



Submission

Submitter:	Miss Caroline Hueston
Organisation Name:	HSE South
Submission Title:	HSE submission Pfizer Ringaskiddy P0013-05 EHIS 1017
Submission Reference No.:	S005871
Submission Received:	12 November 2019

Application

Applicant:	Pfizer Ireland Pharmaceuticals
Reg. No.:	P0013-05

See below for Submission details.

Attachments are displayed on the following page(s).

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Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Health Service Executive (HSE) - South
South Lee Environmental Health Department

Fr. Matthew Quay

Cork

Tel. 021-4927703

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Date: 12 November 2019

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

Re: Industrial Emissions Licence Application P0013-05

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

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 Mr Declan Hamilton, Principal Environmental Health Officer, who will refer your query to the appropriate person

Yours faithfully


Declan Hamilton
Principal Environmental Health Officer

Date: 6 November 2019

Our reference: 1017

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

EPA reference: P0013-05

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 3 October 2019

- Emergency Planning – David O’Sullivan
- Estates – Helen Maher
- Assistant National Director for Health Protection – Kevin Kelleher / Laura Murphy
- CHO – Ger Reaney

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. The company has now applied to the EPA for a review of that licence.

Following treatment in the onsite waste water treatment plant, effluent from the Pfizer Ireland facility in Ringaskiddy is discharged directly to a public sewer located downstream of a municipal wastewater treatment plant before entering Cork Lower Harbour at Dognose Bank.

Following the introduction of revised BAT-AELs for direct discharges to receiving water for the chemical sector (CID 2016/902) Pfizer initiated a review of their existing WWTP. The results of this review determined that the new BAT-AELs for COD and TSS ‘*would not or may not be consistently achieved*’. As a result of these findings, Pfizer initiated a programme to upgrade the WWTP.

The upgrading of the Wastewater Treatment Plant includes the

- installation of feed lines and flow meters
- upgrade of Total Organic Carbon (TOC) monitoring equipment for the final effluent and installation of new TOC monitoring for the WWTP influent
- installation of two additional membrane bioreactor filtration units (MBRs) to serve one of two existing second stage aeration basins, which are currently served by secondary clarifiers. (The remaining second stage basin is currently served by existing MBR filtration units
- provision of screening equipment (coarse filtration) of influent to waste water treatment plant.

The upgrade of the WWTP aims to ensure that mass emissions from the Pfizer facility for a number of parameters will remain at (or be reduced below) BAT mass emission thresholds.

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 site was visited by Ms. Monica Jones and Mr Cian Sweeney, Environmental Health Officers on 25 October 2019.

Site Location

The Pfizer plant occupies a 21 hectare site 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 1.1km away 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 describes three 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.

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'

Mitigation measures employed to protect groundwater includes a hydraulic containment system, which has been in operation for over twenty years. 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.

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

The Environmental Health Service recommends that groundwater monitoring for sodium bromate, dimethylacetamide and 2,2,4-trimethylpentane is phased out as these chemicals are no longer stored on site and that n-hexane and diesel, which are currently stored on site, are included in future groundwater monitoring programmes.

A desktop survey of the GSI well database was undertaken in the compilation of this Baseline Assessment report. It 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 Baseline Assessment Report, '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 storm water outfall. This outfall is referenced in Attachment B.5 'Tabular data on emission and monitoring points' and is continuously monitored for a number of parameters including pH and TOC. The Baseline Assessment Report 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 Baseline Assessment Report 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.

The application states that 27 shallow soil drilling locations were investigated between 22-27 July 2019 in order to identify current soil conditions. Results for VOCs indicated exceedences in the samples for

- benzene 9µg/kg (Controlled Waters GAC=8.7µG/kg)
- p/m-xylene 313µg/kg(Controlled Waters GAC =67µG/kg) and
- naphthalene 73µg/kg (Controlled Waters GAC= 19µG/kg).

Samples analysed for semi VOCs recorded exceedences for

- phenol in one location 214µg/kg (Controlled Water GAC = 4.1µg/kg),
- naphthalene at a further two locations 47µg/kg and 21µg/kg and
- anthracene at two locations, 24µg/kg and 107µg/kg. The Controlled Water GAC for anthracene is 8.2µg/kg.
- fluoranthene from four locations resulted in levels of 153 µg/kg, 16 µg/kg, 24 µg/kg and 12 µg/kg. The Controlled Water GAC for fluoranthene is of 1.7 µg/kg.

