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Our Reference: IE0311237-LET-0017

1st December 2015

Ms Noeleen Keavey
Office of Climate, Licensing, & Resource use
Environmental Protection Agency
PO Box 3000
Johnstown Castle Estate
Co. Wexford

Re: Unsolicited Additional Information - Ref No: P0643-03

The project delivery specialists

Dear Ms Keavey,

The content of this letter forms unsolicited additional information with respect to the AbbVie Ireland NL B.V. Industrial Emissions Licence review application.

I declare that the content of the electronic files submitted with this additional information submission is a true copy of the original hardcopy documents submitted.

Should you have any questions on any of the information provided, please do not hesitate to contact me at 01-4001202 or ciaran.reay@pmgroup-global.com.

Yours sincerely,

_____
Ciarán Reay
EHS Consultant
On behalf of AbbVie Ireland NL B.V.

c.c. Michael Gallagher, AbbVie Ireland NL B.V.

Additional Information regarding the Impact of Formic Acid

This additional information is to read in conjunction with the Air Dispersion Modelling Report (IE0311237-22-RP-0001) and is provided to address the impact of Formic Acid emissions from the existing scrubber on site on the local air quality.

Air Quality Standards (AQSs) for the protection of human health and the environment have been developed at European level and implemented into Irish legislation for a number of atmospheric pollutants. AQSs set limit values for Ground Level Concentrations (GLCs) of certain pollutants for both the short term (hourly, daily) and long term (annual averages).

In the absence of any Air Quality Standard, Appendix K of the EPA AG4 Guidance Note advises the following;

> *Where no EU air quality standard exists, relevant statutory standards from other EU countries such as the UK, Germany or Denmark should be used. The most stringent European guideline / limit value from the sources outlined below should be referenced when determining compliance in the absence of an applicable EU ambient air quality standard. The relevant statutory guidance can be obtained from the following sources:*
>
> a) *Danish C-values (as a 99th%ile) outlined in Danish EPA"s Environmental Guidelines No.1, 2002 Guidelines for Air Emission Regulation Limitation of air pollution from installations.*
>
> b) *Instructions on Air Quality Control – TA Luft from the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety Technical*
>
> c) *Environmental Assessment Level (EAL) based on the Health & Safety Authority publication 2007 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001 (S.I. No. 619 OF 2001). The EAL should be derived using the approach outlined in Appendix D of UK Environment Agency "IPPC H1 - IPPC Environmental Assessment for BAT". The guidance outlines the approach for deriving both short-term and long-term EALs. In relation to the long-term (annual) EAL, this can be derived by applying a factor of 100 to the 8-hour Occupational Exposure Level (OEL). The factor of 100 allows for both the greater period of exposure and the greater sensitivity of the general population. For short-term (1-hour) exposure, the EAL is derived by applying a factor of 10 to the short term exposure limit (STEL). In this case, only the sensitivity of the general population need be taken into account as there is no need for additional safety factors in terms of the period of exposure. Where STELs are not listed then a value of 3 times the 8-hour time weighted average occupational exposure limit may be used*
>
> d) *Appendix D of the UK Environment Agency "IPPC H1 - IPPC Environmental Assessment for BAT" (Environment Agency, 2003)*

Option (c) was deemed the most appropriate method for establishing an Environmental Assessment Level (EAL) as a range of Occupation Exposure Levels (OEL) were available from various material safety data sheets for Formic Acid. The most conservative OEL (8 hr mean) of 9mg/m^3 was chosen. Applying the method from the UK IPPC H1 Guide, we can calculate a short term limit of 27mg/m^3 (27,000µg/m^3).

The Air Dispersion Modelling reports the highest level ground level concentration of Formic Acid to be 2.85µg/m^3 which is well within the limit of 27,000µg/m^3 (<0.01 % of the limit).

Therefore, the air dispersion modelling has demonstrated that emissions to atmosphere from AbbVie Sligo facility will not result in ground level concentrations of pollutants exceeding applicable air quality standard (AQS) limit values.