Annual Environmental Report 2008

Company:	***AHP Manufacturing B.V. T/A Wyeth Medica Ireland.***
Address:	***Buckley's Cross Roads, Old Connell, Newbridge, Co. Kildare.***
Licence Register No:	***P0153-05***
Date:	***March 2008***

EXECUTIVE SUMMARY

The following is the Annual Environmental Report (AER) for the period January - December 2008 for Wyeth Medica Ireland (WMI), Buckley's Cross Roads, Old Connell, Newbridge, Co. Kildare. The AER has been prepared as per the Conditions outlined in Integrated Pollution Prevention Control (IPPC) Licence Register No. P0153-05, and the *Integrated Pollution Control Licensing Guidance Note For: Annual Environmental Report* as issued by the Environmental Protection Agency (EPA).

The WMI facility has been designed and is operated in such a manner that the potential emissions (wastewater, surface water, air) to the environment are minimised or eliminated. In addition, the BAT principle is implemented during the operational phase of the site with respect to the management of the facility. It is contended that the risk of environmental contamination as a result of both existing activities and potential accidental or emergency situations at the WMI facility are minimised or eliminated by adherence to the existing protection programmes. With IPPC Licence requirements, in 2008 there was:

- no exceedance of any emission limit value specified for emissions to sewer (wastewater), storm water emission (surface water), emissions to air (including solvent management plan), noise emissions,
- groundwater was of good chemical quality; and,
- no complaints of an environmental nature were received.

The majority of the objectives and targets set out in the site Environmental Management Programme for 2008 were achieved – those that are ongoing have been incorporated into the 2009 Environmental Management Programme.

The Environmental Monitoring Programme carried out over the 2008 reporting period shows no adverse environmental impact on the environmental media into which discharges from the WMI facility are made.

WMI acknowledge that given the restrictions and limitations on changes that can be made to the production process due to validation requirements and product registration with various drug control bodies, it may not therefore be possible for the company to achieve total sustainable transformation of the production processes conducted at the site. Notwithstanding this WMI are committed to an ongoing improvements programme at the site and the continuous improvement requirement of the IPPC licencing process is fully embraced by the WMI Senior Management Group. To this end it is the policy of WMI to conduct its pharmaceutical manufacturing business in such a manner that associated activities minimise or eliminate any potential adverse effects on the environment. This commitment is expressed in the company's EHS Policy. The success of this policy is reflected by the:

- EPA audit and site inspection conducted at the site which were fully compliant; and,
- Ongoing compliance with ISO14001 EMS certification, and the EMAS Regulation.
- Independent certification of the site Energy Management System to IS393:2005.

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DECLARATION

These results are certified as accurate and representative of the sampling and associated analysis carried out.

Signed: _____

Dr Michael Donlon
Environmental, Health & Safety Director

Date: _____

1. INTRODUCTION

1.1. OVERVIEW

The following is the Annual Environmental Report (AER) for the period January - December 2008 for Wyeth Medica Ireland (WMI), Buckley's Cross Roads, Old Connell, Newbridge, Co. Kildare. The AER has been prepared as per the Conditions outlined in Integrated Pollution Prevention Control (IPPC) Licence Register No. P0153-05, and the *Integrated Pollution Control Licensing Guidance Note For: Annual Environmental Report* as issued by the Environmental Protection Agency (EPA).

AHP Manufacturing B.V. trading as Wyeth Medica Ireland, Buckley's Cross Roads, Old Connell, Newbridge, County Kildare is licensed under Section 90(2) of the Environmental Protection Agency Acts 1992 and 2003, to carry on the following activity:

'the surface treatment of products using organic solvents, in particular for printing, coating, with a consumption capacity of more than 200 tonnes per year'.

IPPC Licence Register No.:	P0-153-05
Company Name:	AHP Manufacturing B.V. T/A Wyeth Medica Ireland
Address:	Buckley's Cross Roads, Old Connell, Newbridge, Co. Kildare.
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1.2. SITE ACTIVITIES - UPDATE

The WMI facility produces a variety of pharmaceutical products. Operations are based on formulation activities, consisting of blending of raw materials, granulation, drying and coating processes, with subsequent filling and packaging operations and product distribution from the site. The production facilities comprise packaging and processing buildings, solvent recovery plant, combined heat & power (CHP) plant and laboratories. Other facilities include warehousing of raw materials / intermediates / finished goods, external materials storage, services including steam, compressed air, nitrogen, cooling water and process water, wastewater pre-treatment plant (WWTP), waste management centre, Oils, Fats and Grease (OFG) Wastewater Treatment Plant, engineering workshops, and an administration building with canteen. The following developments were commenced in 2008:

- Construction of Pharmaceutical Development Centre
- Construction of Analytical Development laboratory
- Construction of MHT laboratory
- Extension of Microbiology laboratory.

Work on the following projects continued in 2008:

- MHT processing facility - *commissioning and validation ongoing in 2009.*
- Levo/EE Continuous Use Production Facility (renamed OC4B) - *commissioning and validation ongoing in 2009.*

Amendments made to Licence Register No. P0153-05 in 2008, as approved by the EPA, are summarised in Table 1.1.

Table 1.1: Amendments made to Licence Register No. P0153-05 in 2008

Change Description	WMI Submission Date	EPA Approval Date (Reference)
Air Emissions: MHT Emission Points	07/02/08	Rejected
Air Emissions: Operation of Emergency Generators – 110Kv Transition	22/02/08	10/03/08
Waste: Revised Table H	03/03/08	Notification only – EPA approval not required
Air Emissions: WWTP, ADL, Levo/EE, OFG WWTP, Satellite Workshops, Laboratory, MHT Laboratory, MHT.	18/04/08	05/06/08 24/06/08 (P0153-05.ap06jmce.doc)
SCA-136 Trial	18/04/08	06/06/08 (P0153-05.ap07jmce.doc)
Air Emissions: Operation of MHT Emergency Generator (Emission Point Reference No. A4-121: load shed testing on the emergency back-up power system for the MHT facility)	21/05/08	23/05/08 (23/05/08 email from jmcentagart@epa.ie to E Molyneaux)
Air Emissions: MHT Emission Points & RMDU Transfer Booths Points	15/07/08	06/10/08 (Technical Amendment B)
Air Emissions: Levo/EE & Decommissioning of Emission Points	24/07/08	05/08/08
Waste: Revised Table H	10/10/08	Notification only – EPA approval not required
Air Emissions: Operation of Emergency Generator (Emission Point Reference No. A4-140: install a new breaker in Building 4)	20/10/08	20/10/08 (P0153-05/ap.08mk.doc)

2. EMISSIONS FROM THE INSTALLATION

2.1. ENVIRONMENTAL PERFORMANCE INDICATORS

Measuring performance via environmental performance indicators (EPIs) may further enable WMI to determine objectively what is working and what is not from a reduced environmental impact perspective. Using EPIs may also assist in the identification of further opportunities to:

- prevent environmental pollution
- use resources more efficiently thereby minimising waste (raw materials usage, energy consumption, water usage)

EPIs are the set of measurements deemed important to understanding a facilities operational efficiencies; and can be used to establish base-line environmental performance and to track changes. By setting EPIs, companies are encouraged to monitor what they are doing and then establish targets to help achieve continuous improvement. EPIs can also be used for external benchmarking i.e. to measure WMI's environmental performance against that of a similar company or against 'best practice' data (if available).

The Wyeth Corporate Environmental, Health & Safety (EHS) Department has set 5 year reduction targets (10% reduction of the 2007 baseline for specific environmental performance indicators) over the period 2008 – 2012 for each Wyeth facility for the following 3 No. environmental aspects which are considered the most important global environmental challenges currently facing industry:

- Waste Arisings (refer to Section 2.7.3)
- Carbon Dioxide (CO_2) Emissions (refer to Section 2.8.1).
- Water Usage (refer to Section 2.8.3)

For the purposes of calculating the reduction targets, each EPI is linked to production output.

2.2. EMISSION TO SEWER

2.2.1. Overview & Results

Effluent discharged through Emission Point Reference No. SE1 was monitored in accordance with *Schedule C.3.2 Monitoring of Emissions to Sewer* of Licence Register P0153-05.

Summary details (averaged mass emission values) for emissions to sewer data for Emission Point Reference No. SE1 for the period January - December 2008 are presented in Table 2.1 and Table 2.2. A comparison of individual parameters expressed as a percentage of the licensed annual mass emission value is presented in Figures 2.1, 2.2, 2.3 and 2.4 respectively. These graphs indicate

that, as for 2004 - 2008, the mass emission for the parameters monitored in 2008 continue to be within the IPPC Licence emission limit values.

2.2.2. Summary of Impacts

In 2008 there were no individual exceedances out of 2839 determinations and all wastewater flow rates and contaminant concentration levels/ranges were within the emission limit values specified within *Schedule C.3.2 Monitoring of Emissions to Sewer* of Licence Register P0153-05.

All wastewater arisings (treated) from the WMI facility are discharged to Osberstown municipal wastewater treatment plant via the on-site wastewater pre-treatment plant (WWTP). The overall net effect of the WMI WWTP has been a significant improvement in the effluent quality reaching Osberstown municipal wastewater treatment plant, and protection to the downstream systems (i.e. River Liffey). In summary, results for 2008 indicate that the effluent discharge from the WMI facility is unlikely to have a significant impact on the performance of the municipal sewage treatment works.

Table 2.1: Summary of Emissions to Sewer (Emission Point Reference No. SE1) 2004 – 2008
Note 1, 2

Parameter				**Mass Emission 2004**	**Licensed Mass Emission 2004**	**Mass Emission 2005**	**Licensed Mass Emission 2005**	**Mass Emission 2006**	**Licensed Mass Emission 2006**	**Mass Emission 2007**	**Mass Emission 2008**	**Licensed Mass Emission 2007-2008**
				(m^3)	**(m^3)**	**(m^3)**	**(m^3)**	**(m^3)**	**(m^3)**	**(m^3)**	**(m^3)**	**(m^3)**
Total Volume				123264	167025	124844	192850	143398	246521	171688 Note 6	208702	283605
	Concentration (mg/l) 2007			**Mass Emission 2004**	**Licensed Mass Emission 2004**	**Mass Emission 2005**	**Licensed Mass Emission 2005**	**Mass Emission 2006**	**Licensed Mass Emission 2006**	**Mass Emission 2007**	**Mass Emission 2008** Note 3	**Licenced Mass Emission 2007-2008** Note 3
	Minimum	**Maximum**	**ELV P0153-05**	**(Kg)**	**(Kg)**	**(Kg)**	(Kg)	(Kg)	(Kg)	(Kg)	(Kg)	(Kg)
Suspended Solids	6	13	500	8140	54750	7730	54750	9590	54750	973 Note 6	2087	54750
BOD	2	45	800	18361	65700	18144	65700	5485	65700	866 Note 6	1369	65700
COD	15	44	2000	47487	164250	46967	164250	11573	164250	3999 Note 6	4157	164250
Total Nitrogen (as N)	3	44	70	2638	7665	2648	7665	1211	7665	1776 Note 6	2713	7665
Total Phosphorus (as P)	1.5	4.7	20	644	2190	868	2190	734.8	2190	496 Note 6	659	2190
Oils, Fats & Greases	1	17	50	1351	5475	1654	5475	971.9	5475	1087 Note 6	357	5475
Ammonia (as N)	0.2	6.5	30	1486	3285	1945	3285	298	3285	22 Note 6	118	3285
Sulphate	9	138	300	6612	10950	5496	10950	6078	23360	7885 Note 6	11345	73000
Chloride	95	187	500	8883	16425	13554	16425	14447	38690	25942 Note 6	29502	127750
Sodium	88	168	800	13483	24660	15533	24660	11697	62050	23993 Note 6	27609	200750
List I Compounds	0.001	0.003	0.2	4.2	36.5	5.3	36.5	2.2	36.5	1.07 Note 6	0.54	36.5
Copper	0.007	0.038	N/A	N/A	N/A	N/A	N/A	0.73	N/A	6.44 Note 6	4.58	N/A
Nickel	0.001	0.013	N/A	N/A	N/A	N/A	N/A	0.19	N/A	0.32	0.59	N/A
Zinc	0.024	0.075	N/A	N/A	N/A	N/A	N/A	1.39	N/A	8.69 Note 6	9.47	N/A
Arsenic	0.001	0.001	N/A	N/A	N/A	N/A	N/A	0.06	N/A	0.48 Note 6	0.31	N/A
Chromium	0.001	0.011	N/A	N/A	N/A	N/A	N/A	0.06	N/A	0.37 Note 6	0.75	N/A
Fluoride	0.1	0.9	N/A	N/A	N/A	N/A	N/A	17.86	N/A	124.28 Note 6	149	N/A
Total Alkalinity	90	220	N/A	N/A	N/A	N/A	N/A	2728	N/A	19903 Note 6	33826	N/A
Pharmaceutical Active – Efexor / Lederle Note 4	0	0	1	255.7	1228.5	491.4	164.25	3.7	164.25	<LOD	<LOD	N/A
Pharmaceutical Active – Tranqs Note 4	0	0	0.5	74.4	547.5	85.5	547.5	1.5	54.75	<LOD	<LOD	N/A
Pharmaceutical Active – HTs Note 4	0	0	0.02	1.30	32.85	<LOD	32.85	0.20	3.29	<LOD	<LOD	N/A
Pharmaceutical Active – OCs Note 4	0	0	0.02	1.10	32.85	0.90	32.85	<LOD	3.29	<LOD	<LOD Note 5	N/A

N/A Not Applicable

<LOD Less than Limit of Detection

Note 1: Figures specified are rounded to 1 or 2 decimal places where applicable depending on format of data presented by laboratory.

Note 2: Refer to previous AERs for notes on 2004-2007 data.

Note 3: Data presented is based on Licence Register No. P0153-05 ELVs. Figures presented are derived from the following calculation: Daily Loading ELV for each parameter as per *Schedule B.3 Emission to Sewer* Licence Register No. P0153-05 and **multiplied by** Number of days licensed to emit (as specified in application for Licence Register No. P0153-05).

Note 4: Refer to previous AERs for limits of detection for Pharmaceutical Actives.