Exceedences for fluoranthene, Benzo (a) pyrene and di-n-butyl phthalate were also recorded.

Soil samples were tested for the presence of metals and it is noted that the results for arsenic, cadmium, copper, lead, nickel, vanadium and zinc all exceeded the relevant Controlled Water GACs.

Regarding VOC's, SVOC's and metals, the Baseline Assessment Report states that *'given that these parameters, with the exception of arsenic, were not reported in groundwater above the respective GACs, AECOM concludes that the reported soil concentrations do not post an unacceptable risk to human health or the environment'*.

The Environmental Health Service draws the EPA's attention to its 'Guidance on the Management of Contaminated Land and Groundwater at EPA Licenced Sites' (EPA, 2013) which advises that *'the sole use of soil or groundwater Generic Assessment Criteria (GAC) for the risk assessment of sites and/or verification of Corrective Action is not recommended. GAC represent concentrations below which impact on receptors (human health, water-dependent ecosystems, etc.) is very unlikely and they are useful for initial screening purposes. Soil and/or groundwater concentrations that are found to exceed GAC (from the GQRA) are an indication of potential risk to receptors and therefore this requires a DQRA [Detailed Quantitative Risk Assessment] to be undertaken.'*

As many of the results from the soil sampling indicated exceedences significantly above Controlled Water GACs, the Environmental Health Service recommends that the EPA is satisfied that a Detailed Quantitative Risk Assessment (DQRA) is not required. If a DQRA is required, its findings should be used to identify the need for corrective action. It is not satisfactory to state that *'metal concentrations, with the exception of arsenic, are generally similar to typical soil concentrations from the area'*. In this regard, it is noted that arsenic is not included on the schedule principal polluting substances listed in *'Attachment A.9 – Indicative list of the principal polluting substances'* and that high levels noted in the soil sampling are most likely due to naturally occurring arsenic in the soil.

- Emissions to air, including noise and odour

It is noted in the application form that all tanks on site are covered, thus minimising the risk of fugitive emissions to air. No plumes or hazardous materials are associated with the plant's cooling systems.

Appropriate management and regular monitoring of the wastewater treatment plant should ensure that it does not become anoxic and therefore likely to create nuisance odours. It was noted that although ammonia levels were well below the licence limit, there were occasions where levels peaked at 17.3mg/l (31 October 2016) and 24.360mg/l 5 December 2016). Such incidences should always be fully investigated.

Section B4 – Industrial Cooling Systems BAT report states that *'a noise monitoring plan is not required for the facility as a noise nuisance is not expected'*

There is a requirement in the existing IE Licence for annual noise monitoring. *'Attachment B.5 – Tabular data on emission and monitoring points'* of the application form indicates that five Noise Sensitive Locations have been identified. The noise levels associated with the operation of the Pfizer plant, as recorded at the noise-sensitive locations and reported annually to the EPA, have *'demonstrated consistent compliance with the limits'*. 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 recommendations in respect of this licence application

- Groundwater monitoring for sodium bromate, dimethylacetamide and 2,2,4-trimethylpentane is phased out as these chemicals are no longer stored on site and that n-hexane and diesel are included in future groundwater monitoring programmes
- That the EPA is satisfied that a Detailed Quantitative Risk Assessment (DQRA) is not required for the Pfizer facility. If a DQRA is required, its findings should be used to identify the need for corrective action with regards to the levels of VOCs, SVOC's and metals found in soil samples.
- Regular monitoring of the proposed wastewater treatment plant should be undertaken to identify any potential risk of an odour nuisance occurring



