



Submission

Submitter:	Eamon Mahon
Submission Title:	Submission
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Application

Applicant:	MSD International GMBH
Reg. No.:	P0011-06

See below for Submission details.

Attachments are displayed on the following page(s).

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HSE SUBMISSION REPORT.
Environmental Health Service Consultation Report.

(As a Statutory Consultee (Planning and Development Acts 2001,
& Regs made thereunder))

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

Type of Consultation: Review of the current IPPC licence POO11-05.

Planning Authority. Not Applicable.

Reference number: For the purposes of this review the reference no. in the register of licences is POO11-06.

Our Reference number: EH0988.

Applicant: MSD Ireland (Ballydine) Kilsheelan Clonmel., Co. Tipperary.

Proposed Development: Application to the Environmental Protection Agency for a review of current IPPC licence POO 11-05.

1) General Introduction.

This report only comments on Environmental Health (EH) Impacts of the proposed development as outlined in this Environmental Report (ER) and the adequacy of the ER from an EH perspective. We have made observations on the following specific EH areas.

Emissions to Ground & Surface Water.

Emissions to Air.

2) Assessment of Principle & Description of the Project.

Merck Sharpe & Dohme is located in the townland of Ballydine and the nearest village is Kilsheelan. Operations at MSD Ballydine consist of the manufacture of bulk Active Pharmaceutical Ingredients and Intermediates and the formulation of tablets. The installation consists of 2 main production buildings supported by a range of services including utilities, solvent recovery and bulk storage. The production buildings consist of a "wet" process area for chemical synthesis, purification, and isolation, and a dry process area for drying, milling, blending and packaging.

The installation operates 24 hours a day 7 days week apart from the scheduled shut downs during August and a short break at Christmas time. The site employs in excess of 450 staff and has its own private drinking water and waste water treatment plants. Water is abstracted from the River Suir and treated on site to provide potable drinking water and a of good quality water supply for the manufacturing process.

The IPPC Licence sets out in detail the conditions under which MSD Ireland (Ballydine) will operate and manage the installation. The site was granted an IPPC Licence (PO011-04) on the 29th December 1995 and has had a number of licence reviews since the original licence was granted the most recent was on September 2013. The current licence review of the IPPC/Waste Licence is being initiated for the purpose of the Environmental Protection Agency to complete a mandatory review of the Industrial Emissions Licence under Section 90(1) (aa) of the Environmental Protection Act 1992 as amended. The purpose of the review is for updating the current licence to ensure compliance with the requirements the European Commission Decision (Commissions Implementing Decision 2016/902/EU) on Best Available Technique (BAT) conclusions applicable to the Ballydine installation. In this particular application, the review applies to discharges to the River Suir from the Waste Water Treatment plant at Merck Sharpe & Dohme.

Various waste streams including sewage and wastes from the manufacturing process including strong solvents (Methanol, Ethanol, and Acetic acid), caustic nitrogen and low solvent contaminated water are sewered from the various manufacturing areas via dedicated piping in a secondary contained duct to the waste water treatment plant. The hydraulic flow through the waste water treatment plant may vary from 2000 to 3500 M3 per day. Rainfall can have a significant impact on the hydraulic loading to the Waste Water Treatment Plant. There are approximately 15 acres of roofs, bunds and pads that are ducted to the treatment plant this can have an impact of an additional 1500 M3 per day. The waste from the processing areas is ducted to the treatment plant by gravity drains and initially passes through a bar screen/macerator, then a solvent interceptor which has the ability to separate solvents, which can be subsequently transferred to an organic tank. The influent then enters a wet well tank which is equipped with a number of pumps which feed to the Equalisation System.

Waste from the Equalisation System then flow to the Neutralisation Tanks where the pH is adjusted to 7.00 or 7.5. From here the neutralised waste enters the Primary Clarification System where excess solids/grit is settled in the primary clarifiers. Primary clarifiers can give rise to anaerobic conditions and odours. Odour block solutions are added to counteract odours. Once the waste has passed through the Primary Clarifiers it enters the Aeration System. The waste stream is initially mixed with recycled secondary sludge in a contact tank and the mixed liquor is then ducted to the aeration basins. Oxygen is injected subsurface via diffused bubblers; this ensures that the biomass is aerated and mixed. The aeration basins are covered to conserve energy and this also reduces any potential odours.

The mixed liquor then enters the Secondary Clarifiers. Polymer is added to the mixed liquor to ensure rapid separation of the sludge and the effluent. The clean effluent then enters the tertiary lagoon. The solids at the bottom of the clarifier are re-cycled back to the contact box prior to the aeration system.