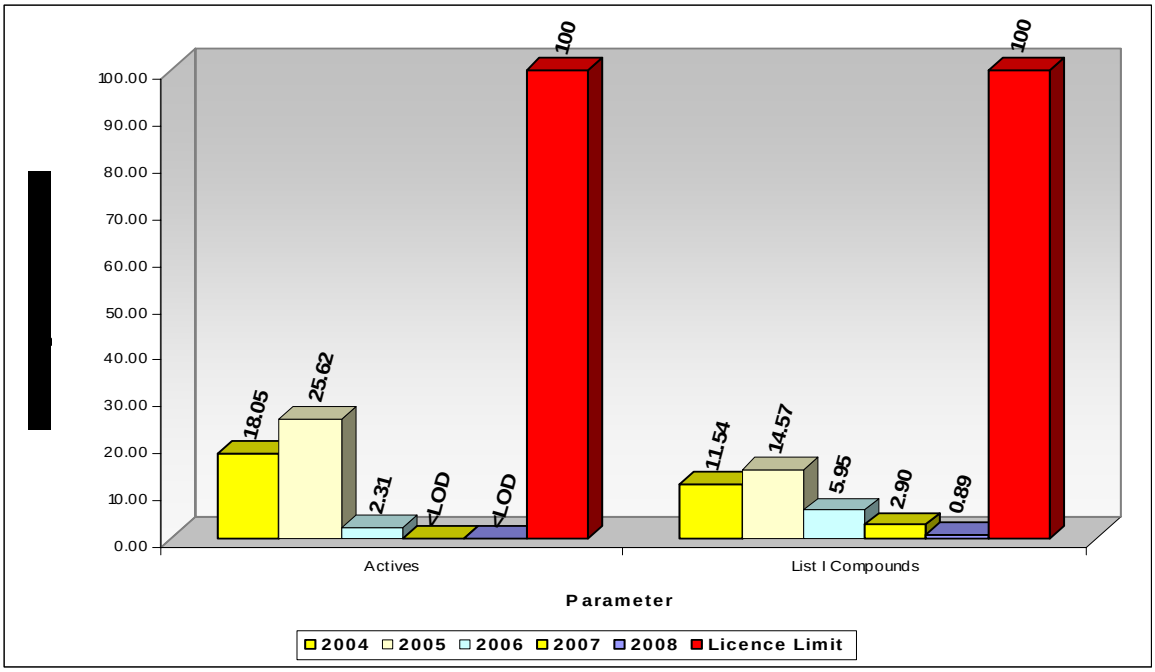
Note 5: Limits of detection for the OC method have decreased due to improvements on the testing methods: <0.4 µg/l Ethinylestradiol, <2 µg/l Gestodene, <2 µg/l Norgestrel/Levonorgestrel.

Note 6: Error in flow calculation in 2007. Figure previously reported as 171,101 m^3 was incorrect; the correct figure was 171,688m^3. As a result mass loadings have increased for 2007.

Table 2.2: Summary of Emissions to Sewer (SE1) Respirometry Testing Results 2004 - 2008

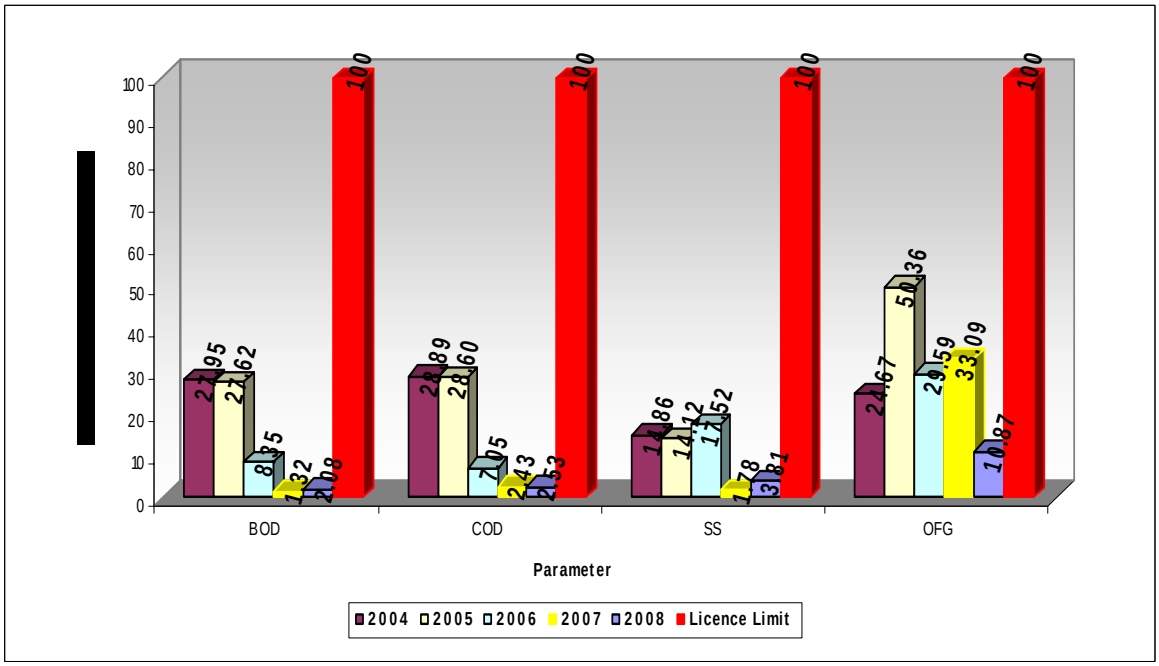
Parameter	Toxic Units				
	2004	2005	2006	2007	2008
180 min EC_{50}	<2	<2	<2	<2	<2

Figure 2.1 Emissions to Sewer (Actives/ Solvents) as a Percentage of IPPC Licence Limit - Yearly Mass Emissions (2004-2008)



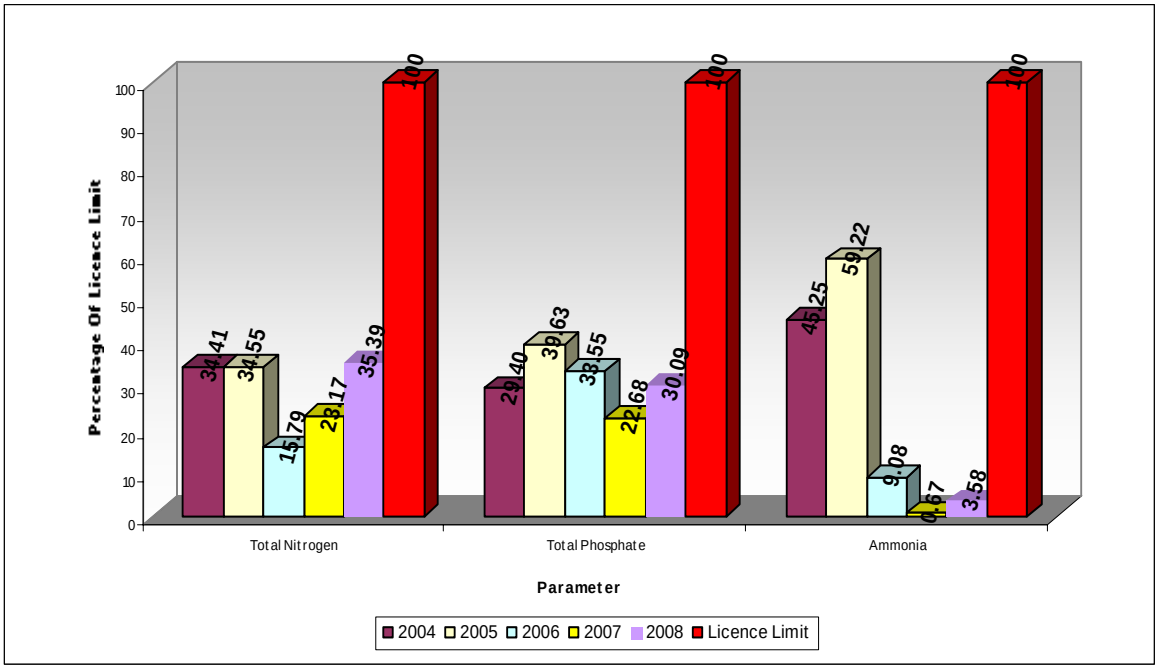
LOD: **Limit of detection**
Note 1: 2008 data is compared to ELVs based on Licence Register No. P0153-05 ELVs.
Note 2: Refer to previous AERs for notes on 2004-2007 data.

Figure 2.2 Emissions to Sewer (BOD, COD, SS, and OFG) as a Percentage of IPPC Licence Limit - Yearly Mass Emissions (2004-2008)



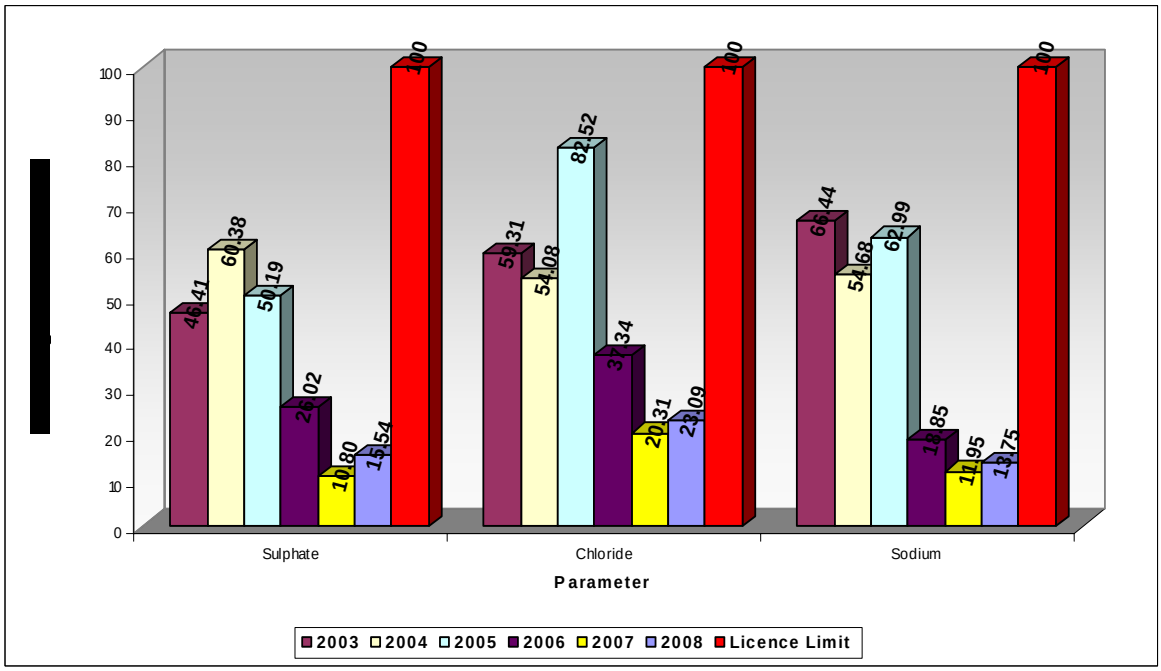
Note 1: 2008 data is compared to ELVs based on Licence Register No. P0153-05.
Note 2: Refer to previous AERs for notes on 2004-2007 data.

Figure 2.3 Emissions to Sewer (Total Nitrogen, Total Phosphate and Ammonia) as a Percentage of IPPC Licence Limit - Yearly Mass Emissions (2004-2008)



Note 1: 2008 data is compared to ELVs based on Licence Register No. P0153-05.
Note 2: Refer to previous AERs for notes on 2004-2007 data.

Figure 2.4 Emissions to Sewer (Sulphate, Chloride, and Sodium) as a Percentage of IPPC Licence Limit - Yearly Mass Emissions (2004-2008)



Note 1: 2008 data is compared to ELVs based on Licence Register No. P0153-05 ELVs.
Note 2: Refer to previous AERs for notes on 2004-2007 data.

2.3. STORM WATER EMISSION

2.3.1. Overview & Results

Schedule C.2.3 Monitoring of Storm Water Emission of Licence Register No. P0153-05 requires WMI to monitor the final discharge point of surface water from the site (Emission Point Reference No. SW1). Monitoring of the surface water discharge for pharmaceutical actives is required on a bi-annual basis as per *Schedule C.2.3* of Licence Register No. P0153-05. Results for surface water discharge monitoring for the period of January - December 2008 are outlined in Table 2.3.

Table 2.3: Summary of Surface Water Discharge Monitoring (Emission Point Reference No. SW1) 2008

Date	pH (pH Units)	Temperature (°C)	COD (mg/l)	Conductivity (µS/cm @25°C)	Organic Solvents		Pharmaceutical Actives (mg/l) Note 2 , 3
					USEPA 524.2 List Substances (µg/l)	Solvents (mg/l) Note 1	
09/01/08	7.62	10.3	<15	0.579	-	-	
23/01/08	-	-	-	-	-	-	<LOD
24/01/08	-	-	-	-	<1	<0.001	
06/02/08	7.62	12.0	22	0.627	-	-	
05/03/08	7.45	18.0	<15	0.563	-	-	
02/04/08	8.12	17.4	<15	0.695	-	-	
28/05/08	7.46	16.5	<15	0.693	-	-	
25/06/08	7.49	15.2	<15	0.176	-	-	
09/07/08	7.71	11.7	<15	0.588	<1	<0.001	
10/07/08	-	-	-	-	-	-	<LOD
06/08/08	8.16	12.2	23	0.280			
03/09/08	7.86	10.5	<15	0.694			
08/10/08	7.7	10.5	15	0.646			
05/11/08	7.89	18.7	<15	0.766			
03/12/08	7.79	12.0	<15	0.705			

LOD Limit of Detection

Note 1: Compounds screened for are Methanol, Ethanol, Acetone, Acetonitrile and Iso-Propyl Alcohol.

Note 2: Limits of detection for the Efexor/Lederle method:<0.015 mg/l Venlafaxine HCL, <0.216 mg/l. Limits of Detection for the Tranquiliser method: <0.04 mg/l Oxazepam, <0.04 mg/l Lorazepam, <0.08 mg/l Lormetazepam. Limits of detection for Hormonals method: <0.02 mg/l MPA, <0.0014 mg/l Trimegestone, <0.013 mg/l Bazedoxifene, <0.30 µg/l 17-Alpha-estradiol, <0.30 µg/l 17-Beta-estradiol, <0.30 µg/l 17-Alpha-dihydroequilin, <3.0 0µg/l Estrone, <0.75 µg/ Equilin l.

Note 3: Limits of detection for the OC method have decreased due to improvements on the testing methods: <0.4 µg/l Ethinylestradiol, <2 µg/l Gestodene, <2 µg/l Norgestrel/Levonorgestrel.

