

### Submission

Submitter:	Mr Gerard Leen
Organisation Name:	Health Service Executive
Submission Title:	HSE submission
Submission Reference No.:	S009907
Submission Received:	05 February 2021

### Application

Applicant:	Roche Ireland Limited
Reg. No.:	P0012-06


See below for Submission details.

Attachments are displayed on the following page(s).

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An tSeirbhís Sláinte Comhshaoil  
Feidhmeannacht na Seirbhíse Sláinte,  
Ionad 6, Páirc Ghnó Bothar Chuinche,  
Inis, Co. An Chlár.

Environmental Health Service,  
Health Service Executive,  
Unit 6, Quin Road Business Park,  
Ennis, Co. Clare.

 (065) 6706660

**Date:** 05<sup>th</sup> February 2021

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

**Re:** Industrial Emissions Licence Application

**EPA Reference:** P0012-06

**Name and Address of applicant:** Roche Ireland Limited, Clarecastle, Co. Clare

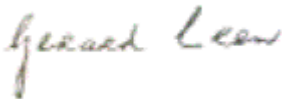
**EHIS Reference:** EHIS 1506

Dear Sir/Madam,

Please find enclosed the HSE consultation report in relation to the above licence application.

If you have any queries regarding any of this reports the initial contact is Mr. Gerard Leen, undersigned, who will refer your query to the appropriate person.

Yours faithfully,



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Gerard Leen  
Principal Environmental Health Officer

**Date:** 05<sup>th</sup> February 2021

**Our reference:** EHIS 506  
**Report to:** Environmental Licensing Programme  
Office of Environmental Sustainability  
Environmental Protection Agency  
Johnstown Castle Estate, Co. Wexford.

**EPA reference:** P0012-06

**Type of Consultation:** Industrial Emissions

**Applicant:** Roche Ireland Limited, Clarecastle, Co. Clare

**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
11.2 (c)	No	Waste	Disposal or recovery of hazardous waste with a capacity exceeding 10 tonnes per day involving blending or mixing prior to submission to any of the other activities listed in paragraph 11.2 or 11.3
11.1	No	Waste	The recovery or disposal of waste in a facility, within the meaning of the Act of 1996, which facility is connected or associated with another activity specified in this Schedule in respect of which a licence or revised licence under Part IV is in force or in respect of which a licence under the said Part is or will be required.
11.6	Yes	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.
5.16	No	Chemicals	The production of pharmaceutical products including intermediates.

## Introduction

The following HSE departments were notified of the consultation request for the licence application on 24<sup>th</sup> December 2020

- Emergency Planning – Kay Kennington
- Estates – Helen Maher
- Assistant National Director for Health Protection – Kevin Kelleher / Laura Murphy
- CHO – Maria Bridgeman

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

## Third Party Submissions

The Environmental Health Department have not received any complaints from the public in relation to this Industrial Emissions Licence.

## General

Roche Ireland Limited is seeking planning permission to demolish and remediate their pharmaceutical facility located in Clarecastle, County Clare, Ireland and construct, operate and decommission a temporary staging area, to facilitate the transportation of wastes and materials associated with the works.

The site consists of various manufacturing and management buildings associated with its previous pharmaceutical operations along with supporting infrastructure. A historic landfill was also operated on site between 1977 and 2006 for the disposal of site waste, including wastes generated by the manufacturing operations onsite.

The Applicant completed environmental assessments of the site in 2017 as part of the site closure strategy, with a view to identifying areas of environmental concern and feasible remedial strategies. Three areas of environmental concern were identified, namely: the area underlying the main process area (AEC1) and the site's historic landfill area and an area in the vicinity of the site's wastewater treatment plant (AEC2).

The Proposed Development will involve the removal of most buildings, structures and infrastructure currently within the existing site boundary fencing and the remediation of the identified areas of environmental concern to return a site suitable for future industrial use.

The Planning History of the Applicant's Site is outlined in Table 3-1.

## Site Location:

The Proposed Development site is located in Clarecastle, County Clare, approximately 4 km south of Ennis town centre. The Proposed Development will utilise a heavy goods vehicle (HGV) haulage route from the existing site entrance, through Clarecastle and along the R458 to junction 11 of the M18 motorway.

