

MSD P011-03. Attachment A.1.

ATTACHMENT No. A.1

NON- TECHNICAL SUMMARY

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Non-Technical Summary of IPPC Licence Application

TABLE OF CONTENTS

Subject	Page
A.1.1. Introduction.	3
A.1.2. The Installation and its Activities.	3
A.1.3. The Raw and Auxiliary Materials, other Substances and the Energy used in or Generated by the Installation.	5
A1.4. The Sources of Emissions from the Installation.	5
A.1.5. The Conditions of the Site of the Installation.	6
A.1.6. The Nature and Quantities of Foreseeable Emissions from the Installation into each Medium as well as Identification of Significant Effects of the Emissions on the Environment.	6
A.1.7. The Proposed Technology and other Techniques for Preventing or, where this not possible, Reducing Emissions from the Installation.	12
A.1.8 Where necessary, Measures for the Prevention and Recovery of Waste Generated by the Installation.	13
<p>A.1.9. Further measures planned to comply with the general principles of the basic obligations of the operator, i.e.,</p> <ul style="list-style-type: none"> (a) all the appropriate preventive measures are taken against pollution, in particular through the application of best available techniques (BAT); (b) no significant pollution is caused; (c) waste production is avoided in accordance with Council Directive 75/442/EEC of 15 July 1975 on waste; where waste is produced, it is recovered or, where that is technically and economically impracticable, it is disposed of while avoiding or reducing any impact on the environment; (d) energy is used efficiently; (e) the necessary measures are taken to prevent accidents and limit their consequences; (f) the necessary measures are taken upon definitive cessation of activities to avoid any pollution risk and return the site of operation to a satisfactory state. 	13
A.1.10. Measures planned to monitor emissions into the environment.	15

A.1.1: Introduction

Merck Sharp & Dohme (Ireland) LTD is a subsidiary of Merck & Co. Inc., New Jersey, USA. Merck & Co. is a worldwide, research intensive healthcare company that discovers, develops and produces human health products and speciality chemicals. The human health products include medicines to combat disease and pain.

Merck Sharp & Dohme (Ireland) LTD is a bulk pharmaceutical manufacturing facility located at Ballydine about ten miles from Clonmel, and 5 miles from Carrick-on-Suir in South Tipperary.

Bulk active ingredients for pharmaceutical products are manufactured at Ballydine and exported to finishing plants around the world, for formulation into final dosage form and distribution to market outlets.

The plant runs 24 hours per day, 7 days per week apart from an annual shutdown and a short break at Christmas. Production is by batch processing. The manufacture of the different products is scheduled on a campaign basis, with the campaigns varying in length dependent on market requirements.

A.1.2: The Installation and its Activities

The Principle Activity is Class 5.16, *“the use of a chemical or biological process for the production of basic pharmaceutical products manufacture”*.

The Associated Activity is Class 11.1, *“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”*.

In 1994 the company applied to the EPA for an Integrated Pollution Control Licence. This was issued in December 1995, Licence No. 11.

In 1996 the company applied for a review of their Integrated Pollution Control Licence. A revised licence, IPC Licence No 208, was issued in 1998.

In June 2006 the company was requested to submit an IPPC Licence Review Application Form to ensure compliance with the Directive.

The pharmaceutical production facility at Ballydine consists of 2 main manufacturing production buildings. These are supported by a range of service areas including administration, technical operations, utilities services, quality

MSD P011-03. Attachment A.1.

operations, maintenance and materials management. Facilities associated with the manufacturing areas include a solvent recovery plant and bulk storage tank farms.

Raw materials are distributed to each point of use. Finished product is returned to the finished goods warehouse from where it is shipped to its next destination.

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.

In the “wet” section of a production building, liquid, solid and gaseous raw materials are mixed and processed in a variety of multi-purpose equipment to produce batches of product. These areas are modular and computer controlled. They consist of some 150 vessels/modules and other equipment interlinked by process manifolds to which all of the vessels are piped. This enables any module within a production building to be connected to any other module within the same building thus providing extremely flexible production facilities.

The wet product, produced in the “wet” section is then further processed in the “dry” section to produce the final packaged product.

Quality is assured by strict process control using computers and batch sheet control documentation and by regular sampling of product through out the manufacturing cycle.

A fundamental requirement of the production areas is an uninterrupted supply of utility services including steam, cooling water, refrigerant, potable water, demineralised water and compressed air.

Solid, liquid and gaseous wastes are generated from all sections of the production plants. A number of abatement systems are used to handle these wastes.