2.3.2. Summary of Impacts

Results indicate that the surface water discharge (surface water run-off from hard-standing areas following a rainfall event) from the WMI facility is unlikely to impact on the receiving waters into which it ultimately discharges (i.e. River Liffey).

In accordance with Condition 6.12.2 of Licence Register No. P0153-05 a TOC Analyser has been installed on the surface water discharge from the WMI site in order to provide continuous monitoring of dissolved carbon based material in the surface water emission from the site. Apart from operational malfunctions of the TOC analyser (refer to Section 2.9 for additional details) neither of the designated TOC warning (20 mg/l) and action (30 mg/) limits were exceeded in 2008.

2.4. AMBIENT MONITORING – GROUNDWATER

2.4.1. Overview & Results

Schedule C.6 Ambient Monitoring – Groundwater Monitoring of Licence Register No. P0153-05 requires WMI to monitor the groundwater quality at Emission Point Reference No. AGW1, AGW2, AGW3 and AGW4 on a bi-annual basis. Groundwater monitoring methodology and results for 2008 are outlined in Appendix 1.

Table 2.4: Summary of Groundwater Monitoring 2008 – Pharmaceutical Actives Analysis

Parameter		Borehole Monitoring Location							
		AGW1		AGW2		AGW3		AGW4	
	Units	Biannual 1 include note to say when sample was taken?	Biannual 2 include note to say when sample was taken?	Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2
Pharmaceutical Actives Note 1,2	ug/l	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD	<LOD

LOD: Limit of Detection

Note 1: Limits of detection for the Efexor/Lederle method:<0.015 mg/l Venlafaxine HCL, <0.216 mg/l. Limits of Detection for the Tranquiliser method: <0.04 mg/l Oxazepam, <0.04 mg/l Lorazepam, <0.08 mg/l Lormetazepam. Limits of detection for Hormonals method: <0.02 mg/l MPA, <0.0014 mg/l Trimegestone, <0.013 mg/l Bazedoxifene, <0.30 µg/l 17-Alpha-estradiol, <0.30 µg/l 17-Beta-estradiol, <0.30 µg/l 17-Alpha-dihydroequilin, <3.0 0µg/l Estrone, <0.75 µg/ Equilin l.

Note 2: Limits of detection for the OC method have decreased due to improvements on the testing methods: <0.4 µg/l Ethinylestradiol, <2 µg/l Gestodene, <2 µg/l Norgestrel/Levonorgestrel.

2.4.2. Summary of Impacts

Results indicate groundwater of good chemical quality with no pharmaceutical actives (Table 2.4) or organic solvents detectable. In addition to natural background concentrations of the groundwater, the elevated concentrations of total ammonia, iron, manganese and potassium detected appear to indicate an impact on groundwater quality from potential upgradient agricultural and/or septic tank sources i.e. results do not indicate the existence of an on-site contamination source given the nature of operation conducted at the site and the groundwater protection measures in place at the WMI facility i.e. secondary containment.

Results of ongoing monitoring of groundwater monitoring wells installed for the purpose of the diesel spill investigation (Emission Point Reference No. AGW5, AGW6, AGW7, AGW8, AGW9, AGW10, AGW11 and AGW12) indicate slight thicknesses of free phase product in selected wells. However these levels do not represent dissolved phase contaminants in the groundwater and confirms the low solubility of the diesel oil and the negligible impact on the groundwater receptor. The Detailed Quantitative Risk Assessment (outlines the predicted migration of dissolved phase hydrocarbons across the site and at the site boundaries), previously submitted to the Agency on 14/02/2008 (RPS report reference: MDE0643Rp0004F01) concluded that any dissolved phase diesel oil, is not likely to travel further than 100 m from the source of the spill area and does not pose a

risk to the Curragh sand and gravel aquifer. The most up-to-date groundwater monitoring results do not change this conclusion. It is also noted that free phase diesel was not detected in any of the 4 monitoring wells located around the WMI plant (Emission Point Reference No. AGW1 – 4) and none of these wells detected dissolved phase levels of DRO, VOC's or mineral oil. This indicates that the original diesel spill has had a limited, if any, impact on the receiving groundwater.

As per Agency correspondence (Reference P0153-05/gc.11mk.doc dated 14/10/2008) and subsequent WMI correspondence dated 21/10/2008, groundwater monitoring wells installed for the purpose of the diesel spill investigation will continue to be monitored on a biannual basis. The objective of this monitoring is to confirm that the contaminant material is limited in extent and does not pose a risk to local/regional sensitive groundwater receptors.

2.5. EMISSIONS TO AIR

2.5.1. Overview & Results

Schedule B.1 Emissions to Air; Dust Emissions to Air of Licence Register No. P0153-05 requires WMI to monitor various air emission points (main emissions to atmosphere and boiler emissions) for parameters including Dust, Flue Gas Emissions (NO_x, CO), Volatile Organic Compounds (VOCs - R40 Compounds, TA Luft Class II and TA Luft Class III) and Total Organic Compounds (as C). WMI engaged with Site-right Environmental Services to carry out the 2008 air monitoring programme (refer to Appendix 2). Of the 86 emission points requiring volumetric flow and particulate matter monitoring, 27 emission points namely A2-1 to A2-9, A2-11 to A2-14, A2-18, A2-20 to A2-22, A2-24, A2-29, A2-33 to A2-35, A2-38 to A2-40, A3-42 and A2-43 were monitored. Table 2.5 outlines the reasons why selected emission points were not monitored in 2008.

Table 2.5: Emissions Points Not Monitored in 2008.

Emission Point Reference No.	Reasons Why Emission Points Were Not Monitored
A2-31, A2-32, A2-26	Not operational in 2008
A2-10, A2-15, A2-17, A2-19, A2-23, A2-25, A2-27, A2-28, A2-30, A2-36, A2-37, A2-44, A2-45, A2-46	Off-line in 2008
A2-49 to A2-94	Undergoing validation/commissioning

Of the 7 emission points requiring TA Luft Class I, II, II and Total Organic Carbon (as C) monitoring, only 3 emission points (A2-6, A2-16 and A2-41) were monitored as the other 4 emissions points (A2-25, A2-30, A2-83 and A2-84) were off-line in 2008.

Of the 14 No. boiler (12 No.) and CHP (2 No.) emission points listed in *Schedule B.1 Emissions to Air; Dust Emissions to Air* of Licence Register No. P0153-05, only 8 boilers (namely A1-4-A1-8, A1-10B, A1-11 and A1-12) were monitored as the remaining boilers were off-line in 2008.

Summary details for air emissions for 2008 are presented in Table 2.6 and Figures 2.5 – 2.6.

2.5.2. Summary of Impacts

In 2008 WMI maintained compliance with the annual mass emission limits for the Dust, NO_x, CO, VOCs and Total Organic Compounds (as C) parameters during normal production operations i.e. 0 individual exceedances out of 152 determinations.

Table 2.6: Summary of Main Emissions to Atmosphere 2004 – 2008 **Note 1**

Parameter	Mass Emission (Kg) 2004	Licensed Mass Emission (Kg) 2004	Mass Emission (Kg) 2005	Licensed Mass Emission (Kg) 2005	Mass Emission (Kg) 2006	Licensed Mass Emission (Kg) 2006	Mass Emission (Kg) 2007	Mass Emission (Kg) 2008	Licensed Mass Emission (Kg) 2007, 2008
Total Particulate	330	1750	104	1680	105.33	2,427	146.44	**132.04** Note 2	5987
NO_x	38466	59189	24914	116242	42209	138582	44006	**32615** Note 3	138582
CO	25077	35542	5800	236521	36557	329827	104102	**28012** Note 3	329827
TA Luft Class I/R40 Compounds	0.1	149	1.7	274.4	0.07	175.2	20.53	**39.58** Note 4	823200
TA Luft Class II	N/A	N/A	N/A	N/A	0.4	5840	0.37	**34.33** Note 5	30864
TA Luft Class III	1267	13464	1155	17907	959.87	19,656	774.59	**1282.68** Note 5	39096
Total Organic Compounds (as C) (A2-16 & A2-41)	0.2	7.1	0.19	14.82	0.21	17.91	6.65	**6.92** Note 6	28.91

Note 1: Refer to previous AERs for notes on 2004-2007 data.

Note 2: 2008 Total Particulate mass emissions are calculated as follows:

- Monitored Emissions (Total Particulate and volumetric flow) are **multiplied by** the licensed running times as submitted to the Agency as part of the application for Licence Register No. P0153-05.

Note 3: 2008 NO_x and CO mass emissions are calculated as follows:

- Monitored Emissions (NO_x and CO) from the 14 No. boiler (12 No.) and CHP (2 No.) emission points listed in *Schedule B.1 Emissions to Air; Dust Emissions to Air* of Licence Register No. P0153-05 is **multiplied by** the actual running times of the boilers in 2008 then **multiplied by** the licenced flow rate in *Schedule B.1 Emissions to Air; Dust Emissions to Air* of Licence Register No. P0153-05.

Note 4: 2008 R40 mass emissions are calculated as follows:

- Monitored Emissions (R40 emissions) from Emission Point Reference No.'s A2-16 and A2-41 **multiplied by** the licensed running times as submitted to the Agency as part of the application for Licence Register No. P0153-05 and then **multiplied by** the licenced flow rate in *Schedule B.1 Emissions to Air; Dust Emissions to Air* of Licence Register No. P0153-05.

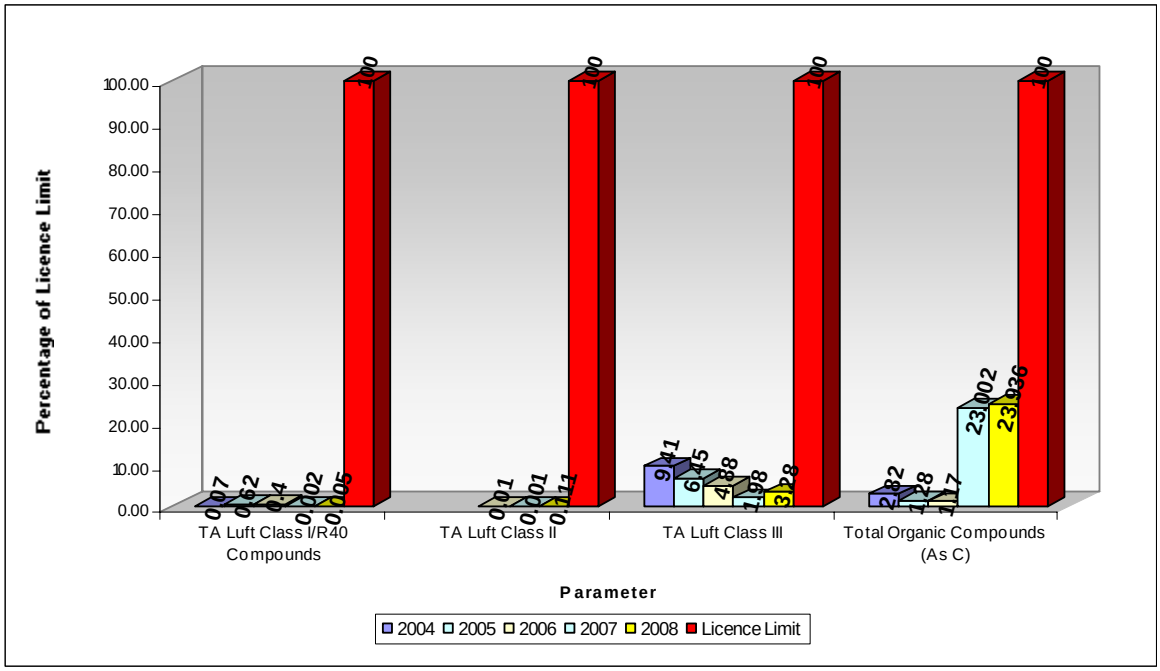
Note 5: 2008 TA Luft Class II mass emissions are calculated as follows:

- Monitored Emissions (TA Luft Class II and III emissions) from Emission Point Reference No.'s A2-16 and A2-41 are **multiplied by** the licensed running times as submitted to the Agency as part of the application for Licence Register No. P0153-05 and then **multiplied by** the licenced flow rate in *Schedule B.1 Emissions to Air; Dust Emissions to Air* of Licence Register No. P0153-05, combined with;
- Monitored Emissions (TA Luft Class II and III emissions and flow rate) from Emission Point Reference No. A2-6 are **multiplied by** the actual running time of the emission for 2008.

Note 6: 2008 Total Organic Compounds (as C) mass emissions are calculated as follows

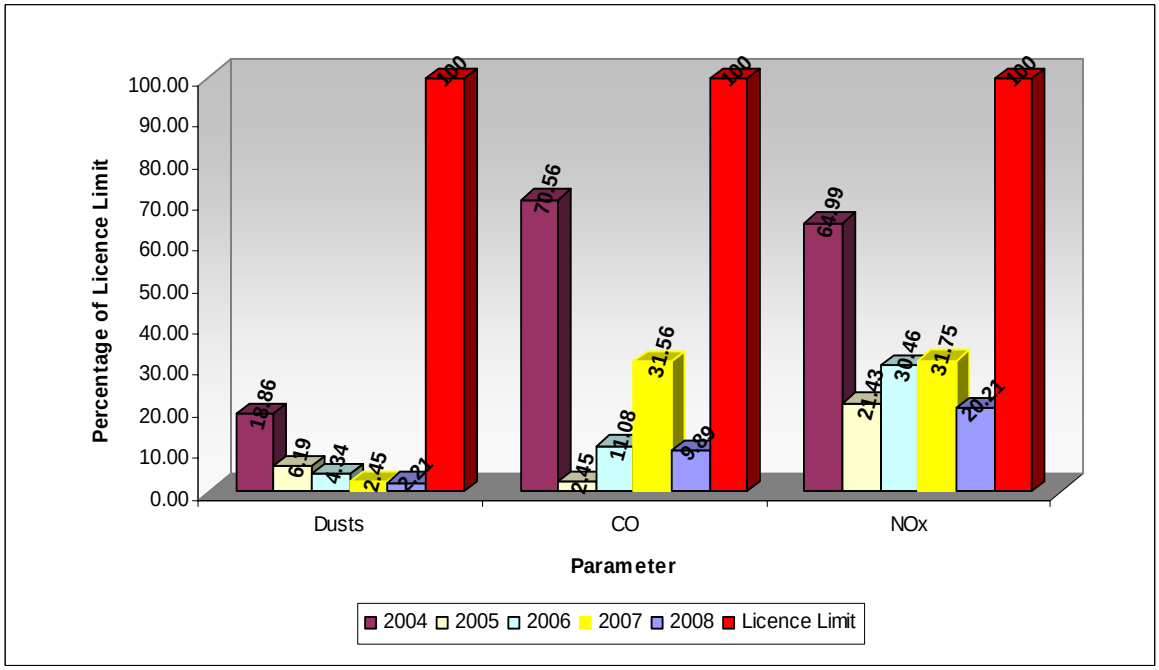
- Monitored Emissions (Total Organic Compounds (as C)) from Emission Point Reference No.s A2-16 and A2-41 are **multiplied by** the licensed running times as submitted to the Agency as part of the application for Licence Register No. P0153-05 and then **multiplied by** the licenced flow rate in *Schedule B.1 Emissions to Air; Dust Emissions to Air* of Licence Register No. P0153-05.

