17.5m above ground level and 500 mm diameter. In support of the technical amendment request, the licensee carried out air dispersion modelling which was received on 10 May 2021.

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

I have consulted with the OEE Inspector, Aisling Ryan, in relation to this technical amendment request. The OEE confirmed that the proposed change to *Schedule B.1 Emission to Air* 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 installed two 1.6 MW liquid petroleum gas boilers (emission points A1-1 and A1-2) on site which are almost 5 m lower than what is specified in its licence P1087-01. The licensee confirmed that the information provided for the two boilers as part of the licence application is different to the actual boiler specification installed at the installation. It is noted that the increase in daily and hourly maximum volume flow rates and reduction in stack height were not part of the licensee objection to the Proposed Determination of its licence P1087-01.

The licensee has planning permission for an integrated biochemical installation (planning permission PL18/185) and Sligo County Council granted planning permission on 05 July 2018 *for the development of land, in accordance with the documents lodged, namely:- development consisting of (a).....(f) the addition of 4 no. new boiler flues, 17.5m above ground level and 500 mm diameter.* I consider that the requested reduction to the stack heights from 17.4m to 12.5m for emissions points A1-1 and A1-2 cannot be accommodated by technical amendment as the licensee did not provide confirmation from Sligo County Council that planning permission was required or a declaration that this change was exempt from planning permission.

The licensee requested a reduction for the stack heights from 17.4 m to 12.5 m and an increase in the volumetric flow from 840 m³/hr to 2,575 m³/hr and from 20,100 m³/day to 61,800 m³/day for the two 1.6 MW liquid petroleum gas boilers (emission points A1-1 and A1-2) installed on-site. In support of the technical amendment request, the licensee carried out air dispersion modelling (received on 10 May 2021), which shows that the predicted environmental concentrations are well below the air quality standards and that the emissions from the installation are not likely to have a significant impact on the environment.

The proposal will result in a 207% increase in the volumetric flow from each of the boilers and an increase in mass emissions for sulphur dioxides and nitrogen oxides from the installation by 200% and 206% respectively (see table below).

Emission Point reference Number	Description (Thermal input MW)	Parameter	ELV mg/m ³	Current licence mass emissions (kg/hour)	Requested change to mass emissions (kg/hour)	Predicted increase (kg/hr)	% increase in mass emissions
A1-1	LPG boiler (1.6)	Sulphur dioxide	35	0.03	0.09	0.06	200%
		Nitrogen oxides (as NO ₂)	200	0.17	0.52	0.35	206%
A1-2	LPG boiler (1.6)	Sulphur dioxide	35	0.03	0.09	0.06	200%
		Nitrogen oxides (as NO ₂)	200	0.17	0.52	0.35	206%

Section 96 (1) of the EPA Act 1992 as amended 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.”*

The licensee has requested to increase the total mass emission from the installation which is not considered to be (a) correcting any clerical error in the licence for Register Number P1087-01 AbbVie Ireland NL B.V.; or (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.

It is not considered that the proposed request may be accommodated under 96(1)(c) for the reason outlined below.

To amend the licence under this criterion two parts need to be satisfied, (i) facilitate the operation of the licence and (ii) does not result in Section 83(5) ceasing to be satisfied.

In relation to the second part, the licensee submitted air dispersion modelling, which shows that the predicted environmental concentrations are well below the air quality standards and that the emissions from the installation are not likely to have a significant impact on the environment. However, under the first part, there will be an increase in volumetric flow from each of the boilers and an increase in mass emissions for sulphur dioxides and nitrogen oxides from the installation and this could not be seen as *otherwise facilitating the operation of the licence.*

I consider that such an increase (1) in the daily and hourly maximum flow rate for both the LPG boilers (A1-1 and A1-2); and (2) total mass emissions from the installation; constitutes an increase of emissions from the activity and does not facilitate the operation of the licence. Therefore, the proposed request may not be accommodated under the technical amendment provisions and a licence review would be required in order to consider the proposed changes as requested in the Technical Amendment. A technical amendment may potentially be considered where there will be no net increase in permitted mass emissions to air from the installation.

5. Recommendation

I recommend that the requested amendment is not accommodated by a Technical Amendment of IE Licence P1087-01.

Signed,



Jennifer Cope
Inspector
Environmental Licensing Programme