

*This Report has been cleared for submission to the Board by Programme Manager,
Marie O'Connor*

Signed:  Date: 08/04/2020

 Environmental Protection Agency <i>An Ghníomhaireacht um Chaomhú Comhshaoil</i>	OFFICE OF ENVIRONMENTAL SUSTAINABILITY
REPORT OF THE TECHNICAL COMMITTEE ON OBJECTIONS TO PROPOSED DETERMINATION	
TO:	Directors
FROM:	Technical Committee Environmental Licensing Programme
DATE:	08 April, 2020
RE:	Objection to Proposed Determination for AbbVie Ireland NL B.V., Reg. No. P1087-01

Application Details	
Class of activity:	5.16 - The production of pharmaceutical products including intermediates.
Location of activity:	Old Bundoran Road, Ballytivnan, Sligo
Licence application received:	5 September, 2018
PD issued:	6 December, 2019
First party objection received:	Yes (3 January, 2020)
Third Party Objection received:	No
Submissions on Objections received:	No

Company

This licence application relates to a proposal by AbbVie Ireland NL B.V. to operate an integrated biochemical installation. The new integrated biochemical manufacturing operation replaces a redundant manufacturing installation at the site.

Planning permission has been granted for the construction. Three submissions were received in relation to the application and these were considered by the Board at PD stage.

Consideration of the Objection

The Technical Committee, comprising of Niamh Connolly (Chair) and Eoin McCaffrey, has considered all the issues raised in the objection and this report details the Committee's comments and recommendations following the examination of the objection, submission on objections and the documents associated with the IE licence application together with discussions with the inspector, Jennifer Cope, who provided comments on the points raised.

This report considers the first party objection received.



First Party Objection

The applicant raised three main points of objection and six main points of clarification relating to specific Conditions and Schedules of the Proposed Determination. Some points have been addressed under one heading, where it is considered appropriate to do so.

Objections

A.3 Condition 4.5 Noise – Labelling of Noise Sensitive Locations

Condition 4.5 states:

Noise from the installation shall not give rise to sound pressure levels measured at the NSLs which exceed the limit value(s).

The applicant requests permission to eliminate the requirement for labelling the off-site noise monitoring locations. The three noise monitoring locations are outside the licence boundary and signage would be highly difficult to maintain.

Technical Committee's Evaluation:

The TC would like to state that Condition 4.5 does not require any such labelling. The TC notes that Condition 3.8 of the PD states '*The licensee shall clearly label and provide safe and permanent access to all on-site sampling and monitoring points and to off-site points **as required by the Agency.** The requirement with regard to off-site points is subject to the prior agreement of the landowners concerned.*'

Condition 3.8 is a standard condition which requires the licensee to label off-site points as required by the Agency. This condition is to provide for appropriate operation of the installation to ensure protection of the environment. Compliance with Condition 11.10 (vi) '*up-to-date site drawing/plans showing the location of key process and environmental infrastructure, including monitoring locations and emission points*' is usually used to locate monitoring locations unless there is some major issue on site. The TC considers it unnecessary to alter Condition 4.5 or Condition 3.8.

Reason for Decision:

The TC proposes no change to Condition 4.5 or Condition 3.8 and has reached its conclusion on the basis of the following considerations:

1. Labelling of Noise Sensitive Locations (NSL) at off-site points is necessary for clarification of the exact locations for noise monitoring personnel. It is noted that this is subject to the prior agreement of the landowners concerned as outlined in Condition 3.8.

Recommendation: No change.

A.5 Condition 6.9 - Bunds

Condition 6.9 states:

The integrity and water tightness of all tanks, bunding structures, containers and underground pipes and their resistance to penetration by water or other materials carried or stored therein shall be tested and demonstrated by the licensee prior to use. This testing shall be carried out by the licensee at least once every three years thereafter and reported to the Agency on each occasion. This testing shall be carried out in accordance with any guidance published by the Agency. A written record of all integrity tests and any maintenance or remedial work arising from them shall be maintained by the licensee.