Primary abatement/treatment systems include scrubbers, thermal oxidisers, carbon adsorbtion and/or fume incineration for gaseous wastes and a waste water treatment plant (WWTP) for liquid wastes.

Solid wastes that do not form part of the streams feeding the WWTP are disposed of off-site.

A Solvent Recovery facility is used to recover solvents for reuse. All materials that cannot be recovered on-site are either recovered off-site or incinerated in facilities equipped with heat recovery.

MSD P011-03. Attachment A.1.

A.1.3 The Raw and Auxiliary Materials, other Substances and the Energy used in or Generated by the Installation.

MSD utilise a wide range of raw materials, intermediates and organic solvents to produce active pharmaceutical ingredients (API's), which in turn are formulated in other Merck facilities worldwide.

IPC Application Form Table 10, "*Details of processing related Raw Materials, Intermediates, products etc, used or generated on the site*" is updated periodically to reflect current processing projections.

The latest revision, No 7, was submitted to the Agency in June 2006, as part of the notification of the Omeprazole product introduction to Ballydine. Ref Boyle to South/South West OEE, 23rd June 2006.

The Ballydine site is a significant user of both electricity and natural gas. The site does not generate electricity. Natural gas is utilised to generate steam and as a support fuel in the fume incinerator.

A minor quantity of diesel (< 50 tonnes per annum) is utilised for road vehicles and stationary motors/engines.

Energy usage is outlined in Attachment G.

A1.4 The Sources of Emissions from the Installation.

The sources of atmospheric and water emissions are listed in previous IPC Licence Applications and supporting documentation.

They are again summarised in **Attachment No D.1.A**, Point Source Emissions to Air, and **Attachment D.2.A**, Emissions to Surface Water.

The Ballydine site is provided with extensive abatement facilities, described in detail in previous licence submissions.

The site has an exemplary record of compliance for emissions to both air and water.

Annual PER balance closures are excellent with fugitive emissions within material balance accuracy levels.

Typically, MSD achieves PER balance closures in the low percentage points for all materials.

A.1.5 The Conditions of the Site of the Installation.

The Merck Sharp & Dohme facility is located in the valley floor of the River Suir, approximately mid-way between Clonmel and Carrick-on-Suir. It is bounded on its southern side by the River Suir and on the northern side by the main Limerick to Waterford Road. A railway cutting runs parallel with the road, adjacent to the site's northern boundary. The river valley runs on an east/west axis and in visual terms it is a landscape of mixed uses. The valley floor has a spread of grassland with small farmsteads and the surrounding hills are forested with scattered dwellings. The lower slopes of the Comeragh Mountains form a ridge which runs on an east-west axis to the south of the site and most long distance views of the facility are from this side. The general area is very scenic.

A.1.6 The Nature and Quantities of Foreseeable Emissions from the Installation into each Medium as well as Identification of Significant Effects of the Emissions on the Environment.

A.1.6.1 Assessment of atmospheric emissions

A.1.6.1.1. An assessment of the impact of all significant emissions to air.

An assessment of the impact to the air of all emissions, from the existing plant and the factory 3 (Capacity Expansion) project, was outlined in Section 10.8 of the EIS which accompanied the 1996 application. The emissions included process vessel off-gases and emissions from fume incineration, steam generation, dry product handling operations, minor and fugitive emissions.

It was concluded that there would be no significant impact due to the air emissions from the existing plant or from the capacity expansion project.

A.1.6.1.2. Details of chemical composition, including the results of any ambient monitoring.

As outlined in Attachment No.12, of the 1994 IPC Licence application, air quality, both in the vicinity of the Ballydine plant and rural areas up to 10 miles distance from the plant, had been monitored by Tipperary South Riding County Council and by Bord na Mona, under County Council direction. Air quality results are held on file by the County Council.

Since 1996 Monitoring results from the main emission points have been submitted to the Agency on a monthly, and recently 3 monthly bases. All results indicate a high level of compliance for all parameters.

A.1.6.1.3. Description of the surrounding habitat and landscape, the topography of the area, highlighting abrupt changes in terrain

The topography, landscape, habitat, flora, fauna and land use surrounding the Merck Sharp and Dohme facility at Ballydine were discussed in detail in the EIS which accompanied the 1996 application and in Attachment No.12 of the 1994 IPC Licence application. The flora, fauna and land use were discussed in Section 11 of the EIS. Topography and landscape were discussed in section 14 of the EIS. The effect of the topography on the prevailing winds is discussed in Section 10.8 of the EIS.

The plant lies in a river valley, with high ground to the north and south. The surrounding land is used for farming, mainly grassland, and coniferous forestry.