Figure 2.5 Emissions to Air (TA Luft Class I/(R40 compounds), TA Luft Class II and TA Luft Class III) Total Organic Compounds (as C) as a Percentage of IPPC Licence Limit - Yearly Mass Emissions (2004-2008)



Note 1: Refer to previous AERs for notes on 2004-2008 data.
Note 2: 2008 TA Luft Class I, II, III and Total Organic Compounds (as C) are compared to the ELVs within Licence Register No. P0153-05.
Note 3: Only emissions from Emission Point Reference No.s A2-6 [TA Luft Class II, III and Total Organic Compounds (as C)], and A2-16 and A2-41 [TA Luft Class I, II, III and Total Organic Compounds (as C)] were used as the other applicable emissions points listed in *Schedule B.1 Emissions to Air; Dust Emissions to Air* of Licence Register No. P0153-5, were not operational in 2008.

Figure 2.6 Emissions to Air (Dust, CO, NO_x) as a Percentage of IPC Licence Limit - Yearly Mass Emissions (2004-2008)



Note 1: Refer to previous AERs for notes on 2004-2008 data.
Note 2: 2008 Dust, CO and NO_x data is compared to ELVs based on License Register No. P0153-05 ELVs.

2.6. NOISE

2.6.1. Overview & Results

Condition 6.13 Noise of Licence Register No. P0153-05 requires WMI to undertake a noise survey at the site on an annual basis. For each measurement location the **specific noise level** attributable to WMI was determined. This survey methodology follows ISO 1996 *"Description and measurement of environmental noise"* and the EPA *"Environmental Noise Survey Guidance Document"* 2004. The specific noise level is the component of the ambient noise that can be attributed to a specific source, in this instance, the WMI plant. The method of assessing the specific noise level dependent on the noise environment encountered is summarised in Table 2.7.

Table 2.7: Method of Assessing the Specific Noise Level

Description of Noise	Parameter Best Representing Specific Noise from Plant
Plant noise dominant, no other significant noise sources.	LAeq
Intermittent interfering noise (e.g. birds, traffic, wind) with underlying plant noise audible.	▪ LA50 - if plant clearly audible, with occasional interference from other noise sources. ▪ LA90 if plant not clearly audible i.e. continual interfering noise.
Plant barely audible (i.e. not immediately noticeable, unless actively listening)	<LA90 (up to 5 dB lower)
Plant not audible	Not Detectible (ND) <<LA90 (more than 5 dB lower than LA90)
The plant specific noise is established during the survey by correlating the live sound level meter readings with the audible sound, as described above. The plant specific noise is verified, where necessary, by examining the profile of logged noise levels.	

Noise monitoring methodology and results for 2008 are outlined in Appendix 3. The parameter judged to best represent the specific noise for each individual measurement is indicated by shading in Table 2.8.

Table 2.8: Summary of Noise Emissions 2008

Noise Sensitive Location	Date	Time Note 1	Measured Noise Level dB(A)					Description of Noise Environment
			$L_{Aeq\ 30mins}$	L_{A90}	L_{A50}	L_{A10}	Specific Note 2	
DAYTIME								
N1	07/05/08	15.05	58	**48**	54	62	**<48**	Traffic, birds, WMI not audible.
N2	07/05/08	12.30	51	**42**	46	52	**<42**	Traffic, birds, WMI not audible.
N3	07/05/08	15.10	65	**54**	62	68	**<43** Note 3	Traffic, WMI not audible.
N4	07/05/08	15.40	72	**60**	69	76	**ND<<60**	Traffic, WMI not audible. L_{Amin} =47dB(A)
NIGHT-TIME								
N1	07/05/08	00:10	58	**46**	49	59	**<46**	Traffic, WMI audible at low level.
N2	07/05/08	22.55	50	**47**	49	51	**<47** Note 3	WMI audible at low level, distant traffic, neighbouring commercial site, birds.
N3	07/05/08	00.50	57	**46**	48	59	**35** Note 4	Traffic, WMI audible at low level.
N4	07/05/08	00.55	66	**45**	54	68	**45**	Traffic, WMI audible at low level.

ND: Not detectable
Note 1: The measurement duration at each location was 30 minutes during both daytime and night-time.
Note 2: Specific noise component attributable to WMI.
Note 3: A steady industrial noise component of 47 dB(A) was detected due to noise from a neighbouring commercial site.
Note 4: Calculated noise level at Old Connell House in accordance with ISO 9613. The steady WMI noise level at the entrance gate was <<54dB(A) during daytime and 46dB (A) at night-time. This extrapolates to <43dB(A) at the house during daytime and 35dB(A) at night-time

2.6.2. Summary of Impacts

Results for 2008 indicate that the noise generated at the WMI site does not have any undesirable effects on the existing neighbouring environment i.e. daytime and night-time limits [$L_{eq,30\ mins}$ 55dB(A) and 45 dB(A) respectively)] are maintained at the nearest sensitive locations (Noise Monitoring Locations N1, N2, N3 and N4). No audible tonal or impulsive component from noise emissions emanating from the WMI facility was recorded at Noise Monitoring Locations N1, N2, N3 and N4 during the 2008 noise survey.

Over the last 5 years, 2004 – 2008, WMI has consistently maintained noise emission levels from the site below the required IPPC licence daytime and night-time limit levels.

2.7. WASTE MANAGEMENT

2.7.1. Waste Arisings

Hazardous waste streams are collected, segregated and labelled on-site and finally transported off-site by licenced waste management companies for appropriate treatment. The non-hazardous waste streams are collected, segregated and transported off-site by licenced waste management companies for recycling and/or disposal. Details of the individual waste fractions sent off-site for treatment including disposal and recycling by appropriately licensed waste management contractors, for the period 2004 - 2008 are presented in Table 2.9. A detailed waste register is presented in the EPRTR submission (refer to Appendix 11).

Table 2.9: Waste Volumes Sent Off-Site for Treatment 2004 – 2008 [Note 1]

Description of Waste	Quantity (Kg)				
	2004 [Note 4]	2005 [Note 4]	2006 [Note 4]	2007 [Note 4]	2008
Hazardous [Note 2]					
Disposed	2,125,000	2,486,000	2,757,000	2,582,000	3,451,000
Recovered	51,000	44,000	72,000	248,000	166,000
Non-Hazardous [Note 3]					
Disposed	1,273,000	1,247,000	1,559,000	840,000	503,000
Recovered	912,000	7,475 ,000	5,182,000	1,891,000	4,242,000

Note 1: The quantity of waste detailed in table includes all waste produced on the site by WMI (including construction) and contractors engaged in projects at the facility.

Note 2: This waste fraction comprised of solid and liquid hazardous waste including out of specification tablets/granulate, packaging in contact with actives/tablets, disposable masks and gloves and material cleaned or vacuumed from the processing area as well as solvent waste, coating/rinse waters containing active, engineering maintenance oils, clinical waste and decommissioned equipment.

Note 3: This waste fraction comprises of solid and liquid non-hazardous waste including canteen waste, paper and cardboard, plastics and metal (which includes aluminium foil, aluminium cans and general metals).

Note 4: Refer to previous AERs for notes on 2004-2007 data

2.7.2. Waste Analysis

As per *Schedule C.4 Waste Monitoring* of Licence Register No. P0153-05 requires WMI to analyse specific hazardous waste arisings. The WMI approach to comply with this requirement was verbally agreed with the Agency during the Site Inspection of 15/04/2004 and subsequent Agency correspondence of 19/08/2005 (EPA Reference: M673/ap16bk). The sampling strategy which was submitted in Appendix 5 of the 2005 AER, has been modified to include new waste streams and an alteration to the laboratories employed to conduct the analysis. This information is summarised in Appendix 4.

Summary results and reports from laboratories that conducted the waste analysis are presented in Appendix 5, and summarised in Table 2.10.

Table 2.10: Contents of Appendix 5

Table No.	Title
A5.1	Pharmaceutical Solid Waste Analysis (Controlled Drugs): The table identifies the number and type of containers [UN approved Boxes, Fibre Kegs, Flexible Intermediate Bulk Containers (FIBCs)] and the Product Family per consignment of controlled drugs.
A5.2	Pharmaceutical Solid Waste Analysis (Obsolete Pharmaceuticals): The table identifies the number and type of containers [UN approved Boxes, Fibre Kegs, Flexible Intermediate Bulk Containers (FIBCs)] and the Product Family per consignment of obsolete pharmaceuticals.
A5.3	Pharmaceutical Liquid – Rinsewater Waste Analysis
A5.4	Pharmaceutical Liquid – Sugar Coating Solutions Waste Analysis
A5.5	Chlorinated Solvent Waste Analysis (Process Waste - SRS)
A5.6	Chlorinated Solvent Waste Analysis (Process Waste - SAS)
A5.7	Chlorinated Solvent Waste Analysis (Laboratory Waste)
A5.8	Non-Chlorinated Solvent Waste Analysis (Laboratory Waste)
A5.9	Wastewater Pre-Treatment Plant Sludge Analysis

2.7.3. Environmental Performance Indicator – Waste Arisings

The Wyeth Corporate EHS Department has set a target of a 10% reduction of the 2007 baseline in waste arisings from WMI to be achieved over the 5 year period 2008 – 2012 (e.g. 2% annual reduction). The 'Waste arisings' EPI includes all hazardous and non-hazardous waste generated on-site. The total waste arisings (Kg) on-site for the period 2005 to 2008 have been divided by the total product (Kg) produced at the WMI site for the same period to calculate the waste arising EPI (Table2.11).

Table 2.11: WMI Waste Arisings EPI 2005 - 2008

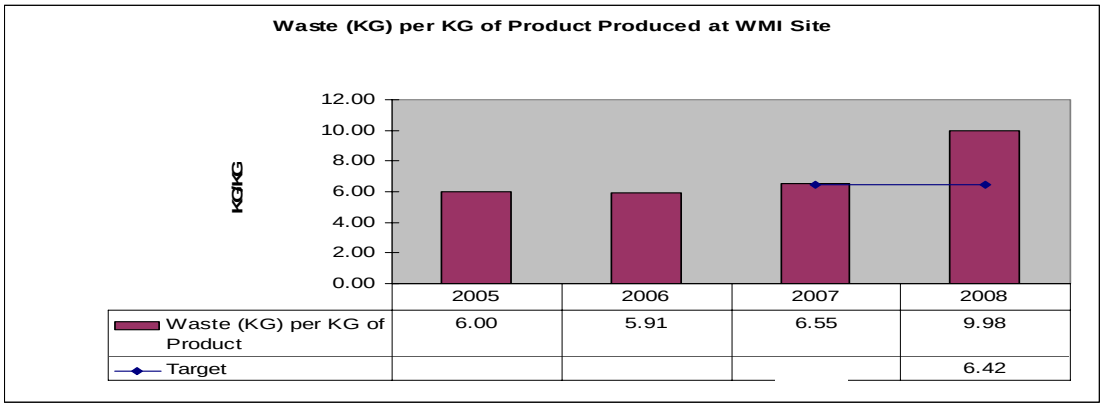
Description of Waste	Quantity	2005	2006	2007	2008
Hazardous Waste	Kg	2,530,000	2,829,000	2,830,000	3,617,000
Non-Hazardous Waste	Kg	8,722,000	6,741,000	2,731,000	4,745,000
Total Waste Produced	Kg	11,252,000	9,570,000	5,561,000	8,362,000
Production Output at WMI	Kg	1,876,827	1,619,823	849,419	837,954
Waste Arisings EPI [Waste (Kg) per Kg of Product]	-	6.00	5.90	6.50	9.98

For 2007, the base year for which the reduction target is set, 6.5 Kg of waste arisings was generated for every Kg of product produced at WMI. As per the Wyeth Corporate EHS target of 10% reduction in the 2007 baseline over 5 years WMI are required to achieve a waste arisings EPI of 5.9 by 2012. In order to achieve this WMI has identified an interim annual reduction target of 2% which equates to 6.4 Kg waste arisings per Kg of product for 2008. In 2008 WMI waste arisings were 9.98 per Kg of product which exceeded the interim reduction target (i.e. 66.3% increase v. 2% decrease). Notwithstanding a decrease in production output for 2008 (production decreased by 1.35% from 849,419 Kg in 2007 to 837,954 Kg in 2008), an increase in waste arisings for 2008 can be attributed to the following:

- Disposal of increased quantities of waste electrical and electronic equipment generated from decommissioned areas and replacement of end-of-life equipment (approximately 31,000Kg).

- Backlog of obsolete pharmaceutical waste disposed of from the Warehouse (approximately 131,791 Kg);
- Ongoing validation and commissioning activities in MHT processing area which generated significant quantities of waste (approximately 400,000Kg);
- Increase on the amount of Construction & Demolition waste due to the construction of the Pharmaceutical Development Centre (3,033,720 Kg in 2008 compared to 934,110 Kg in 2007 i.e. 325% increase).

Figure 2.7: WMI Waste Arisings EPI 2005 - 2008



Note 1: Target is to approach 0 i.e. 0.005 is more efficient than 0.009

Although the 2008 Waste Arising EPI target was not achieved WMI still aim to achieve the 5 year reduction target. WMI's long-term objective to achieve this target is, where possible, to make efficient use of raw materials and increase the recycling of waste materials thereby reducing the quantities of waste requiring off-site disposal and/or treatment. In 2008 this commitment was demonstrated as WMI continued to maximise the quantity of waste undergoing recycling as follows [increased non-hazardous waste recycling rate from 69% (2007) to 89% (2008)]:

- Diversion of gelatine capsules (EWC 07 05 14), lactose (EWC 07 05 99), food waste (EWC 20 01 08) from landfill to composting (approximately 15,000 kg/annum) – *revised Table H notified to EPA on 03/03/2008:*
- Further continuation of initiatives started in 2007 which were fully implemented in 2008:
  - Diversion of blister packs (EWC 20 03 99) from landfill to recovery as mixed recyclables (approximately 82,000 kg/annum).
  - Segregation and recycling of laboratory glass (approximately 6,000 kg/annum).
  - Increased segregation of office recyclables (cardboard, paper, plastic).
- Charge Business Units for Hazardous Waste Management - It is anticipated that once individual business units are charged for management of hazardous waste arisings (implemented as per 2009 site budget) rather than having a centralised site budget, this will encourage these areas towards waste reduction (and hence cost reduction).

