

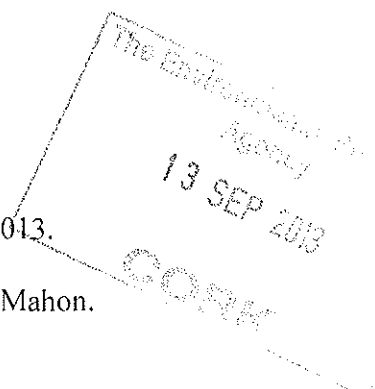


HSE South,  
Community Care Centre,  
Western Road,  
Clonmel,  
Co. Tipperary,  
Ireland.

Tel: 052 6177000  
Fax: 052 6125337

Ms. Maire Buckley  
Environmental Licensing Programme  
Office of Climate, Licensing, & Resource Use  
Environmental Protection Agency.  
Regional Inspectorate,  
Inniscarra,  
Co. Cork.

Your Ref. PO11-05  
My Ref. EH13/35.  
Date: 6<sup>th</sup> September 2013.  
Tel: 052 61 77213  
Please ask for Mr. E. Mahon.



**Re: IPPC Licence Review for MSD International GmbH, Ballydine, Kilsheelan,  
Clonmel, Co. Tipperary.  
Reference No. PO11-05.**

Dear Madam,

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

If you have any queries regarding this report, the initial contact is Ray Parle Principal Environmental Health Officer who will refer your query to the appropriate person.

The following HSE departments were made aware of the consultation request for the proposed review on 2<sup>nd</sup> August 2013 namely,

Emergency Planning –Peter Daly  
Assistant National Director for Health Protection- Kevin Kelleher/Marie Woods.  
RDPI – Pat Healy.  
Estates – Helen Maher, Estates Manager, Environmental Services.  
Mr. Ray Parle (PEHO). Environmental Health Department, South Tipperary Community Care Buildings, Western Rd, Clonmel, Co. Tipperary.

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 on 9<sup>th</sup> of August 2013 by the Environmental Protection Agency. .
- A site visit was conducted on 6<sup>th</sup> of September 2013.
- All commitments to future actions including mitigation and further testing have been taken as read and all data results have been accepted as accurate.
- No additional investigations / measurements were undertaken.
- This report refers only to those sections of the documents which are relevant to the HSE.
- We have made observations and submissions under the following specific areas.

Emissions to Air.

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

Yours faithfully,



Principal Environmental Health Officer



HSE South,  
Community Care Centre,  
Western Road,  
Clonmel,  
Co. Tipperary,  
Ireland.

Tel: 052 6177000  
Fax: 052 6125337

Date: 4<sup>th</sup> September 2013.

**HSE SUBMISSION REPORT.**  
**Environmental Health Service Consultation Report.**

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

**Report to:** Ms. Maire Buckley  
Environmental Licensing Programme  
Office of Climate Change Licensing & Resource Use  
Environmental Protection Agency  
Regional Inspectorate,  
Inniscarra, Co. Cork.

**Type of Consultation:** Review of IPPC licence POO11-05.

**Planning Authority.** Not Applicable.

**Reference number:** POO11-05.

**Our Reference number:** EH13/35.

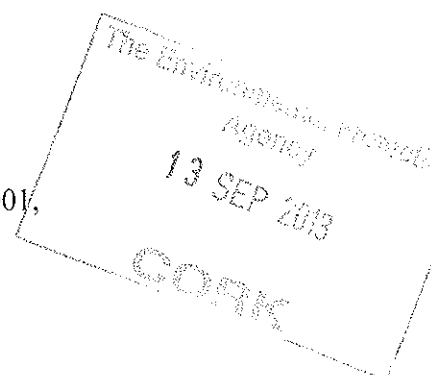
**Applicant:** MSD Ireland (Ballydine) Kilsheelan Clonmel., Co. Tipperary.

**Proposed Development:** Application to the Environmental Protection Agency for a review of IPPC licence POO 11-05 for the purposes of new Industrial Emissions Directive (Directive 2010/75/EU) emission limits which come into effect in January 2014.

**1) General Introduction.**

This report only comments on Environmental Health (EH) Impacts of the proposed application 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 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 400 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 supply of good quality for the manufacturing process.