A.1.6.1.4. Details of other activities, sensitive areas or areas of special interest within 5 kms of the site which could be affected by the emission.

As outlined in Attachment No.12, of the 1994 IPC Licence application, while the plant is surrounded by farmland, two other industries exist within a five kilometre distance of the plant. These are the former Tipperary Crystal, now Blarney Woollen Mills, and a Glan Bia processing plant.(Formerly Miloko)

The River Suir, which runs past the south-western side of the plant, has good stocks of trout and salmon. The tourism potential of the area is good with fishing, river walks, and mountain and wood treks all within easy reach of the plant site.

A number of medieval castle ruins exist within 5 miles of the plant.

Further details on surrounding land use, together with an assessment of local flora and fauna are provided in Section 11 of the EIS which accompanies this application. Local archaeology and cultural heritage are discussed in Section 15 of the EIS.

Section 10.8 of the 1996 EIS indicated that there would be no significant impact due to the existing plant or the planned 1996 expansion.

A.1.6.1.5. Details of any dispersion modelling carried out and the predicted ground level concentration as a result of such emissions

An emission modelling study was carried out for the capacity expansion project in 1996. Full details, a discussion on the results and the printout of the results were provided in Section 10.8 of the EIS which accompanied the 1996 application.

The Industrial Source Complex Short Term (ISCST3) model (Version 3.00) from the U.S. Environmental Protection Agency was used to predict the maximum 1-hr concentrations (micro g/m³) at flagpole heights of 1.5 m of total hydrocarbon produced from EP 1.0 (Scrubber/Oxidiser) and EP 1.1 (proposed Fume Incinerator). Flagpole height of 1.5 m was chosen as human head level in order to ascertain the likely concentrations humans may be exposed to.

Total hydrocarbon emissions rates were calculated for each emission point and a polar grid of receptors surrounding the stacks was generated for sixteen wind directions (N, NNE, NE, ENE, E, ESE, SE, SSE, S, SSW, SW, WSW, W, WNW, NW, NNW) out to a distance of 5000 m. Maximum 1-hr concentrations of total hydrocarbons were predicted using 3-years of meteorological data collected at Kilkenny from 1988 to 1990. Terrain elevations at each receptor point were incorporated into the model and a summary of the predicted maximum concentrations for the different emission parameters are shown in Tables 10.8.3 - 10.8.15 of the EIS.

The maximum predicted 1-hr concentrations of total hydrocarbons produced from the existing Scrubber/Oxidiser and the fume incinerator were low and within typical background levels expected for hydrocarbons in the atmosphere (0 - 500 micro g/m³). In all cases considered, the maximum predicted concentrations were significantly less than 1/40 of the occupational exposure limits (OEL) and the air quality guideline recommended by the World Health Organisation for toluene.

It was concluded that the hydrocarbon emissions produced from the two main emission sources would not have any adverse effects on the surrounding environment.

MSD P011-03. Attachment A.1.

A.1.6.1.6. Impact of Atmospheric emissions on environmental media other than those into which the emissions are to be made

The EIS provided a detailed assessment of the impact of air emissions from the plant at Ballydine on media other than those into which the emission is made and demonstrates that there is no impact.

A.1.6.2 Assessment of Impact on Receiving Surface Water

A.1.6.2.1. Mixing Zone

Treated effluent is discharged to the River Suir at the emission point WEP 1.0. The outfall line is perforated along its length to distribute flow uniformly across 50 % of the river. This is in compliance with the Dept. of Fisheries requirements. Data on the mixing was provided in the Section 7.3 of the EIS.

Modelling studies at Plant design stage indicated three areas of mixing.

- Primary mixing occurs within 3m (10 feet) of the effluent being discharged from the outfall pipe. Within this zone, points of maximum surface concentration occur and concentrations drop to below 10 % of original emitted values.
- Secondary mixing occurs over the next 7.6m (25 feet) at which point any emitted effluent has dropped to below 2% of emitted concentrations.
- A third mixing zone can be seen over the next 56.4m (185 feet) encompassing a river cascade, where any effluent concentrations drop to below 0.5%

The mixing zone is discussed in Attachment No.15, of the 1994 IPC Licence Application and Section 7.3 of the 1996 EIS. Included in Attachment 15 of the 1994 IPC Licence Application are details of the outfall pipe in the river.

A.1.6.2.2 Modelling of Effluent Emissions and Dilution Available.

The modelling of effluent concentration profiles is discussed in Attachment 15, Section 6.2.2 of the 1994 IPC Licence Application and Section 7 of the 1996 EIS. These profiles are derived from “River Outfall Concentration Diagrams” which are included in Attachment 15 of the 1994 IPC Licence Application.