## Land, Soils and Geology:

Chapter 5 of the EIAR presents an assessment of the impacts of the Proposed Development on land, soils and hydrogeology.

A summary of the baseline conditions advises that soils onsite have been impacted by the site's historical pharmaceutical processing, with elevated concentrations of contaminants including benzene, toluene and naproxen detected in soils during previous site investigations.

Previous site investigations and groundwater monitoring have identified elevated concentrations of THF and toluene and, to a lesser extent, acetone and DCM/methylene chloride in groundwater.

The EIAR states that based on the baseline data, the soil and groundwater environment beneath the site is considered to be of medium sensitivity. While the bedrock aquifer is classified as 'Regionally Important', it is noted that groundwater within 50 m to 100 m of the eastern site boundary interacts with the brackish water from the River Fergus and is consequently unsuitable for public supply.

Section 5.4 in the EIAR looks at the assessment of impacts for the different activities for the demolition of the plant. These activities include,

- Demolition Activities in the Vicinity of Contaminated Ground,
- Excavation of Contaminated Soil and Pumping of Groundwater,
- Excavations and Stockpiling of Materials and Wastes,
- Use of Concrete and Lime,
- Accidental Spills and Leaks,
- Potential Activities in Vicinity of Features of Geological or Geomorphological Interest and Importance,
- Use of Natural Resources,
- Cumulative Impacts and
- Transboundary Impacts.

For each of these activities it gives a description of the impact and significance of the activity. It then describes how it will mitigate and monitor and it then outlines the residual impacts. A summary of the land and soil impact assessment is outlined in Table 5-18.

**The EHS have looked all these activities and assessed the proposed mitigation and monitoring measure and are satisfied that once the developer implements them in full any risk to the surrounding environment will be low.**

#### **Water:**

Chapter 6 of the EIAR presents an assessment of the impacts of the Proposed Development upon the water environment.

A summary of the base line conditions advises that the soils and groundwater on site have been impacted by the site's historic use for pharmaceutical processing. Previous site investigations and groundwater monitoring have identified elevated concentrations of compounds including THF, toluene, naproxen and ammoniacal nitrogen.

Section 6.4 in the EIAR looks at the assessment of impacts for the different activities for the demolition of the plant. These activities include,

- Installation of Temporary Drainage Systems to Facilitate Works
- Demolition Activities in the Vicinity of Previously Unidentified Contaminated Ground
- Bulk Excavation and Extraction of Groundwater During Remediation
- Dewatering Operations
- Excavations and Stockpiling of Materials and Wastes
- Use of Concrete and Lime
- Accidental Spills and Leaks
- Backfilling of Excavations
- Change in Site Levels and Land Cover
- Cumulative Impacts and,
- Transboundary Impacts and,

For each of these activities it gives a description of the impact and significance of the activity. It then describes how it will mitigate and monitor and it then outlines the residual impacts. A summary of the land and soil impact assessment is outlined in Table 6-13.

**The EHS have looked all these activities and assessed the proposed mitigation and monitoring measure and are satisfied that once the developer implements them in full any risk to the surrounding environment will be low.**

#### **Air Quality:**

Chapter 7 of the EIAR presents an assessment of the impacts of the Proposed Development on air quality and climate.

The EIAR has identified 10 dust and particulate matter sensitive receptors within 350 m of the site. A number of these receptors are residential. They are all shown in Figure 7-3. Table 7-14 outlines the risk of dust impact occurring across the study area with embedded controls and table 7-15 outlines the risk of dust impact occurring at selected individual receptors with embedded controls.

The EIAR acknowledges that the risk of impacts occurring across the study area as a whole is considered high for dust soiling, due to the scale of the works required and the number of receptors located close to the south western, western and north western site boundary.

The EIAR identifies that the risk of impact to concentrations of PM10 and human health is less severe as a result of the good standard of existing air quality in the study area. The EIAR further advises that there is a medium risk of dust impacts and human health impacts at receptors immediately adjacent to the northwest site boundary, the western site boundary. A low risk of dust impacts was identified elsewhere.