The applicant has requested to alter the condition as all new bund structures and new underground pipes have been tested during commissioning within the last six months. Evidence for this testing may be provided and the applicant does not consider it appropriate to have to retest in such a short timeframe.

Technical Committee's Evaluation:

Post grant of licence, the applicant can submit the recently completed bund and pipeline integrity test to the Agency and this will be assessed with respect to the requirements of Condition 6.9. The TC considers it unnecessary to alter Condition 6.9.

Reason for Decision:

The TC has reached its conclusion on the basis of the following considerations:

1. In the interest of clarity and consistency in the licence.

Recommendation: No change.

A.6 Schedule B.3 – Discharge Location SE1

The applicant has requested to alter the grid coordinates for the discharge location of emission point SE1 in Schedule B.3 from 169924E, 337330E to 169925E, 337335N. The

location of the sampling point is close to the original grid reference. The change was made as the original location was difficult to access from a health and safety perspective.

Technical Committee's Evaluation:

For accuracy purposes the TC recommends that the grid reference for the discharge location be altered from 169924E, 337330E to 169925E, 337335N.

Reason for Decision:

The TC proposes to amend Schedule B.3 as set out below and has reached its conclusion on the basis of the following consideration:

1. In the interest of accuracy of the discharge location in the licence.

Recommendation: Amend <i>Schedule B.3 Emissions to Sewer</i> to read as follows:		
Emission Point Reference No:	SE1	
Name of Sewer:	Irish Water Sewer	
Monitoring Location:	Waste Water Tanks Building Flow meter SE1a (Grid Reference (169843E, 337621N) Composite Sampler SE1b (Grid Reference (169845E, 337620N)	
Discharge Location:	SE1 (Grid Reference 169925E, 337335N)	
Volume to be emitted:	Maximum in any one day:	180 m ³
	Maximum rate per hour:	12.7 m ³

Clarifications

A.1 and A.2 - Firewater Retention Risk Assessment

Condition 3.12.1 states:

The licensee shall carry out a risk assessment to determine if the activity should have a fire water retention facility. The licensee shall submit a report to the Agency

for approval on the findings and recommendations of the assessment within six months of the date of grant of this licence.

The applicant is seeking clarification on whether a firewater retention risk assessment submitted as part of the application to the Agency on the 23rd of September 2019 meets the requirements of condition 3.12.1.

Condition 3.12.3 states:

In the event of a fire or a spillage to storm water, the storm water shall be diverted for collection.

The applicant is seeking clarification from the Agency to confirm if condition 3.12.3 is now redundant based on the findings/conclusions of the Firewater retention risk assessment submitted on the 23rd of September 2019.

Technical Committee's Clarification:

The TC acknowledges the submission of the document entitled 'Firewater retention' with the licence application, and the TC has determined that it does not meet the requirements of 'The Guidance Note to Industry on Fire Water Retention Facilities' (EPA, 2019). The condition was not satisfied during the application process. Therefore, Condition 3.12.3 will continue to be relevant until an updated firewater retention risk assessment is submitted and assessed by the Agency following the grant of the licence.

Recommendation: No change.

A.4 Condition 5.5.3 - Emissions to Sewer

Condition 5.5.3 states:

A summary report of volumes of trade effluent and other matter discharged to the sewer along with monitoring and analysis data as specified in Scheduled B: Emissions to Sewer, of this licence and Schedule C: Control & Monitoring, of this licence shall be forwarded to both Irish Water and the Local Authority in a manner and timeframe as may be specified by Irish Water.

Clarification was required by the applicant if the condition above supersedes the requirements of the site's Discharge to Sewer Licence number 927442 issued by Irish Water and thus meaning that the applicant is no longer required to satisfy the conditions outlined in the Irish Water Licence.