The final stage of the treatment process is the Tertiary Lagoon. This is essentially an aerated lagoon approximately 15000 M3. It has a retention time of 5 to 7 days. Effluent then continuously discharges to the River Suir via a diffuser pipe. The effluent dilution factor versus the receiving river water is approximately 2000 M3 in Summer time and approximately 5000 M3 in the average winter flows.

A by- product of the BOD treatment is excess solids /biomass generation. These are pumped to a gravity solids thickener and the concentrated material is then dewatered to approximately 20% solids using a belt filter press. The material is then loaded via a conveyor to a storage hopper and dried at a rate of 700 kgs. / hour in sludge drier. The dried sludge is then discharged to large containerised bins for disposal by incineration in a licensed waste facility in Co. Meath. The dried sludge has been classified as non hazardous waste.

3) Assessment of the Waste Licence Application.

I have since had an opportunity to look at the licence application detail. I visited the site at Ballydine on the 28th of August 2019 and spoke to Mr. David O' Gorman Environmental Chemist for Merck Sharpe & Dohme. Mr. O' Gorman escorted me around the site and explained the process for the Waste Water Treatment Plant and systems in place for monitoring discharges from the plant to the river Suir. From my observations during the time of my visit, the site is well managed and maintained to a very high standard. There is an ongoing programme for maintaining and upgrading plant and equipment in order to meet the standards set for controlling/minimising emissions to air and water. A strict regime of monitoring for emissions to air and water is in place in accordance with the licence conditions.

Monitoring for emissions to water includes the following parameters, Temperature, pH, Toxicity, Suspended Solids, Total Dissolved Solids, Ammonia, Chlorides, Nickel, Copper, Cyanides, and Total Phosphorus etc. The frequency of monitoring depends on specific parameters and this can range from continuous monitoring to daily, weekly, monthly, quarterly and annually. Analysis of all emissions is undertaken by an external accredited laboratory off site. Records of all emission test results are maintained on site as part of the licence conditions. In addition, independent monitoring of the river Suir is undertaken on a regular basis by a separate agency upstream and down stream of the Ballydine plant to ensure discharges from the plant comply with the licence conditions. Mr. O' Gorman informed me that all emissions both to air and water are well within the emission limit values set by the licence conditions, and he did not envisage any problems with the licence review.

I have since had an opportunity to look at the at the licence conditions set by the Environmental Protection Agency. The licence conditions are stringent and set emission limits to air, water, and noise emissions from site. In addition, a strict monitoring regime is in place as required by the licence and all discharges from the plant both to air and water are monitored and records must be maintained and be available for inspection to the Agency. The reason for setting emission limits is to provide protection of the environment by way of control and limitation of emissions, and where appropriate treatment of emissions with current abatement technology to minimise emissions that may be otherwise harmful to the environment. In circumstances where emission limits are exceeded, this triggers any incident which must be reported to the Agency for investigation.

In my opinion, the licence conditions more than adequately address any concerns from the Environmental Health Department perspective (i.e. Emissions to Air, Emissions to Ground and Surface Water.) I therefore have no additional or adverse comments to make in respect of the proposed waste licence review.

Conclusion

A review of the existing IPPC Licence (Register No POO11-O5) granted to MSD International GmbH, trading as MSD Ireland (Ballydine), Kilsheelan, Clonmel, Co. Tipperary, is currently being undertaken. The initial IPPC licence was granted on 29th of December 1995 and has been revised on several occasions, the most recent in September 2013. A review of the current licence was initiated on the 7th of June 2019 by the Environmental Protection Agency for the purpose of the Agency to complete a mandatory review of the Industrial Emissions Licence under section 90(1) (aa) of the EPA Act 1992 as amended. In addition, a review will also be carried out for the purposes of updating the licence to ensure compliance with the requirements of the European Commission decision on BAT conclusions applicable to the installation. The licence application together with the current licence conditions have been examined by this department in detail, and the site was visited on the 28th of August 2019 to assist in the determination of this Department's comments on the proposed licence review. The Licence review was discussed in detail with Mr. David O'Gorman Environmental

Chemist for Merck Sharpe & Dohme and the Waste Water Treatment Plant area of the site was inspected and emission test results were inspected. All monitoring results examined were well within the parameters set by the licence. The site appeared to be well managed and maintained to a high standard and emission monitoring regime was in place. Having examined all the available information it was felt that all the concerns from an Environmental health perspective have been adequately addressed in the current licence conditions and therefore this Department has no further comments to make with regard to the licence review.

Signed: 

Date: 28th August 2019.

All correspondence or any queries with regard to this report including acknowledgement of this report should be forwarded to (Principal Environmental Health Officer)
Environmental Health Department, Community Care Buildings, Western Rd. Clonmel,
Co, Tipperary.

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