Section 7.1.2.5 of the EIAR looks at predicted baseline conditions. It advises that existing baseline annual mean NO2, PM10 and PM2.5 concentrations are well below the National Air Quality Standard values for those pollutants.

Section 7.1.3 in the EIAR looks at the assessment of impacts for the different activities for the demolition of the plant. These activities include,

- Dust and Particulate Matter Emissions
- Odour Emissions
- Road Traffic Emissions
- Cumulative Impacts
- Transboundary Impacts

For each of these activities it gives a description of the impact and significance of the activity. It then describes how it will mitigate and monitor and it then outlines the residual impacts. A summary of the Air Quality and Climate Change Impact Assessment Summary is outlined in Table 7-30.

**The EHS have looked all these activities and assessed the proposed mitigation and monitoring measure and are satisfied that once the developer implements them in full any risk to the surrounding environment will be low.**

## Noise

Chapter 8 of the EIAR presents an assessment of the impacts of the Proposed Development on noise and vibration.

The EIAR states that sensitive receptors with the potential to be impacted by noise and vibration were determined from a desktop review of publicly available information and a site walkover. It acknowledges that due to the location of the Proposed Development, there are many sensitive receptors surrounding the site and the staging area, including residential properties and a cemetery. Six receptors were selected surrounding the site for this assessment of noise and vibration impacts from the demolition and remediation works and 9 were selected that represented traffic impacts. These are detailed in Table 8-4.

The EIAR advises that in order to determine the existing baseline environment, daytime attended sound monitoring was undertaken at the following four locations around the site boundary on 21 June 2019:

- M1 - Clarehill – near to the water tower
- M2 - Patrick Street (R458) – outside the Clarecastle Health Centre
- M3 - Main Street (R458) – opposite side of road to Magpies Bar
- M4 - Quay Road – at the entrance to the Port of Clare

The four locations were chosen as being representative of receptor groups likely to be affected by the site works, based on inspection of local mapping and street views. LAeq, LMax, LA10 and LA90 values were all logged, the results of which are shown in table 8-14. The EIAR states that in all location the dominant noise source was road traffic. Other contributions to the sound climate included people on the street and occasional emergency sirens and horn beeps.

The Assessment of impacts are outlined in section 8.4 and they include the following:

- Demolition and Remediation Noise Impacts
- Demolition and Remediation Vibration Impacts
- Demolition and Remediation Road Traffic Noise Impacts
- Demolition and Remediation Traffic Vibration Impacts
- Construction and Operational Noise and Vibration Impacts from the Staging Area

- Demolition and Remediation Noise and Vibration Impacts Upon Public Amenity Areas
- Cumulative Impacts, and
- Transboundary Impacts

For each of these activities it gives a description of the impact and significance of the activity. It then describes how it will mitigate and monitor and it then outlines the residual impacts. A summary of the Noise and Vibration Impact Assessment is outlined in Table 8-36.

There are no plans for night-time work with the EIAR stating that normal construction working hours of 07:00 to 19:00 Monday to Friday, 08:00 to 14:00 on Saturdays will be followed. The EHS have looked all these activities and assessed the proposed mitigation and monitoring measure and are satisfied that once the developer implements them in full any risk to the surrounding environment will be low.

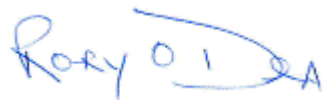
## Conclusion

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

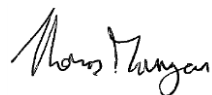
The EIAR states that *“the groundwater monitoring that will be carried out during the remediation works will be agreed with the EPA as part of the IEL review prior to the commencement of the remediation works.”* It further advises that *“Groundwater results will be reported to the EPA, with an action plan to be agreed and implemented in the event of elevated concentrations”*

The EHS advises that ground water monitoring should be continued for a period of 5 years after the remediation works have been completed and that the monitoring should be independently verified when reporting the results to the EPA.

All correspondence or any queries with regard to this report, including acknowledgement, should be forwarded to Mr. Gerard Leen, Principal Environmental Health Officer, at the above address.



Rory O'Dea  
Senior Environmental Health Officer



Thomas Mangan  
Environmental Health Officer  
Environment Operational Unit

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