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May 23rd 2014

Grainne Oglesby
Environmental Licensing Programme
Office of Climate, Licensing and Resource Use
EPA Headquarters
Johnstown Castle Estate,
Co. Wexford.

Environmental Protection Agency 2 7 MAY 2014

Reference Number:

P0991-01

Applicant:

Regeneron Ltd

Location:

Raheen Business Park, Raheen, Co. Limerick

Our ref:

0165

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

If you have any queries regarding any of these reports, the initial contact is Mr. Andrew Curtin, A/ Principal Environmental Health Officer, who will refer to an appropriate person in the responsible department.

The following HSE departments were made aware of the consultation request for the proposed development:

- Emergency Planning Paschal Diviney
- Estates Helen Maher, Estates Manager Environmental Services
- Assistant National Director for Health Protection Kevin Kelleher / Marie Woods
- RDPI Matt Hurley

Environmental Health Report

The EH service response to the proposal is in the attached consultation report.

- The assessment is based on an assessment of documentation submitted to this office.
- Environmental Health were not included at the Screening / Scoping stage of this application.
- This report refers only to those sections of the documents which are relevant to the HSE.

Yours Sincerely,

Andrew Curtin

A/Principal environmental Health Officer

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Environmental Protection Agency

27 MAY 2014

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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).

Report to: Office of Climate, licensing and Resource Use, EPA Headquarters, Johnstown Castle

Type of consultation: EIS √ Scoping □ Screening (constraints) □ Other (please specify)

Planning Authority:

Limerick County Council

Reference Number:

P0991-01

Applicant:

Regeneron Ltd.

Location:

Raheen Business Park, Raheen, Co. Limerick

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0165

Proposed Development:

IPPC Licence Application for a biopharmaceutical manufacturing facility which will require the alteration and extension of the existing building, the installation of ancillary external utilities in the existing yards and all associated site development works.

Note:

While the EIS states that the authors conducted a scoping exercise in consultation with Local Authorities, the EPA and other interested parties, the HSE was not consulted during this process.

Introduction:

For the purposes of EIA, the authors divide the project into two stages – Construction and Operational.

From a public health perspective, the impacts from the two phases are assessed vis-à-vis:

- Noise & Vibration Impacts
- Air Quality Impacts
- Water/Wastewater Treatment

Noise and Vibration Impacts

Construction Phase

A study of the existing ambient noise characteristics has been compiled and, due mainly to its proximity to the M20 motorway and resulting background noise, the area does not meet the criteria to be classified as a "Quiet Area" under the EPA NG4 Guidance Note. It is anticipated using modelling, that there will be a moderate negative impact from construction noise, but that this will be short-term in nature as the construction phase will last under 24months.

Operational Phase

Due again to the background noise of the M20 and the proposed development's location within the Raheen Business Park, predictive modelling of the projected noise during the operational phase has anticipated imperceptive impact from the operational phase.

Air Quality Impacts

Construction Phase

No significant air quality impacts are envisaged from the construction phase, other than those normally associated with construction projects. As such, various mitigation measures such as stockpiling of soils, silt screens to contain silt run-off from stockpiles, dust suppression techniques are proposed to reduce the impact on air quality from the construction.

Operational Phase

The report divides the potential sources of air pollution from the operational phase into:

- Traffic emissions
- Production process
- Others Dust/Powder emissions from Raw Material delivery

VOC's from the QC Laboratory

Fugitive emissions from filling of diesel tanks

HVAC Vents - these will produce clean air only

Traffic emissions modelling as well as air dispersion modelling has been carried out.

It is envisaged that while there will be an increase in NOx emissions, the resulting maximum concentration levels are predicted to remain at 39.5% of the Concentration limit values.

Traffic emissions will comprise of CO, NO_x, PM₃ and Benzene.

Overall the predicted modelling indicates that the impact will be long-term negative, but imperceptible.

Water/wastewater Impacts

Construction Phase

As with any construction project, there is potential for adverse impact on surface waters due to unforeseen events such as spillages of chemicals such as fuels during the construction phase. Mitigation measures such as designated bunded re-fuelling locations are proposed.

Operational Phase

Wastewater from the plant will require treatment such as:

- Temperature adjustment
- pH balancing
- Removal of suspended solids.

Wastewater will be disposed of to the main sewer via an on-site wastewater treatment system. The emissions will be subject to licence and therefore on-going testing of wastewater will be required.

Stormwater and surface water run-off will be channelled to a petrol interceptor and disposed of to the Shannon Development surface water system which empties into the Loughmore Canal.

The proposed plant will contain a staff canteen to cater for the large number of employees. No details of the greasetrap which will treat the wastewater from the staff canteen have been provided. This process shall be clarified and shall be in accordance with the local authority requirements.

Department of Public Health Comment (as compiled by Dr. Tessa Greally SPHM & Dr. Mai Mannix A/DPHM):

The production process is a biotechnology process—this means that the process wastewater waste from the production process is cellular in character. The EIS indicates that only limited preliminary treatment (incl heat treatment) will be used within the plant to reduce the complexity of treatment required on-site and that consultation with Limerick County Council has indicated that capacity exists within the Bunlicky Waste water treatment Plant to cope with the volumes envisaged over the initial 10 year period of the planning permission.

To confirm that this is sufficient, specific volumes of waste should be defined by the applicant and the operator of the WWTP in terms of:

- a) the population equivalent (P.E.) of waste predicted from the new plant in both phases
- b) the current level of spare capacity in terms of PE (the EIS states that the current licensed capacity is 130,000 population equivalents.)
- c) the priority given by Irish Water to improve the capacity of the WWTP in its Capital Investment Plan to accommodate the proposed Phase 2 of production described in the EIS.
- 3. Noise and ill-health
- a) The hours of operation of the proposed plant are expected to be 24/day and 7 days/week
- b) With the support of the European Commission, the WHO Regional Office for Europe has developed night noise guidelines for Europe to help Member States develop legislation to control noise exposure. The guidelines are based on scientific evidence on the effects of noise and the thresholds above which these effects appear to harm human health. Based upon this evidence the report proposed a guideline target limit of outdoor night noise of 40 dB (annual average defined as 'Lnight' in the Environmental Noise Directive).

Predictive modelling of the projected noise during the operational phase has anticipated imperceptive impact from the operational phase due to the background noise of the M20 and the proposed development's location within the Raheen Business Park. However the fact that the outdoor night noise limit of 45 dB proposed is above the Who guidance level would suggest that potential residential development within the vicinity would be curtailed for at least the period of the planning permission granted. i.e. until 2024

Yours faithfully,

Thomas Boland

Environmental Health Officer

James Cahill

Senior Environmental Health Officer