In 2009 WMI will continue to examine options for reduction and recycling of hazardous and non-hazardous waste (refer to Objective 4 of the Environmental Management Programme 2009 - Appendix 7).

2.8. ENERGY USAGE

2.8.1. Energy Usage – CO_2 Emissions

The Wyeth Corporate EHS Department has set a target of a 10% reduction of the 2007 baseline of CO_2 emissions from WMI to be achieved over the 5 year period 2008 – 2012 (e.g. 2% annual reduction). CO_2 emissions from the WMI site are generated from the following direct (sources of combustion) and indirect sources:

- **Direct CO_2 Emissions**
  - Natural Gas: Used to power the CHP Plant (**Electricity Generated**) as well as operate the boilers;
  - Diesel Oil: Used in the emergency generators (backup power supply in the event of an interruption to the electricity supply to the site and/or associated equipment) and firewater pumps onsite (which are fired on a weekly basis to ensure they are operating correctly); and,
  - Propane: Used as an ignition fuel for the boilers when they are combusting natural gas or diesel oil.
- **Indirect Direct CO_2 Emissions**
  - **Electricity Purchased**: Purchased from the national grid to power on-site activities.

The total CO_2 emissions (Tonnes) on-site for the period 2005 to 2008 have been divided by the total product (Kg) produced at the WMI site for the same period to calculate the CO_2 emissions EPI (Table2.12).

Table 2.12 WMI CO_2 Emissions EPI 2005 – 2008

		2005	2006	2007	2008
CO_2 Emissions – Electricity Generated Note 1	**Tonnes**	16,209	17,311	22,640	22,109.26
CO_2 Emissions – Electricity Purchased Note 2	**Tonnes**	25,938	26,889	24,501	25,958.48
CO_2 Emissions - Diesel Oil Note 1	**Tonnes**	7.47	12.67	6.54	10.15
CO_2 Emissions - Propane Note 1	**Tonnes**	1.55	0.80	0.98	0.30
Total CO_2 Emissions	**Tonnes**	42,157.14	44,213.69	47,147.66	48,078.19
Production	**KG**	1,876,827	1,619,823	849,419.01	837,953.65
CO_2 Emissions EPI [CO_2 Emissions (Tonnes) per Kg of Product]	**Tonnes/kg**	0.022	0.027	0.056	0.057

Note 1: Submitted to EPA as per verified AIER 2005, 2006, 2007, 2008

Note 2: Tonnes CO_2 from electrical usage are calculated by multiplying the site electrical usage (kWh) by 584.18g (in line with Wyeth Corporate EHS guidelines)

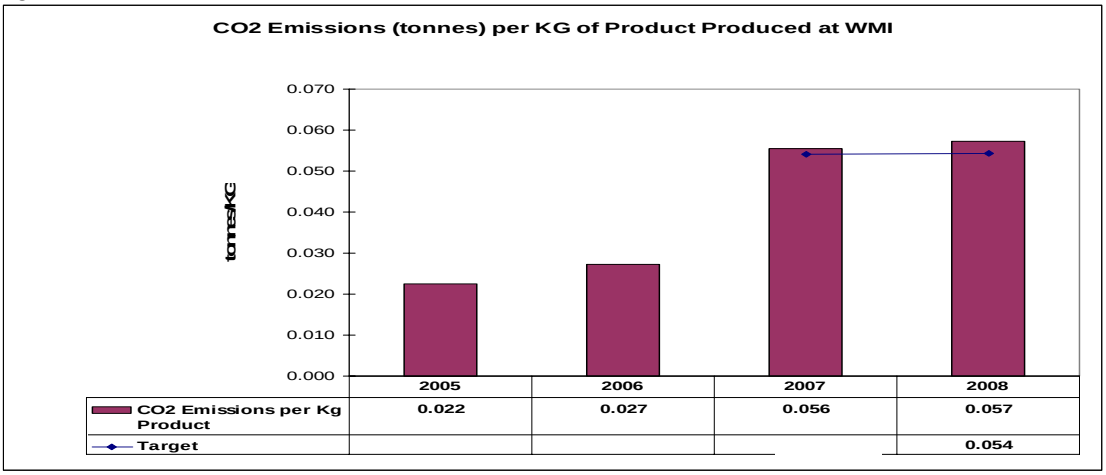
As per Table 2.12 there was a significant increase in the CO_2 emissions per Kg of product produced from 2006 to 2007. This can be explained by the following:

- New CHP plant which was commissioned in 2006 was fully operational throughout 2007 to meet with the increased on-site energy demand. Natural gas usage increased as a result from 93,795 MWh in 2006 to 121,888 MWh in 2007 (30% increase).

- Increased energy demand associated with on-site construction developments and subsequent completed developments (additional 6.75 MW of electrical load associated with utilities upgrade, WWTP, Waste Management Centre, MHT & Levo/EE production facilities).

For 2007, the base year for which the reduction target is set, 0.056 tonnes of CO_2 emissions were generated for every Kg of product produced at WMI. As per the Wyeth Corporate EHS target of 10% reduction in the 2007 baseline over 5 years WMI are required to achieve a CO_2 emissions EPI of 0.050 tonnes/Kg by 2012. In order to achieve this WMI has identified an interim annual reduction target of 2% which equates to 0.055 tonnes CO_2 emissions per Kg of product for 2008. In 2008 WMI CO_2 emissions were 0.057 tonnes CO_2 per Kg of product which exceeded the interim reduction target (i.e. 3.6% increase v. 2% decrease). Notwithstanding a decrease in production output for 2008 (production decreased by 1.3% from 2007 to 2008), an increase in CO_2 emissions for 2008 can be attributed to as follows. Due to decreased operation of the CHP plant there was a subsequent 6% increase in the amount of electricity purchased in 2008 in order to meet with the site electrical demand (44,436 MWh in 2008 compared to 41,490 MWh in 2007). This resulted in an increase of 1,457.97 tonnes CO_2 emissions from purchased electricity in 2008 (i.e. 6% increase 2007 v. 2008).

Figure 2.9 WMI CO_2 Emissions EPI 2005 – 2008



Note 1: Target is to approach 0 i.e. 0.05 is more efficient than 0.09

Although the 2008 CO_2 emissions EPI target was not achieved WMI still aim to achieve, and possibly exceed (i.e. if possible revert to pre-2007 CO_2 emissions), the 5 year reduction target. The area of energy and water usage reduction continues to be a key objective for the site as presented in *Objective 3: Energy Efficiency* of Environmental Management Programme – Proposal 2009 (Appendix 7). It should be noted that following installation of an energy management system (eNMS) at the site in 2008 that energy related objectives and targets are formulated via an energy management programme (eNMP). WMI's eNMS is designed to:

- Optimise the use of energy in the plant and minimise the cost and environmental impact of these activities.
- Identify areas for energy use reduction.

It applies to all energy sources including electricity, natural gas and water. The eNMS includes a list of Key Performance Indicators relative to energy performance of systems and equipment and associated targets. Scheduling, resource allocation and responsibilities are included in the eNMP to allow for the successful achievement of the energy objectives and targets. The eNMP develops specific, prioritized actions dealing with processes, products, services, projects, and facilities. Energy objectives established to meet the goals of the WMI energy policy are currently under review (refer to Section 4.7).

2.8.2. Energy Usage – European Union Emissions Trading Scheme

Greenhouse gases are believed to cause the greenhouse effect i.e. increase in global temperatures as a result of such emissions. The only greenhouse gas covered by the *Emissions Trading Directive* is CO_2 created from the direct combustion of fossil fuel sources (e.g. natural gas, gas oil, propane). WMI has been granted a Greenhouse Gas Emission Permit (Permit Register No. GHG057-5). This permit authorises WMI undertake energy consumption activities associated with on site boilers and the combined heat and power (CHP) plant (combustion installation) which result in emissions of the greenhouse gas, CO_2. Participation in the continued development of appropriate climate change and greenhouse gas policies of the EU Emissions Trading Schemes should facilitate WMI to reduce energy consumption and associated greenhouse gas emissions at the site. CO_2 emissions for 2005 - 2008 for WMI are presented in Table 2.13.

Table 2.13 CO_2 Emissions 2005 - 2007

Parameter	Tonnes CO_2			
	2005	2006	2007	2008
Allocation	22693	30397	30397	37695
Verified Emissions	16218	17324	22647	22120
Surplus	6475	13073	7750	15575

The reason for the decreased CO_2 emissions in 2008 when compared to 2007 and when compared to the allocation to the site was due to:

- reduced operational time of the CHP plant arising from technical upgrades of the system(i.e. installation of high pressure gas fuel line, connection to 110 kV electrical supply).
- reduced operation of selected boilers.

2.8.3. Energy Usage - Water Consumption

The Wyeth Corporate EHS Department has set a target of a 10% reduction of the 2007 baseline of water usage from WMI to be achieved over the 5 year period 2008 – 2012 (e.g. 2% annual reduction). The main water users at the WMI site include:

- Cooling Towers
- Purified Water Systems
- Process Water
- Boilers Supply
- Chilled Water
- Low Pressure Hot Water
- Domestic Water Supply.

Potable water, which is supplied to WMI via Kildare County Council (KCC) mains water supply, is routed to the following areas within the site:

- Fire tanks
- Building 1/1A (canteen, toilet facilities)
- Incoming raw water storage tanks at Building 6.
- Incoming raw storage tanks at Building 6 (which serve buildings 3A, 3B, 4, 5, 9, 10, 11 and the Sub-Contractors Compound).

The total water usage (m^3) on-site for the period 2005 to 2008 has been divided by the total product (Kg) produced at the WMI site for the same period to calculate the Water Usage EPI (Table2.14).

Table 2.14 WMI Water Usage EPI 2005 – 2008

		2005	2006	2007	2008
Water Consumption	**m^3**	181,770	342,589	344,267 Note 2	285,112 Note 1
Production	**Kg**	1,876,827	1,619,823	849,419	837,953.65
Water Usage EPI [Water Consumption (m^3) Per Kg of Product]	**m^3/Kg**	0.097	0.211	0.405	0.340

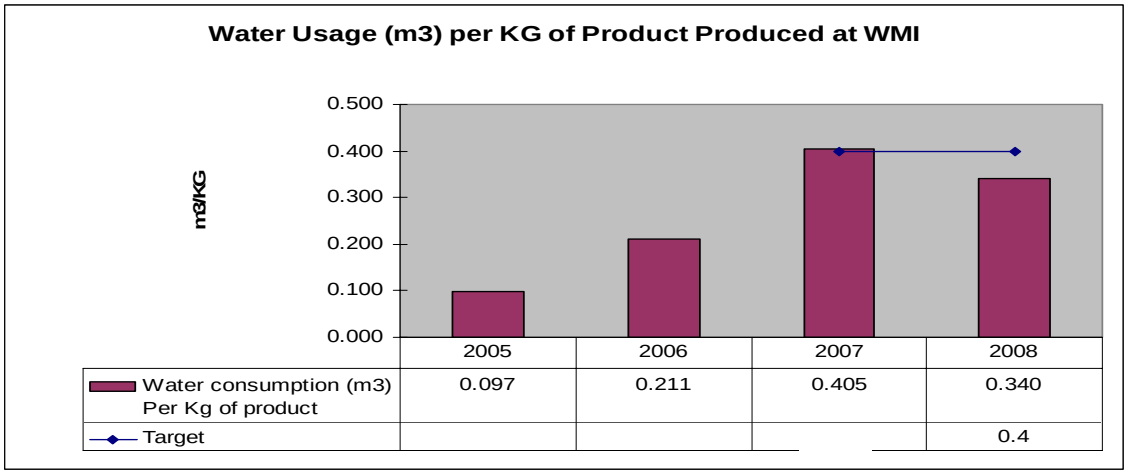
Note 1: Water usage data generated from Local Authority Invoices (Local Authority flow meter registers all flow of potable water to the WMI site).

Note 2: Revised figure from 2007 AER.

As per Table 2.18 there was a significant increase in water consumption in 2006 (an increase of 88.5% on 2005 usage). This was attributed to an increased water usage demand associated with on-site construction developments (MHT & Levo/EE production facilities, WWTP, utilities upgrade, Waste Management Centre) and subsequent completed developments (in particular ongoing validation and commissioning activities in MHT processing area which requires significant quantities of water for equipment cleaning activities). This trend continued in 2007 where there was an increase of 0.5% in water consumption on 2006 water usage.

For 2007, the base year for which the reduction target is set, 0.405 m^3 of water was used for every Kg of product produced at WMI. As per the Wyeth Corporate EHS target of 10% reduction in the 2007 baseline over 5 years, WMI are required to achieve a Water Usage EPI of 0.365 m^3 of water per Kg of product by 2012. In order to achieve this EPI target WMI has identified an interim annual reduction target of 2% which equates to 0.397 m^3 of water usage per Kg of product for 2008. In 2008 the WMI Water Usage EPI was 0.340 m^3 of water per Kg of product which meets with both the interim and long-term reduction targets (i.e. 14.4% decrease v. 2% decrease; 14.4% decrease v. 10% decrease). This significant reduction in water usage (16% reduction 2007 v. 2008) can be attributed to the repair of a substantial leak at the raw water storage tanks at Building 6. The leak was detected as a result of ongoing monitoring of the water mass balance for the site [based on water intake from Local Authority (**Water In**) in from KKC and effluent discharged via WWTP (**Water Out**)] is being reviewed quarterly, and allows WMI to monitor water usage proactively.