MSD P011-03. Attachment A.1.

Effluent concentration profiles were modelled at dry weather flow conditions for the River Suir over a range of effluent flow rates from 70,000 IMPgals/day to 2 million IMPgals/day (336 to 9600 m³/day).

From the modelling studies completed, it was concluded that at or below current licensed flow rates, effluent concentrations would be at or below 10% of emitted concentrations at a point 3m (10 ft) downstream from the diffuser and below 2% at a point 9m (30 ft) downstream of the diffuser. A cascade, spanning the river, is located approximately 9.75m (32 ft) downstream of the diffuser which further enhances mixing and dilution.

Effluent continues to diffuse and be diluted across the width of the river reaching an estimated concentration, at both river banks, at or below 0.5% of emitted concentrations. This occurs approximately 67m (220 ft) downstream of the diffuser. This equates to a 200 fold dilution at maximum licensed discharge rates.

The modelling of effluent diffusion indicates that, under all conditions, adequate dilution is available for effluent discharges from the Merck Sharp & Dohme Ballydine facility. This is consistent with the satisfactory biological, chemical and physical quality of the River Suir.

A.1.6.2.3. Re-aeration Characteristics

Re-aeration of the river occurs between sampling points upstream and downstream of the plant outfall. This is borne out by EOLAS (now Forbairt) studies over a number of years. Re-aeration is assisted by the presence of a cascade in the river just downstream of the outfall line. Essentially the same dissolved oxygen level is obtained at both locations.

No adverse effect on the river's re-aeration capacity results from discharges from the Merck Sharp & Dohme site.

Re-aeration of the river is discussed in Attachment 15, Section 6.2.4 of the 1994 IPC Licence application and Section 7 of the EIS.

A.1.6.2.4. Receiving Water and Sediment Quality

The physical and chemical quality of the River Suir receiving waters are discussed in Attachment 15, Section 6.2.5 of the 1994 IPC Licence application and Section 7 of the 1996 EIS. Based on a large body of data referred to in the 1994 application and in the EIS, the river water quality is acceptable and the effluent from MSD has had no deleterious effects.

A.1.6.2.5. Existing or Proposed Uses and/or Designations of Receiving Waters

Merck Sharp & Dohme extracts its entire water supply from the River Suir. This is treated for use as both drinking (Potable) and Process water. The inlet is upstream of the effluent discharge pipe. No further proposed uses of the river waters are anticipated by the Merck Sharp & Dohme at this time.

There are no potable water supply intakes from the receiving waters downstream of the plant. However, due to projected population growth in the Suir catchment, it is necessary to maintain continuous water quality monitoring and control.

Although not a designated as a "sensitive area" under EEC Directives on receiving waters, the River Suir is a significant amenity for trout and salmon fishing. This angling is primarily recreational, but commercial fishing is conducted many kilometres downstream in the estuary reaches. Salmonoid spawning and nursery areas are widespread along the length of the river.

Further discussion on the uses and designation of the River Suir receiving waters, including reference to the Water Quality Management Plan for the River Suir, were provided in Attachment 15, Section 6.2.6 of the 1994 IPC Licence Application.

A.1.6.2.6. Assessment of the Receiving Waters with particular Reference to the Presence of any Biological Species Sensitive to any Substance in the Emission.

An assessment of the receiving waters with particular reference to the presence of any biological species sensitive to any substance in the emission is provided in Attachment 15, Section 6.2.7 of the 1994 IPC Licence Application and in section 7 of the 1996 EIS. A large number of surveys on the biological quality of the River Suir carried out between 1977 and 1993 were discussed.

Data from the biological impact studies of part of the river stretch with reference to the effluent discharges by Merck Sharp & Dohme conclude that the company's effluent has no deleterious effect on river quality. It is noted that water quality is influenced by factors upstream of Kilsheelan, most likely due to discharges from Clonmel. Q Values of 3-5 have been reported for the water reaches both upstream and downstream of the

MSD P011-03. Attachment A.1.

effluent outfall line from Merck Sharp & Dohme. The biological component of the surveys indicate that water quality overall remains fair.

A.1.6.2.7. Sensitive Areas or Areas of Special Interest within 2km of the Emission Point which could be effected by the Emission

Other than as discussed above there are no other sensitive areas and there are no areas of special interest within 2km of the emission point which could be affected by emissions to the River Suir from Merck Sharp & Dohme Ballydine.

Refer to Attachment 15, Section 6.2.8 of the 1994 IPC Licence and to Section 7.3 of the 1996 EIS.