Technical Committee's Clarification:

Irish Water, under Section 99E of the EPA Act 1992 as amended, gave its consent for the proposed processed effluent discharges from the installation, specifying certain ELVs, as well as certain other conditions and monitoring requirements which have been incorporated into the PD. The TC can confirm that the EPA licence supersedes the

Discharge to Sewer Licence number 927442 once the EPA licence is granted. The TC recommends no change to Condition 5.5.3.

Recommendation: No change.

A.7, A.8 and A.9 - Emissions and Monitoring of Emissions to Sewer

In its objection the applicant sought clarification on a number of points in *Schedules B.3 Emissions to Sewer, C.3.1 Control of Emissions to Sewer and C.3.2 Monitoring of Emission to Sewer*.

Schedule B.3 Emission to Sewer

The applicant requested clarity as to whether the volume to be emitted to sewer per hour (12.7 m³) (re. Schedule B.3) relates solely to the volume of wastewater emitted from the low strength process waste tanks or does it refer to the total amount of wastewater emitted from the site at SE1?

Schedule C.3.1 Control of Emissions to Sewer

The applicant is also seeking confirmation that this monitoring is being undertaken immediately following the wastewater treatment plant. In addition, confirmation is required that this monitoring point is SE1a.

Schedule C.3.2 - Monitoring of Emissions to Sewer

As per Condition C.3.1 above it is believed that these parameters are being monitored following wastewater treatment. Confirmation is required that this emission monitoring point is SE1b.

Technical Committee's Clarification

The TC would like to state that this text in *Schedule B.3* is as follows:

B.3 Emissions to Sewer

Emission Point Reference No:	SE1	
Name of Sewer:	Irish Water Sewer	
Monitoring Location:	Waste Water Tanks Building Flow meter SE1a (Grid Reference (169843E, 337621N)) Composite Sampler SE1b (Grid Reference (169845E, 337620N))	
Discharge Location:	SE1 (Grid Reference (169924E, 337330E))	
Volume to be emitted:	Maximum in any one day:	180 m ³
	Maximum rate per hour:	12.7 m ³

Parameter	Emission Limit Value	
Temperature	35 °C (max)	
pH	6 - 9	
	mg/l	kg/day
BOD	377	61
COD	599	97

The TC would like to clarify that the volume of wastewater emitted per hour refers to the total volume of treated process effluent emitted from the site at SE1a. To ensure that the sanitary wastewater discharge is excluded from the monitoring it is essential that monitoring is undertaken directly after the flow balancing and pH neutralisation at SE1a and SE1b.

Recommendation: No change.



Environmental Impact Assessment Directive – Reasoned Conclusion Update

The TC has reviewed the assessment in the Inspector’s Report and, taking into account all objections and submission on objections received, and the contents of this TC report, the TC considers that the potential significant direct and indirect effects of the activity have been identified, described and assessed in an appropriate manner as respects the matters that come within the functions of the Agency, and as required by Section 83(2A) of the EPA Act 1992 as amended.

It is considered that the monitoring, mitigation and preventative measures proposed in the Inspector’s Report and as detailed in this TC report, will enable the activity to operate without causing environmental pollution, subject to compliance with the licence conditions included in the PD, with the inclusion of the amendments proposed in this report.



Appropriate Assessment – Technical Committee Review

The TC has reviewed the inspector's Appropriate Assessment in the Inspector's Report and, taking into account all objections and submission on objections received and the content of this TC report, the TC is satisfied that the Inspector's Report provides an adequate examination and evaluation of the effects of the proposed activity on the European Sites concerned, Cummeen Strand Drumcliff Bay (Sligo Bay) SAC (000627) and Cummeen Strand SPA (004035) in the light of their conservation objectives.



Overall Recommendation

It is recommended that the Board of the Agency grant a licence to the applicant,

- (i) for the reasons outlined in the proposed determination and
- (ii) subject to the conditions and reasons for same in the Proposed Determination,
and,
- (iii) subject to the amendments proposed and the reasons set out in this report.

Signed

A handwritten signature in cursive script, reading "Niamh Connolly", written over a horizontal line.

Niamh Connolly

for and on behalf of the Technical Committee