Figure 2.10 WMI Water Usage EPI 2005 – 2008



Note 1: Target is to approach 0 i.e. 0.5 is more efficient than 0.9

Despite the fact that WMI have already achieved the 5 year Water Usage EPI reduction target, the site strategy is, as far as is practicable, to revert to 2005 water usage levels. The area of water usage reduction therefore continues to be a key objective for the site [as presented in *Objective 3: Energy Efficiency* of Environmental Management Programme – Proposal 2009 (Appendix 7)] which is co-ordinated using the WMI eNMS (which applies to all energy sources including water). A summary of water conservation projects proposed for implementation at the site in 2009 is presented as follows:

- Continue to assess areas the feasibility for re-use of WWTP effluent as cooling tower make up.
- Conduct a water usage survey to enable identification of water conservation projects.

2.9. EPA MONITORING & ENFORCEMENT

2.9.1. EPA Monitoring

The Agency conducted monitoring (grab sampling) of emissions to sewer at the grab sample location for Emission Point Reference No. SE1 on 17/01/2008, 11/03/2008, 01/09/2008 and 20/11/2008. For direct comparison purposes it is noted that on taking of the EPA sample a second sample was taken to facilitate separate analysis by WMI. EPA analytical data generated for the samples extracted generally corresponded with that generated by the laboratory sub-contracted by WMI (Alcontrol Laboratories, Dublin). No exceedances for the parameters measured were detected by the EPA or WMI.

On 08/05/08 the Agency conducted air monitoring (sub contracted to Euro Environmental) on site. No non-compliances were recorded.

2.9.2. EPA Enforcement

EPA inspectors carried out a Licence Audit and Site Inspection of the WMI facility on 28/04/2008 and 24/06/2008 respectively. No non-compliances were noted.

2.10 REPORTABLE ENVIRONMENTAL INCIDENTS & COMPLAINTS

2.10.1 Reportable Environmental Incidents

Reportable environmental incidents that occurred at the WMI site in 2007 (which were previously notified to the EPA) are summarised in Table 2.15.

Table 2.15: Reportable Environmental Incidents 2008

Date of Incident	Non-Compliance	Cause	Authorities Notified	Corrective Action
Leak from treated effluent conveyance system				
25/02/08?	An unknown quantity (estimated to be <1m^3) of treated effluent released to ground.	A failure in a gasket on a clean out point (Clean Out Point No. 1 located adjacent to the WWTP to the South East of the site) on the treated effluent conveyance system.	Not a pollution incident. For Information purposes EPA notified on 25/02/08. No acknowledgement received from EPA.	Gasket replaced
Discharge of Surface Water during period of excessive rainfall				
16/08/08	Due to flooding of the site surface water may have discharged to surface water sewer at pH greater than action level i.e. 9.1pH units.	Excessive rainfall which causes flooding to the site	Not a pollution incident. For Information purposes EPA notified on 16/08/08. EPA Inspector Martina Kirwan responded on 18/08/08.	N/A
TOC Analyser (Total Organic Carbon analyser)				
23/07/08 to 26/08/08	A malfunction of the TOC Analyser, noticed on 26/08/2008 during routine maintenance by the Vendor (Water Technology Limited), which resulted in false readings from 23/07/2008 to 26/08/2008.	Due to operational error	Notified EPA on 03/10/08. No acknowledgement received from EPA.	PM Work instruction updated to ensure that operational error does not re-occur
07/10/08 to 09/10/08	A malfunction (power outage) in the TOC Analyser which occurred on the 07/10/08 between 05:30 and 12:12 and on the 09/10/2008 between 13:00-17:30 hrs	Trip out of power supply to the TOC Analyser	Notified EPA on 15/10/08. No acknowledgement received from EPA.	Investigation conducted on Electrical installation associated with the TOC analyser. Remedial works identified during this investigation have been completed
28/10/08	A malfunction (power outage) in the TOC Analyser which occurred on the 27/10/08 between 13:40 to 14:53 and 18:15 to 22:30.		Notified EPA on 28/10/08. No acknowledgement received from EPA.	

2.10.2 Environmental Complaints

WMI have received no complaints of any nature in 2008.

3. MANAGEMENT OF THE INSTALLATION

3.1. ENVIRONMENTAL MANAGEMENT SYSTEM

3.1.1. Overview

As part of the requirements of the Condition 2.2.1 of Licence Register No. P0153-05, WMI has developed its Environmental Management System (EMS) based on the requirements of ISO 14001. SGS Ireland Ltd., and SGS United Kingdom Ltd., audit and independently certify and verify the WMI EMS as complying with the requirements of ISO14001 standard and EU Eco-Management and Audit Scheme (EMAS). Following audits conducted by SGS in 2008 the WMI EMS was certified as complying with the requirements of ISO14001:2004 standard and the EMAS Regulation.

3.1.2. Environmental, Health & Safety Policy

It is the policy of WMI to conduct its business in such a manner that associated activities minimise or eliminate any potential adverse effects on the environment. This commitment is expressed in the company's EHS Policy, presented in Appendix 6.

3.1.3. Environmental Management Organisation

A basic principle of EMAS and the ISO14001 EMS, installed at WMI is that all employees of the company, at every level, have a responsibility to apply the principles of the EMS and the company's EHS Policy, while performing their work. While each individual within the organisation has a role to play in the ongoing environmental improvement programme at the WMI site, those with key responsibilities are as follows. The Managing Director holds overall responsibility for the environmental performance of the site. Each Director (who are part of WMI Senior Management Group) holds responsibility for their specific area while the EHS Director together with the environmental officers within the EHS Department are responsible for the day to day maintenance associated with the environmental management system.

3.1.4. Environmental Management Programme

The Environmental Management Programme (EMP) forms part of the strategic environmental planning process for WMI. The purpose of the EMP is to ensure that the requirements of the EHS Policy are met. The EMP documents the strategy for achieving the planned objectives and targets and will:

- Identify the specific actions required to ensure the environmental objectives are achieved.
- Assign appropriate responsibilities for achieving each element of the environmental programme.

- Set deadlines for achieving the various stages of the planned activities.

The EMP is prepared, reviewed and updated annually to account for yearly improvements resulting from the phased introduction of the objectives and targets programme, and to ensure that new developments or products are covered and are maintained within the scope of the EMS.

3.1.5. Environmental Management Programme – Proposal 2009

Environmental objectives and targets, which are generated through WMI EMS standard operating procedures, are identified following identification of environmental aspects and reviewed on an annual basis as part of the EMP. Individual environmental objectives and the methods by which they will be achieved over a specified period of time (targets) are presented in the EMP Proposal for 2009 (Appendix 7). WMI welcome any Agency feedback on the 2009 EMP which is currently undergoing implementation.

3.1.6. Environmental Management Programme – Report 2008

A review of the status of the individual environmental objectives and targets previously detailed in the EMP for 2008, are outlined as in Table 3.1. The majority of the objectives and targets set out in the site Environmental Management Programme for 2008 were achieved – those that are ongoing (due to unforeseen delays from other projects to which the objective was linked or due to a more extensive scope of work than originally anticipated) have been incorporated into the 2009 Environmental Management Programme (refer to Appendix 7).Documentation supporting these environmental objectives and targets are available for review by Agency personnel.

Table 3.1: Environmental Management Programme – Report 2008

Objective 1: Emissions, Control & Monitoring – General, Process Effluent, Fire Water Retention	▪ To achieve compliance with all WMI IPPC Licence requirements, in particular Emission Limit Values, and to measure site environmental performance.
General – Monitoring Programme (Condition 5.1, 6.1)	▪ Emissions to Sewer, Surface Water, Air, Noise – 100% compliance with ELVs ▪ Groundwater – No issues
General - Environmental Performance Indicators (Condition 2.2.2.2)	▪ EPIs (Waste Arising, CO_2, Emissions, Water Usage,) & Reduction targets (10% reduction in the 2007 baseline over the 5 year WMI period 2008 - by 2012) selected by cEHS ▪ Quarterly updates (Actual EPI performance v. 2% EPI annual reduction target) submitted to cEHS ▪ EPIs to be included in AER for 2008.
Process Effluent (Condition 6.11.3)	▪ Correspondence sent to EPA on 27/06/08 regarding project time-line change due to delay in WWTP Performance Verification process.
Fire Water Retention (Condition 3.9)	▪ Preliminary evaluation of 2005 Fire-Water Retention Study completed by DPS Consulting Engineers (November 2008). ▪ Phase 2 of the study currently ongoing
EPRTR	▪ Report prepared and submitted as per EPA deadline
Objective 2: Environmental Training, Awareness & Management Systems	▪ To achieve compliance with the requirements of the current WMI IPPC Licence (Licence Register No. P0153-05), in particular *Condition 2.2.2.6*.
Environmental Training – New Employee (IPPC Condition 2.2.2.6)	▪ Revised environmental induction training for new employees issued (Launched November 2008)
Environmental Training – Current Employee (IPPC Condition 2.2.2.6)	▪ Revised training package (computer based training) for refresher environmental training for existing employees on IPPC Licence & cEHS environmental policies (Launched September 2008)
Environmental Training – Contractor (IPPC Condition 2.2.2.6)	▪ Revised training package (computer based training) for environmental induction training for contractors (Launched September 2008)
Environmental Awareness (IPPC Condition 2.2.2.6)	▪ Waste Management awareness programme implemented. ▪ Tours of areas of environmental significance within WMI plant conducted with various Green Teams (WWTP, Waste Management Centre. Roof – Air Emissions).
Objective 3: Energy Efficiency	▪ Continue to reduce energy and water consumption and improve the energy and water usage efficiency of on-site operations.
Energy Management System (Condition 7.1, 7.2)	▪ Energy Management System certified to IS393:2005 (June 2008) ▪ ▪ New site energy lead appointed (October 2008)
Water Usage – WWTP / Cooling Towers (Condition 7.3)	▪ Meetings held between WMI and water treatment chemical supplier & cooling tower provider to assess feasibility of project. ▪ Draft report on cEHS monitoring programme conducted on effluent undergoing review
Objective 4: Resource Use	▪ Continue to ascertain if more sustainable forms of production and consumption can be adopted at the site (product and process improvement).
Efficiency of Raw Materials Use – HT / CNS (Condition 7.4)	▪ Report submitted to EPA (March 2009).
Objective 5: Waste Management	▪ Examine options for reduction of solvent waste and continue to examine options for improving on-site waste logistics.
Waste Reduction – Hazardous Waste (SAS Solvent Waste)	▪ The Kuhni was taken off-line in 2008 for upgrade works with the SAS waste stream diverted to the Proscon unit. Due to reduced production the Kuhni remains of-line .The use of the more efficient Proscon system has resulted in a decrease in the amount of SAS waste produced – approximately 33% reduction in SAS waste ▪ .
Waste Reduction – Hazardous Waste (Rinsewaters)	▪ Validation of equipment, update of operational oprcedures and training of personnl on operation of equipment completed in 2008. System proposed for operation in Q2 2009.
Waste Reduction – Hazardous Waste (Rinsewaters)	▪ All rinsewaters from MHT, HT, CNS & OC production areas diverted to WWTP. Performance Verification of WWTP is ongoing for Efexor API (anticipated completion Q2 2009)..
Waste Reduction/Recycling - Non-Hazardous Waste	▪ Non-hazardous waste recycling rate for the site has increased from 69% to 89% due to implementation of the following: o Diversion of gelatine capsules (EWC 07 05 14), lactose (EWC 07 05 99), food waste (EWC 20 01 08) from landfill to composting(approximately 15,000 kg/annum) o Further continuation of initiatives started in 2007 which were fully implemented in 2008: ▪ Diversion of blister packs (EWC 20 03 99) from landfill to recovery as mixed recyclables (approximately 82,000 kg/annum). ▪ Segregation and recycling of laboratory glass (approximately 6,000 kg/annum). ▪ Increased segregation of office recyclables (cardboard, plastic bottles, aluminium drinking cans, etc).

3.2. POLLUTION EMISSIONS REGISTER- EPRTR

Regulation (EC) No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register (the 'E-PRTR Regulation') came into force on 24/02/2006. The E-PRTR Regulation aims to contribute to the prevention and reduction of pollution, delivering data for policy makers and facilitating public participation in environmental decision making. The PRTR is a European pollutant emission reporting system, which aims to enhance the availability of information to the general public on the sources and amounts of emissions to air, water and land from European industry.

Licensees report emissions and waste transfers off-site via an electronic system. The Agency subsequently collate AER information and will extract those emissions and waste transfer records exceeding the European reporting thresholds for onwards reporting to the European Commission. Please note that that while the WMI PRTR submission is presented in Appendix 11 of the AER, difficulty has been encountered in uploading the PRTR XML file to the EPA website. This has been communicated to the Agency as per email correspondence presented in Appendix 11 of the AER. When this issue is resolved, a copy of the confirmation from the Agency that the data has been validated will be issued as an addendum to the AER, as soon as it is received.

3.3. SOLVENT MANAGEMENT PLAN

3.3.1. Introduction

In accordance with *Schedule D: Annual Environmental Report* of Licence Register No. P0153-05 WMI is required, as part of the AER, to prepare a Solvent Management Plan (SMP) to demonstrate compliance with *Condition 5.4* and *Condition 6.15* of the IPPC Licence. To-date, in accordance with a request from the Agency [as per EPA Site Inspection Report of 19/04/2004 (Reference: M673/gc001bk.doc)], WMI have submitted SMPs for the site in AERs 2004-2007. A summary of the main findings from the previous SMPs carried out for the site is presented in Table 3.2.

Table 3.2: SMP 2004 – 2007 **Note 1**

Year	Total VOC Consumed on-site (Kg)	Total VOC Emissions to air from Entire Site [Direct & Fugitive] (Kg)	% VOC Emissions to air from Entire Site	Emission Limit Value Note 2
2004	384,800	15,334.77	3.99	Total emissions to air of volatile organic compounds shall be reduced to no more than **5%** of the total solvent input.
2005	628,930	19,133.81	3.04	
2006	629,966	23,892	3.79	
2007	699,755	24,965.55	3.57	

Note 1: Refer to previous AERs for notes on 2004-2007 data

Note 2: As per *Condition 5.4.1(ii)* of Licence Register No. P0153-05. As discussed during the EPA site audit on 27/03/07, WMI agreed with the Agency that there is no longer a need to complete two separate SMP balances for the site [in order to illustrate compliance with both *Condition 5.4.1(i)* and *Condition 5.4.1(ii)* of Licence Register No. P0153-05] and as a result WMI need only prepare a single SMP balance for the entire site. The agreement was based on WMI complying with the tighter of the two limits for the entire site, namely *Condition 5.4.1(ii)* i.e. Total emissions to air of volatile organic compounds shall be reduced to no more than 5% of the total solvent input.