A.1.6.2.8. Impact of Emissions to Receiving Waters on other Media.

There is no impact on land, air or other media as a result of emissions to the River Suir from the MSD facility.

Refer to Attachment 15, Section 6.2.9 of the 1994 IPC Licence Application and to Section 7 of the 1996 EIS.

A.1.6.2.9. Flow Data and Chemical Composition of Waters Upstream and Downstream of the Emission Point.

Water flow data and chemical composition for the River Suir, upstream and downstream of the MSD emission point, is provided in Attachment 13 of the 1994 IPC Licence Application.

Ongoing surveys of the river bottom are conducted both up and downstream of the facility. No adverse effects have been identified

A.1.7. The Proposed Technology and other Techniques for Preventing or, where not possible, Reducing Emissions from the Installation.

Attachment 7 of the 1994 Application, Attachment 12A of the 1996 Application and Section 10.3 of the 1996 EIS describe the abatement facilities provided at Ballydine.

All abatement facilities meet the requirements of BAT and all emissions are within licence ELV's.

A.1.8 Where necessary, Measures for the Prevention and Recovery of Waste Generated by the Installation.

Section C.17 and C.19 of the 1996 IPC Application and Section 6 of the accompanying EIS detail measures to prevent and recover wastes generated by the facility.

A.1.9 Further measures planned to comply with the general principles of the basic obligations of the operator, i.e.**a) all the appropriate preventive measures are taken against pollution, in particular through the application of best available techniques (BAT);**

MSD has a continuous programme of investment to ensure that all appropriate abatement and preventative technologies are provided at their Ballydine site.

The MSD Ballydine plant has invested over €72 million in environmental protection facilities during the period 1987 to 2005.

The Ballydine facility is a mature plant and is equipped with all the appropriate wastewater treatment and emission abatement infrastructure and monitoring equipment. See the 1996 IPC application and EIS.

See Attachment D.6 for a discussion on BAT

b) no significant pollution is caused;

All studies to date indicate that the operations of MSD do not have a detrimental impact on the local environment.

See the 1996 IPC application and EIS.

c) waste production is avoided in accordance with Council Directive 75/442/EEC of 15 July 1975 on waste; where waste is produced, it is recovered or, where that is technically and economically impracticable, it is disposed of while avoiding or reducing any impact on the environment;

See the 1996 IPC application and EIS.

d) energy is used efficiently;

MSD P011-03. Attachment A.1.

Merck has set itself an aggressive 2008 target of reducing energy usage by 25% over the 2004 baseline year.

MSD Ballydine is party to this initiative and is on track to meet our targets.

Extensive investment has been made in the energy conservation area. An Energy manager has been appointed. Energy Consultants have been retained. A continuous auditing programme has been initiated which identifies opportunities. A plantwide energy monitoring and tracking system has been installed.

See also Attachment G.

e) the necessary measures are taken to prevent accidents and limit their consequences;

Section 20 of the 1996 Application contains details on accidental emission prevention and management. Additional details can be found in Attachment 8, section 4.2.1 of the 1994 Application.

The site is operated continuously and is fully staffed at all times with suitably qualified and experienced personnel.

f) the necessary measures are taken upon definitive cessation of activities to avoid any pollution risk and return the site of operation to a satisfactory state.

MSD will adhere to all Agency requirements relating to environmental liability risk assessment and residuals management.

A.1.10 Measures planned to monitor emissions into the environment.

A.1.10.1. Emissions to Atmosphere

The main atmospheric emission points for the Thermal Oxidiser and the Fume Incinerator are provided with TUV approved CEM's.

Boilers are fueled on natural gas. Emissions are monitored annually for agreed parameters.

Dust emissions from all licenced emission points are monitored annually by manual gravimetric methods.

MSD P011-03. Attachment A.1.

All monitoring requirements for atmospheric emissions, as outlined in Licence P0011-02, Formerly No. 208, will be adhered to in full.

A.1.10.2. Emissions to Surface Water.

All emissions to the main water emission discharge point are collected with a flow proportionate sampler and analysed as per the schedules.

Surface water discharge is inspected daily and monitored weekly for agreed parameters.

The flow of Reverse Osmosis Effluent is continually recorded. Agreed parameters are monitored monthly.

All monitoring requirements for emissions to water, as outlined in Licence P011-02, Formerly No. 208, will be adhered to in full.

A.1.10.3. Ground Water Monitoring.

There are no ongoing sources of pollution to groundwater.

The frequency of Schedule 5(i) monitoring for selected parameters was, as agreed with the Agency, reduced from bi-annual to annual. Ref Barry to O'Brien, 17th August 1999.

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