Monica Jones
Environmental Health Officer
Cork



Caroline Hueston
Environmental Health Officer
Environment Operational Unit

HSE South Emergency Management Consultation Report				
Report to	Declan Hamilton, PEHO, Cork South Lee		Date	31 10 2019
Type of consultation: EIS <input type="checkbox"/> Scoping <input type="checkbox"/> Screening <input type="checkbox"/> EIAR <input type="checkbox"/> EPA X				
Other (please specify): Industrial Emissions (IE)				
Authority	EPA			
Authority Reference Number	EPA Ref. No.P0013-05 EHIS 1017			
EM Reference Number	EMENV027			
Applicant	Pfizer Irl. Pharmaceuticals, Balintaggart, Ringaskiddy, Co. Cork.			
Proposal	The production of pharmaceutical products including intermediates			

HSE South Emergency Management Observations:

Please be advised that the HSE South Emergency Management function does not have any specific observations to make with respect to this application. However, please note the following recommendations within the context of site operations:

1. Should an incident occur at the site and the site operator requires the assistance of the emergency services, the incident information should be provided in the 'ETHANE' format (please see attached).
2. Emergency Services access to the site should be clearly identified. This should be undertaken via appropriate high visibility signage, i.e. a green sign with a yellow border and white lettering citing the abbreviation RVP.
3. The site should have a mechanism in place to account for personnel during an evacuation in order to provide the responding emergency services with an estimate of the number of people accounted and unaccounted for.
4. The site should identify any critical / vulnerable facilities within the geographical catchment area, such as hospitals, schools, nursing homes, etc, that could be directly or indirectly affected by an incident at the site.
5. Where the 'off-site' impacts of an incident at the site affects a vulnerable cohort / population such as children within crèches, schools; patients / clients / residents within nursing homes, etc; the emergency services will require assistance from the site operator in determining the impact on the local community.
6. The site operator is encouraged to develop a business continuity plan that includes a plan for severe weather. For more advice on this, please see the Department of Business, Enterprise and Innovation, *Business Continuity Planning in Severe Weather*.
<https://dbe.gov.ie/en/Publications/Publication-files/Business-Continuity-Planning-in-Severe-Weather-Check-List-for-Businesses.pdf>

All correspondence or any queries with regard to this report should be forwarded to Ms. Maryanne Horgan, Emergency Management Office, HSE South, Eye, Ear and Throat Hospital, Western Road, Cork, T12 WP62 or maryanne.horgan@hse.ie

	years by the National Finance Dept.	
	(c) Administration Review PEHOs called for the Review of EHS Administration to commence as it impacts greatly on the delivery of work in accordance with the requirements of the NFRs.	(c)ROG to raise with EHMT with view to the commencement of the Review in 2020 if not before.
Health Safety and Wellbeing	PEHOs asked about HSW grants. Grants are available via EHS and CHOs and PEHOs should make their bids to both separately. 2019 bids closed.	PEHOs to make bids to RCEHO and CHO for 2020.
AOB	<p>(a) Food Business Staff Sanitary Accommodation Consistency around the provision of separate staff sanitary accommodation to food business premises was discussed. Some PEHOs suggested that Food Hygiene Regulations 1950-71 could still be enforced. It was agreed that the matter be referred to the Food Safety OU for decision.</p> <p>(b) Food Product Safety Network PEHOs enquired whether they could send the non-PEHO network member AND another member of staff to represent the PEHO Network member to FPSOU Network meeting as they felt micro and chemical sampling too complicated for one staff member to attend from their teams. ROG agreed.</p>	CD to raise with FSOU.
Schedule of meetings for 2019.	Next Regional Management Team meeting is scheduled for Thursday 28 th November in Clonmel.	RP to organise meeting room.



Dial 999 / 112 – Request the service you require: An Garda Síochána, Ambulance Service and / or Fire and Rescue Service

WHEN YOU ARE CONNECTED TO THE REQUISITE SERVICE(S)

<u>GIVE THE FOLLOWING INFORMATION</u>	
This is: _____ Eircode _____ (Name, Telephone Number and Eircode Address of site)	
<i>An incident has occurred at this site - standby for ETHANE message</i>	
E	
	Exact location of the incident
T	
	Type of incident, e.g.: fire, explosion, gas leak, etc
H	
	Hazards – current and potential
A	
	Access and Egress – what is the safest approach route for responding emergency services and where is your emergency services meeting point (RVP)
N	
	Number of casualties and their condition – specify adult / children if known
E	
	The emergency services present and required
<i>N.B. If you require another emergency service stay on the line and repeat the steps again</i>	