Submission	
Submitter:	Mr Adrian O Sullivan
Organisation Name:	Health Service Executive
Submission Title:	HSE Submission
Submission Reference No.:	S010149
Submission Received:	19 November 2021
Application	
Applicant:	Pfizer Ireland Pharmaceuticals
Reg. No.:	P0013-06
See below for Submission details. Attachments are displayed on the following page(s).	

Date: 18 November 2021

Our reference: 2005

Report to: Environmental Licensing Programme
Office of Environmental Sustainability
Environmental Protection Agency
Johnstown Castle Estate
Co. Wexford

EPA reference: P0013-06

Type of Consultation: Industrial Emissions

Applicant: Pfizer Ireland Pharmaceuticals, P.O. Box No. 140, Ballintaggart, Ringaskiddy, Cork.

Nature of Activity:

Classes and Nature of Activity in accordance with the EPA Act 1992 as amended			
Class of Activity	**Main Activity**	**EPA Act Sector (where applicable)**	**Class of Activity Description**
11.6	No	Waste	Temporary storage of hazardous waste, (other than waste referred to in paragraph 11.5) pending any of the activities referred to in paragraph 11.2, 11.3, 11.5 or 11.7 with a total capacity exceeding 50 tonnes, other than temporary storage, pending collection, on the site where the waste is generated.
11.2 (e)	No	Waste	Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving solvent reclamation or regeneration
11.4 (a)(i)	No	Waste	Disposal of non-hazardous waste with a capacity exceeding 50 tonnes per day involving one or more of the following activities (other than activities to which the Urban Waste Water Treatment Regulations 2001 (S.I. No. 254 of 2001) apply): biological treatment
5.16	Yes	Chemicals	The production of pharmaceutical products including intermediates.

Introduction

The following HSE departments were notified of the consultation request for the licence application on 18 October 2021

- Emergency Planning – David O'Sullivan
- Estates – Helen Maher
- Assistant National Director for Health Protection – Kevin Kelleher / Helen Mulcahy
- CHO – Michael Fitzgerald

This report only comments on Environmental Health impacts of the licence application.

General

Pfizer Ireland Pharmaceuticals has been in production at Ringaskiddy since 1972. An Industrial Emissions Licence P0013-04 was issued by the EPA in 2006. A review of this licence was initiated in April 2021 as a result of upgrade works to the facility's Waste Water Treatment Plant (WWTP). Pfizer has now applied to the EPA for a review of the Industrial Emissions licence as they propose to construct the Ringaskiddy Clinical Manufacturing Facility (RCMF) and to install a replacement End of Line Thermal Oxidiser (EOL TO) unit.

The Non-Technical Summary accompanying the licence application states that the RCMF will include the following:

'• A new five storey clinical manufacturing building (approximately 11,468m2 with a maximum height of 29.425m) which will include production areas, laboratories, ancillary office space, warehouse, and plant and utility space.
• A single storey warehouse drum store building (approximately 420m2 with a maximum height of 13m);
• An external utility yard comprising; a two storey electrical building (approximately 94m2 and a maximum height of 11.7m), an emergency generator with flue stack, 1No. liquid nitrogen tank, 2No. evaporators, 3 No. bunded chillers, 2 No. bunded receiver tanks, 2 No. bunded glycol tanks, a three storey steel frame structure (to a maximum height of 12.91m) to accommodate: dry coolers, heat exchangers and other miscellaneous utility plant and machinery above the utility yard;
• An elevated structural steel piperack (approximately 210m in length with a maximum height of 9.19m) to provide piped utility services to the new facility; and
• Associated site development works, including roads, paths, yards, underground services and landscaping.

The replacement EOL TO will comprise of the following:
• End-of-line thermal oxidiser stainless steel unit with a footprint of approximately 650m2 and a maximum height of 12.5m;
• Vent stack (approximately 32m);
• The new collection system, which will be installed via the above ground pipe rack;
• Surface water drainage channels; and
• Ancillary works include interconnecting pipework and the installation of three storage tanks sodium hydroxide, sodium bisulphite and an urea holding tank.'