3.3.2. Methodology

The methodology which was applied to previous SMPs (which is outlined in detail in AERs 2004-2007) was used in the preparation of the 2008 SMP.

3.3.3. Scope of SMP

The following tasks were considered as part of the scope of work in preparing the SMP:

- Identification of all organic solvents used at the WMI site with relevant usage detail (Table 3.3); and,
- Identification and quantification of the potential loss pathways for the various solvents used at the WMI site (Table 3.4).

3.3.4. Solvent Identification

Table 3.3 presents a summary of all organic solvents and materials which contain organic solvents that are currently used at WMI. The VOC content of each material was determined by reference to the Material Safety Data Sheet held at WMI for each material used on-site.

As can be seen from Table 3.3 the main solvents used on-site are:

- DCM
- Methanol
- IMS
- IPA
- Pharmaglaze
- Acetronitrile.

DCM and Methanol are the main solvents used in the coating process in the Efexor manufacturing process, while IMS is the main solvent used in the Hormone Therapy manufacturing process. Together, these 3 solvents account for over 96% of solvent used at the WMI site. For this reason, these solvents were chosen for detailed examination as part of the SMP, in order to assess compliance with the ELVs outlined in *Condition 5.4.1(ii)* of Licence Register No. P0153-05.

3.3.5. SMP Mass Balance for the Entire Site

A summary of the component loss estimates for DCM, Methanol and IMS are presented in Table 3.5. The total amount of organic solvents used on site (total input) in 2008 was approximately 662,491.1kg (referring to Table 3.3). DCM, Methanol and IMS account for >96% (641910.28kg) of total solvent input on-site for 2008.

Key figures from Table 3.5 are as follows:

- Total solvent emissions to air for DCM (O1+O4) is: 362.23kg.
- Total solvent emissions to air for Methanol (O1+O4) is: 201.21kg.
- Total solvent emissions to air for IMS (O1+O4) is: 1,261.14kg.
- This results in a Total solvent emission to air for all 3 solvents of: 1,824.58kg.

This is equivalent to total solvent emissions to air of less than 1% of the total solvent input (662,491.1kg) for these three solvents which demonstrates compliance with *Condition 5.4.1(i)* of Licence Register No. P0153-05 i.e. Total emissions to air of volatile organic compounds shall be reduced to no more than 5% of the total solvent input.

Apart from the 3 primary solvents used on site (DCM, Methanol, IMS) there are also a wide range of other solvents used on-site (refer to Table 3.3) Year 2008 data indicated that there was approximately 20,520.6 kg of various other organic solvents used on-site. Currently there is insufficient information to perform a complete mass balance on all of these solvents. Where possible these various other organic solvent wastes are collected in drums and transported off-site for appropriate treatment. However assuming a worst-case scenario of 100% of the remaining solvents being emitted to air this would result in total solvent emissions to air for the entire organic solvent range used on site of approximately 22,345.18 kg (20,520.6 kg + 1,824.58 kg), representing 3.37% of the total solvent input at the WMI facility. This still demonstrates compliance with Condition 5.4.1(i) of Licence Register No. P0153-05.

Table 3.3: Type and Quantity of Organic Solvents Used in 2008 for the Entire Site

Solvent Containing Materials	Amount Used in 2008 (Kg) Note 1	VOC Content (%) Note 2	Amount VOC Used 2008 (Kg)
Methylene Chloride (DCM)	395457 Note 3	100.00%	395457
Methanol	241598.5 Note 3	100.00%	241598.5
Industrial Methylated Spirits	1260 Note 3	100.00%	1260
IPA	4200 Note 4	100.00%	4200
Pharmaglaze	3711.7 Note 3	50.00%	1855.845
Ink Black Opacode S-8-27741	446.6 Note 3	44.50%	198.737
Ink White Opacode S-8-28905	494.3 Note 3	23.75%	117.3963
Opacode S-8-29007	52 Note 5	40.00%	20.8
Opacode	1100 Note 5	40.00%	440
Opacode A-14004 /A-14030 Pink	150	40.00%	60
Mineral Spirits Odourless	265.4 Note 3	100.00%	265.4
Domino 0121X Makeup	1000 Note 5	98.50%	985
Domino 1000 Wash	1000 Note 5	80.00%	800
Domino WL200 Wash	1000 Note 5	80.00%	800
Black Printing Ink	3000 Note 5	98.00%	2940
TEK ink SW-9007/9008	5 Note 5	90.00%	4.5
Videojet Ink 16-8420	1000 Note 5	92.00%	920
Videojet Ink 16-8425	1000 Note 5	92.00%	920
3M Stainless Steel Cleaner	1 Note 5	5.00%	0.05
Chemcraft Label Remover	1 Note 5	60.00%	0.6
General Purpose Thinners	1 Note 5	80.00%	0.8
IPA Wipes	10 Note 5	50.00%	5
Acetonitrile	4847 Note 3	100.00%	4847
Acetone	190 Note 3	100.00%	190
Acetic Acid	135.2 Note 3	100.00%	135.2
Butan-1-ol	16.2 Note 3	100.00%	16.2
2-Butanol	4.04 Note 3	100.00%	4.04
Cyclohexane	69.92 Note 3	100.00%	69.92
1,2 Dichloroethane	141 Note 3	100.00%	141
Laboratory DCM	325 Note 3	100.00%	325
Diethyl Ether	45.5 Note 3	100.00%	45.5
Ethanol	126 Note 3	100.00%	126
Ethyl Acetate	60.75 Note 3	100.00%	60.75
Formic Acid	24.68 Note 3	100.00%	24.68
Isopropylether	5.4 Note 3	100.00%	5.4
Laboratory IMS	143.78 Note 3	100.00%	143.78
Methanol	3126 Note 3	100.00%	3126
n-hexane	21.42 Note 3	100.00%	21.42
Nitro ethane	15.75 Note 3	100.00%	15.75
Pentane	10.02 Note 3	100.00%	10.02
Petroleum Ether	3.2 Note 3	100.00%	3.2
Propan-1-ol	5.93 Note 3	100.00%	5.93
Propan-2-ol	67.15 Note 3	100.00%	67.15
Propan 1,2, diol	7.73 Note 3	100.00%	7.73
Pyridine	23.76 Note 3	100.00%	23.76
Tert butyl methyl ether	14.8 Note 3	100.00%	14.8
Tetrahydrofuran	71.2 Note 3	100.00%	71.2
Toluene	54.95 Note 3	100.00%	54.95
Trichloroethylene	3.65 Note 3	100.00%	3.65
Triethylamine	55.3 Note 3	100.00%	55.3
Trifluoride Methanol	4.79 Note 3	100.00%	4.79
2,2,4-Trimethylpentane	10.5 Note 3	100.00%	10.5
Xylene	10.88 Note 3	100.00%	10.88
Total	**666394.99**		**662491.1**

Note 1: Unless otherwise stated material usage figures supplied by WMI Finance Department.

Note 2: VOC content was determined by reference to the MSDS filed on-site for each material.

Note 3: Amount used in 2008 determined from SAP data recording/processing system.

Note 4: Usage data was taken from *Table G.1(i): Details of Process Related Raw Materials, Intermediates, Products, etc., Used or Generated on the Site* as submitted to the Agency for approval 05/02/09 and was a combination of usage figures for IPA and Isopropanol.

Note 5: Amount used taken from *Table G.1(i): Details of Process Related Raw Materials, Intermediates, Products, etc., Used or Generated on the Site* as submitted to the Agency for information purposes on 05/02/2009.

Table 3.4: Mass Balance Terminology and Relevance to WMI

Mass Balance Terms		Relevant to WMI
Inputs of Organic Solvent (I)		
I1	***The quantity of organic solvents or their quantity in preparations purchased which are used as input into the process in the time frame over which the mass balance is being calculated.***	***Relevant: Records obtained from SAP data recording/processing system***
I2	The quantity of organic solvents or their quantity in preparations recovered and reused as solvent input into the process.	Not Relevant: No Organic Solvents are reused on-site.
Outputs of Organic Solvent (O)		
O1	***Emissions in waste gases.***	***Relevant: From the Efexor SAS systems (A2-16 - Kuhni, A2-41 - Proscon) & HTs (A2-6)***
O2	***Organic solvents lost in water, if appropriate taking into account waste water treatment when calculating O5.***	***Relevant: Residual solvent discharged in the final effluent.***
O3	**The quantity of organic solvent that remains as contamination or residue in products output from the process.**	***Relevant: Residual solvent remains on tablets.***
O4	***Uncaptured emissions of organic solvent to air (Fugitive emissions). This includes the general ventilation of rooms, where air is released to the outside environment via windows, doors, vents and similar openings.***	***Relevant: Solvents used in small quantities for general cleaning purposes and printing inks. Includes breathing losses from tanks and from transfer of solvents between containers (Fugitive emissions).***
O5	Organic solvents and/or organic compounds lost due to chemical or physical reactions (including for example those which are destroyed, e.g. by incineration or other waste gas or waste water treatments, or captured, e.g. by adsorption, as long as they are not counted under O6, O7 or O8).	Not Relevant: All solvents are either emitted to atmosphere, in the final effluent, collected as waste or are included under O4 (Fugitive emissions).
O6	***Organic Solvents contained in collected waste.***	***Relevant: Solvents recovered from the Efexor SRS/SAS systems are collected as waste and sent off-site for appropriate treatment. Laboratory waste solvents are also collected and sent off-site for appropriate treatment.***
O7	Organic solvents, or organic solvents contained in preparations, which are sold, or are intended to be sold, as a commercially valuable product.	Not relevant: WMI does not sell any preparations/products containing solvents.
O8	Organic solvents contained in preparations recovered for reuse but not as input into the process, as long as not counted under O7.	Not relevant: All solvent recovered on-site is transported off-site for incineration not re-use.
O9	***Organic solvents released in other ways.***	***Relevant: Bypasses of the Efexor SAS systems. No means of quantifying this in 2007 SMP. Losses are expected to be minimal. Any losses will be incorporated in O4 figure above.***

Table 3.5: Mass Balance Calculation Results – Entire Site

Mass Balance Component		Solvents (kg)			Total (kg)
		DCM	Methanol	IMS	
I1 – Inputs	Processing	395457	241598.5	1260	638315.5
	Laboratories	309	3232	114	3655
	Total	**395766**	**244830.5**	**1374**	**641970.5**
O1 – Organic solvent emissions in waste gases	Processing Note 1	29.64	7.39	1258.74	1295.77
	Laboratory	3.09	32.32	1.14	36.55
	Total	**32.73**	**39.71**	**1259.88**	**1332.32**
O2 – Organic solvents lost in water	Total Note 1	0.33	31	1.26	32.59
O3 – Organic Solvents remaining on Product	Total	36.36	72.71	-	109.07
O4 – Fugitive organic solvent emissions	Total	329.5	161.5	1.26	492.26
O6 - Collected Waste Solvent	SRS/SAS Note 2	395061.5	241356.9	N/A	636418.4
	Laboratories	305.9	3199.68	112.86	3618.44
	Total	**395367.4**	**244556.58**	**112.86**	**640036.84**
Total emissions of solvent to air – Method 1 (O1+O4) = I1–(O2+O3+O6)	**Total**	**362.23**	**201.21**	**1261.14**	**1824.58**

Note 1: Organic solvents emissions to air figures and organic solvents lost in water are based on recorded analytical results for emission to air and emission to water.

Note 2: SRS/SAS collected waste solvent figures are based on a minimum 99.9% recovery efficiency of the SRS/SAS systems.

4. LICENCE SPECIFIC REPORTS

The following is an update on licence specific reports as listed in *Schedule D Annual Environmental Report* of Licence Register No. P0153-05.

4.1. REVIEW OF RESIDUALS MANAGEMENT PLAN (RMP)

As per *Condition 10.2* of Licence Register No. P0153-05 WMI is required to annually review the RMP and include this review as part of the AER for agreement by the Agency. The RMP for 2009 is included in Appendix 8.

4.2. BUND INTEGRITY TESTING

As per *Condition 3.6.5* of Licence Register No. P0153-05 WMI is required to demonstrate the integrity and water tightness of bunds at least once every 3 years.

In 2008 183 No. bunds were tested. Of the bunds tested 177 passed with 6 failures (refer to Appendix 9). Of the bunds that failed 5 No. were temporary bunds (which were subsequently decommissioned) and 1 No. was a permanent bund (emergency generator bund PE41). An incident report was prepared and remedial work has been scheduled for the 1 No. permanent bund. Once the remedial work has been completed the bund will be retested to confirm integrity. It is noted that there is no environmental impact associated with the integrity test failure for this bund as diesel levels in the generator have been maintained and there is no evidence of diesel leaking from the generator to the bund.

4.3. TANK AND PIPELINE INSPECTION REPORT

As per *Condition 6.9* of Licence Register No. P0153-05 WMI are required to submit a Tank and Pipeline Inspection Report to the Agency every 3 years.

WMI have commissioned CEDA Chartered Engineers to inspect, test and prepare a tank and pipeline inspection report. The scope of this inspection included:

- WWTP - Influent Wet Well, Effluent Wet Well, 2 No. Balance Tanks, 2 No. Biology Tanks, 2 No. MBR Tanks.
- 8 No. Lift stations
- Trade and foul sewer conveyance system.

Once the final report is issued WMI will forward the soft copy to the Agency for review.

4.4. BOILER MAINTENANCE PROGRAMME

As per *Condition 6.16* of Licence Register No. P0153-05 WMI are required to submit a report on the implementation of the programme for the adequate maintenance of boilers on site. This information is presented in Appendix 10.

4.5. PHARMACEUTICAL ACTIVE DUST EMISSIONS: REPORT ON REDUCTION OF STACK NUMBERS

As per *Condition 6.17.3* of Licence Register No. P0153-05 WMI are required to submit a report on the implementation of the programme to reduce the number of particulate emission points discharging pharmaceutical actives to air annually as part of the AER.

As previously outlined in the AER 2007 and WMI correspondence of 10/06/2008, there were no minor emission points suitable for amalgamation while only 2 No. main emissions points were short listed for evaluation of amalgamation (i.e. Emission Point reference No.s A2-16 and A2-41). A technical review of emission points A2-16 and A2-41 demonstrated that the cost of amalgamating the emission points is prohibitive, with respect to the potential benefits i.e. reduced number of emission points.