The IPPC Licence sets out in detail the conditions under which MSD Ireland (Ballydine) operates and manages the installation. The site was granted an IPPC Licence (POO11-04) on the 29<sup>th</sup> December 1995 and has had a number of licence reviews since the original licence was granted. The current licence review is to include the operation of a new regenerative thermal oxidiser on site and to rationalise a number of minor emission points to air. The new regenerative thermal oxidiser (RTO) is being installed to abate off-gases from processing activities. Currently these off-gases are treated in either of the two existing regenerative thermal oxidisers and /or fume incinerator. However, the existing regenerative thermal oxidisers (RTO) were not designed to meet the new Industrial emissions Directive (Directive 2010/75/EU) emission limits which will come into effect in January 2014.

There are currently three main sources of emission to air from the plant, these are the stack from the boiler house, the existing regenerative thermal oxidiser stack and the fume incinerator stack. The proposed new regenerative thermal oxidiser stack will be the fourth major emission point and is the main subject of this licence review. Once the licensing of the new thermal oxidiser has been granted the existing thermal oxidisers 1 & 2 will be decommissioned and the emission points no longer utilised. The fume incinerator regenerative thermal oxidiser (RTO) No 3 will be retained for limited processing and/or backup.

### 3) Assessment of the Licence Application.

I have since had an opportunity to look at the licence application in detail. I visited the site at Ballydine on the 6<sup>th</sup> of September 2013 and spoke to Mr. Robert Boyle Environmental Chemist for Merck Sharpe & Dohme. Mr. Boyle escorted me around the site and explained the regenerative thermal oxidiser process and systems in place for monitoring emissions from the various discharge points to the atmosphere. All the main atmospheric emission points for the existing thermal oxidisers and the fume incinerator are provided with Continuous Emissions Monitoring Systems which are approved to international technical standards certification. The new regenerative thermal oxidiser will also be equipped with an approved Continuous Monitoring System. The Industrial Emissions Directive (Directive 2010/75/EU) which will come into effect in January 2014 and will impose tighter limits on emissions of Total Organic Carbon. The new regenerative thermal oxidiser is designed to achieve 100% compliance with the Industrial Emissions Directive Total Organic Carbon emission limit values. Dispersion modelling of the worst case emissions to air from the new regenerative thermal oxidiser together with the other main emissions to air from the site was undertaken in early 2013. The results of the modelling indicated that the emissions from the plant have no significant environmental effect and do not breach current statutory air quality standards.

Monitoring for emissions to air from the various exhaust stacks includes the following parameters, Nitrogen oxides, Oxides of Sulphur, Carbon Monoxide, Hydrogen chloride, Ammonia, Hydrogen fluoride 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 some of the emissions is undertaken by the laboratory on site, but analysis of the more complex emissions are sent to an external accredited laboratory for analysis. Records of all emission test results are maintained on site as part of the licence conditions. Mr. Boyle 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 current licence review. From my observations during the time of my visit, the site is very well managed and maintained to a high standard. There is a constant 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 are in place in accordance with the current licence conditions.

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 also 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 are maintained and are available for inspection to the Agency.

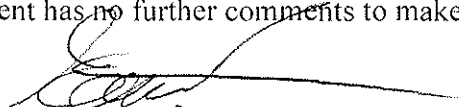
The reason for setting emission limits is to provide protection to the environment by way of control and limitation of emissions, and where appropriate treatment of emissions with current abatement technology to minimise emissions that may be otherwise harmful to the environment. In circumstances where emission limits are exceeded an incident is triggered which must be reported to the Agency for investigation. In my opinion, the current licence conditions more than adequately address any concerns from the Environmental Health Department perspective. I therefore have no additional or adverse comments to make in respect of the proposed 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 purpose of the review of the IPPC Licence is to include the operation of a new regenerative thermal oxidiser (RTO) on site and to rationalise a number of minor emission points to air for the purposes of complying with the new more stringent Industrial Emissions Directive (Directive 2010/75/EU) which comes into force in January 2014. The initial IPPC licence was granted on 29<sup>th</sup> of December 1995 and has been reviewed on several occasions to date.

A review of the current licence was initiated on the 17<sup>th</sup> of July 2013. The licence application together with the current licence conditions have been examined by this department in detail, and the site was visited on the 6<sup>th</sup> of September 2013 to assist in the determination of this Department's comments on the proposed licence review. The Licence review was discussed in detail with Mr Robert Boyle Environmental Chemist for Merck Sharpe & Dohme. 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:



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