All commitments to future actions, including mitigation and further testing, have been taken as read and all data has been accepted as accurate. No additional investigation/measurements were undertaken in the review of this application.

The Environmental Health Service has not received any complaints regarding the Pfizer plant in Ringaskiddy.

In respect of this application for a discharge licence, the areas reviewed were those of concern to Environmental Health which are:

- any potential contamination of surface water or ground water
- emissions to air, including noise and odour

The Environmental Health Service acknowledges that recommendations included in its submission report in respect of the existing licence (P0013-05) have been considered by the applicant.

The area in which the facility is located was visited by Ms. Monica Jones, Environmental Health Officer and Ms Phil Curran, Senior Environmental Health Officer on 10 November 2021.

Site Location

The Pfizer plant occupies a site of approximately 33 hectares and is located in an area with a mixture of industrial and agricultural uses. It is adjacent to Monkstown Creek, an inlet in Cork harbour. The nearest sensitive receptors are 0.4km to the west at Shanbally, where there is a school, a church and a number of residential dwellings.

Ground water, surface water and soil

The Soil and Groundwater Baseline Assessment which was submitted as part of the application indicates that '*there are no direct emissions to soil or groundwater at the plant'* and describes historical incidences of unintentional emissions to ground from a facility based on the site. Details are provided of remediation undertaken to address the impacts of these events on soil and water including the installation of a hydraulic containment system (HCS) in 1996. This system comprises two active abstraction wells and changes the natural gradient conditions and is designed to prevent groundwater with low concentrations of VOCs from reaching the northern site boundary. Monitoring of dissolved phase VOCs at these two abstraction wells is undertaken biannually.

The Pfizer facility is underlain by a bedrock aquifer which is classified as a '*locally important aquifer'* with vulnerability classified by the GSI as '*high to extreme'*

Groundwater monitoring is conducted twice every year from a total of seven wells at various locations across the site.

The Environmental Health Service notes the reference to dimethylacetamide contained in Chapter 4.6 of the 'Soil and Groundwater Baseline Assessment' and is satisfied with the proposal that '*Dimethylacetamide will be added to the analytical suite (as a VOC tentatively identified compound (TIC)) for biannual groundwater monitoring, however, as it is no longer stored on site, if it is not reported as detected in two consecutive biannual groundwater monitoring rounds then its removal from further sampling events should be agreed with the EPA'*. Similar proposals are contained within the 'Soil and Groundwater Baseline Assessment' report for Sodium Bromate and 2, 2, 4-trimethylpentane.

Should the presence of these compounds not be detected in two consecutive monitoring rounds the Environmental Health Service is satisfied that there is no potential significant risk to public health and routine monitoring for such compounds should cease.

It is noted that n-Hexane, which '*is stored in bulk and has been historically stored without secondary Containment*' '*will be added to future analytical suites (as a VOC TIC) for biannual groundwater monitoring'.* (Chapter 4.10 Soil and Groundwater Baseline Assessment'*)*
The Environmental Health Service welcomes this proposal and the proposal that *'specific analysis for diesel hydrocarbons will be added to the biannual groundwater monitoring analytical suite'*. (Chapter 4.4 'Soil and Groundwater Baseline Assessment')

A search of the GSI well database identified four wells within 1000 m of the site which identified four wells within 1km of the site, which were previously used to service the Pfizer plant. According to Chapter 6.4.1 'Wells and Springs' of the 'Soil and Groundwater Baseline Assessment', '*these wells are all redundant*' and the plant is now supplied by the public mains water supply. It is noted that '*there are no drinking water supply source protection areas mapped within a 5 km radius of the site'.*

The site is well serviced with a stormwater drainage network which collects all rainwater which is directed to a single monitored location (Storm Water Outfall). This outfall is continuously monitored for a number of parameters including pH and TOC. The 'Soil and Groundwater Baseline Assessment' describes measures to mitigate against impacts on surface and groundwater from a spill into the storm water system. In this event, the storm water drainage system would be diverted using an automated diversion valve to the firewater containment pond, which would then be either transferred to the WWTP for treatment or removed for off-site disposal.

