Submission	
Submitter:	Mrs Lisa Maguire
Organisation Name:	HSE
Submission Title:	Environmental Health Submission
Submission Reference No.:	S010270
Submission Received:	31 March 2022
Application	
Applicant:	Forest Laboratories Ireland Limited
Reg. No.:	P0306-04
See below for Submission details. Attachments are displayed on the following page(s).	

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HSE EIS SUBMISSION REPORT
Environmental Health Service Consultation Report
(as a Statutory Consultee (Planning and Development Acts 2000,
& Regs made thereunder).

Date:	31st March 2022
Our Reference:	2188
Report To:	Environmental Licensing Programme Office of Environmental Sustainability Environmental Protection Agency Johnstown Castle Estate Co. Wexford
EPA Reference:	P0306-04
Type of Consultation:	Industrial Emissions
Applicant:	Forest Laboratories Ireland Limited
Nature of Activity:	Activity Class 12.2.2 "The use of coating materials in processes with a capacity to use at least 10 tonnes per year of organic solvents"

Introduction

The following HSE departments were notified of the consultation request for this development on 31st January 2022.

- Emergency Planning – Brendan Lawlor
- Estates – Helen Maher/Stephen Murphy
- National Clinical Director for Health Protection
- CHO – Mellany McLoone

This report only comments on Environmental Health impacts of the licence review application. 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 investigations/measurements were undertaken in the review of the application.

In respect of this application, the areas reviewed were those of concern to Environmental Health and which are:

- Any potential contamination of surface water and ground water
- Emissions to air including noise and process emissions

Description

Forest Laboratories Ireland Ltd. is engaged in the production of pharmaceutical products in the form of dry powder inhalers, tablets and capsules. The current licensable activity under licence P0306-03 at the facility is the use of solvents (Ethanol, Acetone and Isopropanol) in the coating process (Class 12.2.2). A Regenerative Thermal Oxidiser is used to treat the waste gases/off-gases from these production processes.

The current licence encompasses three areas including Building 1, Building 2 and Site 3 (an empty lot used for car parking/contractor compound), all of which are located in Clonshaugh Industrial Estate. Forest Laboratories Ireland Ltd. now proposes to cease the licenced activity (i.e. tablet coating) in Building 2 and relocate this activity to Building 1. This includes for the relocation of the Regenerative Thermal Oxidiser to Building 1. All other emission points from Building 2 will be decommissioned and all other licenced activity and monitoring will be discontinued at Building 2. Building 2 and Site 3 will then be surrendered from the licence.

Site Location

Forest Laboratories Ireland Ltd. is located in the Clonshaugh Business & Technology Park, which is situated in Coolock, Dublin 17, approximately 8km north of Dublin City Centre. The N32 is located to the north of the Business Park, while the M1/M50 is located at the western boundary of the Business Park. The Clonshaugh Road, the Northside Shopping Centre and residential estates are situated to the east of the Business Park.

The existing environment of the site consists of buildings and artificial surfaces. It is stated the site has little or no biodiversity value and is of little ecological significance.

EIA Screening

An EIA Screening report was carried out by RPS Group in September 2021. The overall determination of the Screening Report was that the proposed changes sought under the Licence Review will not result in the potential for significant impacts to arise on the environmental receptors. As such it is concluded that an Environmental Impact Assessment Report is not required to support this application.

Ground Water Supply

There are no emissions to ground from the Forest Laboratories Ireland operation and there are no effective changes of groundwater quality, yield and/or flow paths as a result of the proposed changes in the licence review. Groundwater monitoring is currently undertaken annually at six groundwater monitoring wells in accordance with the applicants existing licence, both up-gradient and down-gradient of the site.

Surface Water

It is stated that surface water runoff from the site discharges to the municipal storm water network within the industrial estate and ultimately to the Santry River. No process water or effluent discharges via surface water systems.

The proposed changes seek to cease the monitoring of surface water discharge at SW2a and SW2b, located at Building 2 and reduce the licenced surface water discharge monitoring points from five to three. Storm water discharges from Building 2 will continue but will not be from an EPA licensed facility and hence will no longer require monitoring.

Soiled & Process Water

Process wastewater from the installation discharges to the public sewer from two existing locations; SE1 and SE2, and is ultimately treated at the Ringsend Waste Water Treatment Plant.

There is no effective change in the management of process effluent and domestic effluent between the current licenced activity and the changes proposed under the licence review. The increase volume flow at SE-1 accounts for the reduced emissions associated with the discontinued SE-2. In this regard, there is no net change in emissions to sewer as a result of the proposed changes sought.

Waste

Hazardous, non-hazardous and inert waste generated onsite are managed, stored and

recorded in accordance with the existing licence. Waste Volumes are reported annually as part of the Annual Environmental Return.

Air Emissions

The effects of changes to air with the proposed changes sought under the Licence Review have been assessed using the air dispersion model AERMOD and in line EPA Guidance Note AG4 'Air Dispersion Modelling for Industrial Installations'.

The results of this modelling indicate that the proposed changes show no significant change in impact from the existing emissions. It is actually indicated that the net change in particulate emissions is an overall reduction given the decommissioning of all particulate emission points at Building 2. The relocation of the Regenerative Thermal Oxidiser is predicted to shift the emissions plume of organic solvents from the existing Building 2 area to Building 1 but with levels remaining very low with "*no potential for risk to human health*".

The results of the modelling indicate the ground level concentrations of Pharmaceutical Dusts and Total Organic Carbon from the existing emissions profile at the site are currently having no adverse impact on the neatest human receptors within the area. All predicted ground level concentrations of all parameters are well below the relevant statutory limit for the protection of human health or guideline (where no limit exists) at all properties.

Noise

The primary external noise sources at the site are from chiller units, air conditioning units, boiler house and external dust extraction units installed at the facility. The boiler units are housed internally in the boiler house. The effects on noise from the proposed changes have been assessed and it is indicated these changes will not result in any significant change in the noise environment at the site boundary.

Currently, measurements are conducted at the nearest noise sensitive locations as outlined in the existing licence requirements. The most recent noise monitoring was undertaken in 2020. Analysis of the data determined that the background noise in the vicinity of the noise sensitive locations is high due to road/motorway traffic and that aircraft noise is the dominant noise source. It is stated that noise measurements show compliance with the noise criterion outlined in the EPA's NG4 guidance document and the site's licence.

Conclusions

I could not locate any proposals for the decommissioning of the obsolete building 2 and former car park at site 3 in the applicants documents. It is recommended any proposal for decommissioning should outline measures which ensure the protection of the environment

during the decommissioning process. It is also recommended that any decommissioning proposals should incorporate measures to increase green planting and improve biodiversity on the site.

The proposed changes requested in the licence review is a consolidation of the existing process into one building from the current two buildings. This will result in minimal changes in the emissions to the environment. The Environmental Health Service has no additional comments to make.

Should you have any queries in relation to this report please contact me at lisa.maguire@hse.ie

Lisa Maguire

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Lisa Maguire
Environmental Health Officer