The 'Soil and Groundwater Baseline Assessment' also contains details of the Weak Effluent System (underground system) and the Strong Effluent Line (above ground system). All underground drainages are integrity tested and the Weak Effluent System effectively acts as a backup in the event of a leak in the Strong Effluent Line.

The application provides a description of containment measures employed in the event of a spillage of chemicals, oils and solvents.

- **Emissions to air, including noise and odour**

Attachment 7.1 'Emissions Overview' indicates that there are 31 main emission points to air. Measures to reduce, minimise and /or prevent emissions are outlined in Attachment 7.4.1. The Air Emissions Impact Assessment indicates that the new five-storey Ringaskiddy Clinical Manufacturing Facility (RCMF) *'will result in additional minor, potential and fugitive emission points'* to air and that *'all vents from the production area of the RCMF will tie into the existing VOC plant at OSP (Organic Synthesis Plant), which is a licensed main emission point under IE Licence P0013-05'.*

Air Dispersion Modelling has been undertaken for the existing and proposed air quality scenarios. No increase in ground level concentrations of NO2, CO2, dioxins, hydrogen bromide, hydrogen fluoride, hydrogen chloride, ammonia or PM is predicted to occur due to the proposed development.

A 3.95% increase in ground level concentrations of 1-hour SO2 is predicted to occur due to the proposed development. No increase in ground level concentrations of 24-hour or annual mean SO2 is predicted to occur due to the proposed development. A <1% increase in GLC of TOC is predicted as a result of the proposed development.

The Air Emission Impact Assessment concludes that *'no potential significant negative effects on human health are predicted as a result of the proposed developments'*.

Details of the measures proposed/used to minimise the impact on the environment of an accidental emission or spillage are included in Attachment 9.1 'Environmental Management Techniques'

There is a requirement in the existing IE Licence (P0013-05) for annual noise monitoring. Baseline noise levels obtained from the 2019 Environmental Noise Monitoring Survey Report for the Pfizer Ringaskiddy site identify five Noise Sensitive Locations. Monitoring results show the Pfizer facility to be in accordance with the noise

emission limits as per IE Licence P0013-05. The Environmental Health Service is satisfied that mitigation measures currently in place are sufficient to protect public health from noise impacts.

Conclusion

The Environmental Health Service makes the following recommendation in respect of this licence application

- **That all mitigation measures and monitoring included in Chapters 9 (Air Quality), 10 (Noise and Vibration), 14 (Land, Soil and Hydrology) and 15 (Water) of the EIAR included in the licence application are implemented in full**

Monica Jones
Environmental Health Officer
Cork

Environmental Health Officer
Environment OU
Ennistymon Health Centre
Ennistymon
Co. Clare

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Environmental Health Department
Health Service Executive
Fr Mathew Quay
Cork T12 EWVO
Phone: 021 4927703

Date: 18 November 2021

Name: Environmental Licensing Programme
Office of Environmental Sustainability
Environmental Protection Agency
Johnstown Castle Estate
Co. Wexford

Re: Industrial Emissions Licence Application P0013-06

Applicant: Pfizer Ireland Pharmaceuticals

Dear Sir/Madam

Please find enclosed the HSE consultation reports in relation to the above licence application. If you have any queries regarding any of these reports the initial contact is Adrian O'Sullivan, Principal Environmental Health Officer, who will refer your query to the appropriate person

Yours faithfully,

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Adrian O'Sullivan
Principal Environmental Health Officer