In accordance with Condition 6.17.3 of Licence Register No. P0153-05 and further to WMI correspondence of 13/12/2007 (Reference: M673/ap14bk), as part of any development, it is standard engineering design to keep roof penetrations to a minimum which in turn ensure that the number of emission points is minimised. In this instance this assessment was carried out for all emission points installed in 2008 (refer to Table 1.1 for summary of Condition 1.4 submissions)

4.6. ENVIRONMENTAL LIABILITIES RISK ASSESSMENT REVIEW

As per *Condition 12.2.* of Licence Register No. P0153-05 WMI submitted a fully costed Environmental Liabilities Risk Assessment (ELRA) to the Agency on 18/10/2007. The ELRA addresses liabilities from past and present activities. WMI await feedback from the Agency on the findings of the assessment, including the additional information submitted to the Agency on 08/08/2008, after which WMI will make the necessary financial provision to underwrite the environmental liabilities.

4.7. ENERGY EFFICIENCY & WATER USAGE SUMMARY

The area of energy and water usage reduction continues to be a key objective for the site as presented in *Objective 3: Energy Efficiency* of Environmental Management Programme – Proposal 2009 (Appendix 7). It should be noted that following installation of an energy management system (eNMS) at the site in 2008 that energy related objectives and targets are formulated via an energy management programme (eNMP) rather than the EMP. In addition to information

presented in Section 2.8.1 (Energy Efficiency) and 2.8.3 (Water Usage) it is proposed to continue to assess areas where improved efficiency can be achieved by identifying the main areas of electricity and water consumption at the site. Projects to reduce energy consumption and improve the energy efficiency of on-site operations are assessed for completion on an ongoing basis by the Site Energy Committee and the WMI Senior Management Group. This assessment is based on capital investment requirements and time-frame for implementation (short-term, long-term).

A summary update on energy saving projects and initiatives implemented at the site in 2008 is presented as follows:

- Equipment shut-down at weekends
- Installation of variable speed drive on HVAC installed on OC pans (enables out-of-hours set back of system to lower limits)

Energy objectives established to meet the goals of the WMI Energy Policy as per the eNMP for 2009 include the following:

- HVAC: Reduce energy consumption from 48% (2008) to 45% (2009) of site energy load.

Approximately 100 Variable Speed Drives (VSD's) to be installed across HVAC Plant (Supply, Extract & Recirculation Units). This will enable timer on/off control and out-of-hours ramp down of HVAC systems which will result in:

  - More efficient use of systems during production / packaging activities e.g. control of air change rates closer to acceptable limits, as opposed to well beyond acceptable limits (e.g. 20 down to 8 air changes per hour.)
  - Out-of-hours set back of systems to lower limits.
  - Minimisation of HVAC usage during non-production times.

- Utilities: Reduce energy consumption from 36% (2008) to 26% (2009) of site energy load.

  - Re-use of CHP Low Temperature Hot Water (into new processing buildings).
  - Compressed Air Remediation (repair of leaks in distribution pipework).
  - Efficiency & Control of Medium Temperature Hot Water and Chilled Water.

- Equipment Decomissioning: Reduce energy consumption from 8% (2008) to 7% (2009) of site energy load.

In addition a suitable staff awareness programme continues to be developed and implemented to increase awareness of energy efficiency and targets to be achieved. It is expected that these projects will result in both financial (i.e. reduced energy costs) and environmental (i.e. increased energy efficiency) benefits.

4.8. REPORT ON THE ASSESSMENT OF EFFICIENCY OF USE OF RAW MATERIALS IN PROCESSES

4.8.1. Overview

It is noted that there are significant limitations as to the degree of process change that are possible to reduce raw materials usage, and so increase raw materials usage efficiency. These limitations relate to product registration (with various drug control bodies such as the Irish Medicines Board and the U.S. Food & Drugs Administration), and validation. Certain parameter or variable values have already been set with little scope to make change without incurring a very significant monetary expense, and time requirement due to re-validation and re-registration. There is therefore limited potential for WMI to deliver significant transformation of existing production processes at the site. Notwithstanding this WMI are continuing to ascertain if more sustainable forms of production (increased product yield) and consumption (raw material usage) can be adopted at the site (product and process improvement). The area of raw material usage efficiency (RMUE) therefore continues to be an objective for the site as presented in *Objective 1: Compliance - Efficiency of Raw Materials Use – Efexor/OC* of Environmental Management Programme – Proposal 2009 (Appendix 7).

WMI continues to implement the Raw Material Efficiency Assessment Protocol as previously approved by the Agency (EPA reference M673/ap12mmcg.doc dated 01/02/2005). It is expected that each product study (including revisiting previous studies when appropriate) will result in the identification of a number of actions that may be implemented to improve raw material usage efficiency. A summary update for the 2008 raw material efficiency assessment's carried out and the study proposed for 2009 is presented in Section 4.8.2 and 4.8.3 respectively.

4.8.2. Raw Materials Usage Efficiency 2008 - Hormone Therapy & Central Nervous System

In 2008, continuing on work which had been undertaken in previous years, WMI extended the annual RMUE study to the Hormone Therapy (HT) and Central Nervous System (CNS) manufacturing areas. The methodology and scope of works generally follows that used in previous RMUE studies carried out. A detailed report on this study was submitted to the EPA in March 2009. The following is a summary of same:

- URS undertook a raw material usage efficiency assessment of the HTs and CNS processing areas at WMI. The detailed examination of the two manufacturing processes indicated losses during the manufacturing process are being minimised within both areas via the implementation of all reasonable measures to minimise the loss of raw materials.
- Currently, process yields within HTs and CNS areas are on average 96% and 94.2% of process inputs respectively. This compares favourably with other areas within WMI such as Efexor and Oral Contraceptives where similar process yields were identified in previous RMUE studies.

- Raw material loss, albeit small, which does occur within these areas identified during this RMUE occurs via a number of loss pathways, namely:

  - Loss of solid product (and so raw materials) during processing (e.g. sieving over and under size, machine set up, raw materials adhering to production vessels between process steps, etc);
  - Process sampling;
  - Spillages;
  - Operator Errors;
  - Equipment Failure; and,
  - Off-specification product.

  Of the above loss pathways, raw material loss through processing and off-specification product (in particular in the CNS area) were identified as the main loss pathways. Other losses were negligible in comparison. In this regard, WMI initiated the "Product Quality Improvement Programme" within CNS process area with the aim of improving process yield by minimises in as far as practicable losses as a result of Off-specification product. As a result of this programme, a total of 140 areas of improvement were identified. These mainly related to prevention of contamination of product batches with foreign material (i.e. hair, lint). An action plan was agreed to implement these measures. This plan included a total of 23 projects aimed at reducing potential contamination associated with hair (2 projects), lint (7 projects), other material (4 projects) and process improvements (10 projects).

4.8.3. Raw Materials Usage Efficiency Proposal 2009 – Efexor & Oral Contraceptives

Previous Raw Material Usage Efficiency (RMUE) studies had been carried out in the Efexor and Oral Contraceptives (OCs) manufacturing areas in 2005 and 2006 respectively. As part of the 2009 RMUE study WMI has revisited both of these previous studies as follows.

- Data relating to process yields was examined for the period 2006 through to 2008 with the aim of assessing raw material efficiency within both areas since the completion of the previous studies. A summary of the 2006 to 2008 process yield data for Efexor and OCs are presented in Table 4.1 and 4.2 respectively.
- From Tables 4.1 and 4.2, it is evident that process yields in both Efexor and OCs generally range from the low to mid 90% range in all years analysed.
- Within the Efexor area, a comparison of the data obtained for the past three years with that obtained in 2003 indicate that yields generally fluctuate within 1-2% above or below the baseline data of 2003. Code C and D both seem to show a continuous yield below that obtained in 2003.

Table 4.1: Efexor Process Yields 2003 - 2008

Efexor Family Code				
	Note 2			
Code A	94.9%	96.3%	98.1%	97.6%
Code B	95.0%	91.0%	94.5%	94.3%
Code C	99.7%	94.6%	94.1%	95.3%
Code D	98.4%			
Code E				
Code F	95.9%	-	94.0%	91.5%

Note 1: Data for 2005 and start of 2006 was unavailable as recording system software was changed.
Note 2: Data for 2003 taken from original Efexor RMUE study completed in 2005.

Table 4.2: Oral Contraceptive Process Yields 2004 - 2008

OC Family Code					
	Mar – Dec 04				
Levo E (Wet)	89%				
Gestodene EE (Wet)	88%				
Gestodene EE (Dry)	92%	94.6%	93.9%	94.1%	89.0%
Levo E (Dry)	-	-	-	94.6%	91.8%

Note 1: Data for start of 2006 was unavailable as recording system software was changed.
Note 2: Levo E (Dry) was not manufactured in 2004 or 2005.
Note 3: Data for 2004 and 2005 taken from original OC RMUE study completed in 2006.

- Within the OC area, a comparison of the data obtained for the past three years with that obtained in 2004 indicate similar trends as in observed in Efexor with yields generally fluctuating within 1-2% above or below the baseline data of 2004.

  A detailed RMUE report on the findings of this review of Efexor and OCs manufacturing areas, outlining changes and/or improvement measures implemented within both areas and containing a detailed analysis of the resulting yield data, will be submitted to the EPA during 2009.

5. CONCLUDING REMARKS

5.1. MONITORING

The WMI facility has been designed and is operated in such a manner that the potential emissions (wastewater, surface water, air) to the environment are minimised or eliminated. In addition, the BAT principle is implemented during the operational phase of the site with respect to the management of the facility. It is contended that the risk of environmental contamination as a result of both existing activities and potential accidental or emergency situations at the WMI facility are minimised or eliminated by adherence to the existing protection programmes. With IPPC Licence requirements, in 2008 there was:

- no exceedance of any emission limit value specified for emissions to sewer (wastewater), storm water emission (surface water), emissions to air (including solvent management plan), noise emissions,
- groundwater was of good chemical quality; and,
- no complaints of an environmental nature were received.

5.2. OBJECTIVES

The majority of the objectives and targets set out in the site Environmental Management Programme for 2008 were achieved – those that are ongoing have been incorporated into the 2009 Environmental Management Programme.

5.3. SUMMARY

The Environmental Monitoring Programme carried out over the 2008 reporting period shows no adverse environmental impact on the environmental media into which discharges from the WMI facility are made.

WMI acknowledge that given the restrictions and limitations on changes that can be made to the production process due to validation requirements and product registration with various drug control bodies, it may not therefore be possible for the company to achieve total sustainable transformation of the production processes conducted at the site. Notwithstanding this WMI are committed to an ongoing improvements programme at the site and the continuous improvement requirement of the IPPC licencing process is fully embraced by the WMI Senior Management Group. To this end it is the policy of WMI to conduct its pharmaceutical manufacturing business in such a manner that associated activities minimise or eliminate any potential adverse effects on the environment. This commitment is expressed in the company's EHS Policy. The success of this policy is reflected by the:

- EPA audit and site inspection conducted at the site which were fully compliant;
- Ongoing compliance with ISO14001 EMS certification, and the EMAS Regulation; and,
- Independent certification of the site Energy Management System to IS393:2005.

Appendix 1

Groundwater Monitoring Report –2008

Groundwater Monitoring at Wyeth Medica Ireland

2008

DOCUMENT CONTROL SHEET

Client	Wyeth Medica Ireland					
Project Title	Groundwater Monitoring at Wyeth Medica Ireland Ltd., in compliance with the Conditions of Licence Register No. PO153-05					
Document Title	2nd Biannual Groundwater Analysis 2008					
Document No.	MDE0529Rp0009					
This Document Comprises	DCS	TOC	Text	List of Tables	List of Figures	No. of Appendices
	1	1	19	6	-	1

Rev.	Status	Author(s)	Reviewed By	Approved By	Office of Origin	Issue Date
F01	**Issued to Client**	Niall Mitchell	Louise Burden	S. Herlihy	West Pier	3rd Feb 2008

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1 INTRODUCTION

This report outlines the results of biannual groundwater monitoring for 2008, as conducted by RPS Group specialist groundwater monitoring personnel, on behalf of Wyeth Medica Ireland (WMI) at their facility in Newbridge, Co. Kildare.

The 2008 biannual monitoring events were carried out on the 12th of February and the 15th July of 2008. Groundwater samples were collected from four monitoring wells AGW1, AGW2, AGW3 and AGW4, prior to undergoing laboratory analysis for the suite of parameters specified in Schedule *C.6 Ambient Monitoring* of licence Register No. P0153-05.

2 METHODOLOGY

Groundwater samples were collected from the four groundwater-monitoring wells (AGW1, AGW2, AGW3, AGW4) on site, using dedicated Waterra tubing in accordance with RPS Group's sampling protocol. The required length of tubing was cut, allowing 1 m excess above the top of the well casing. A non-return foot valve was fixed to the bottom of the tubing and inserted into the well, reaching the base of the bore. Separate tubing and foot valves were used at each monitoring well to eliminate the possibility of cross contamination.

Groundwater in the well casing is not considered representative of the groundwater quality at a given location. For this reason, four well volumes were purged from each well prior to collecting the groundwater sample. Common procedure is to purge a well until between 3 and 5 borehole volumes have been removed. This ensures that the groundwater sample extracted from the monitoring borehole is representative of the water held in the subsurface strata and not water held stagnant in the borehole casing. The purged volumes were calculated on-site from the measured static water levels and total well depths, using an electronic dip meter.

In order to ensure optimal evaluation, the pH, conductivity and temperature of the extracted water were continually monitored using a field meter, which was calibrated on the day of use. Groundwater samples were collected in laboratory supplied containers and stored in chilled cool boxes following sampling and during transit to the laboratory, Alcontrol Geochem, Dublin. A rigorous chain of custody procedure was used during the sample round.

The groundwater samples were analysed for the following suite of parameters:

- Heavy Metals
- Total Nitrates (as N)
- Total Nitrites (as N)
- Total Ammonia (as N)
- Chemical Oxygen Demand (COD)
- Conductivity
- pH
- Dissolved Oxygen
- Temperature
- Major Anions & Major Cations
- VOCs/Organohalogens
- Colour

Groundwater samples were analysed by Alcontrol Geochem, which is a UKAS accredited laboratory. All laboratory analysis was carried out in accordance with UKAS Accredited techniques. The table below indicates the analysis techniques used by the laboratory:

Table 1: Analytical Methodologies – Alcontrol Geochem Laboratories Dublin

Parameter	Analytical Methodology
Heavy Metals	Inductively Coupled Plasma Mass Spectrometer- (ISO 17025)
Total Nitrates	Spectrophotometer (ISO 17025)
Total Nitrites	Spectrophotometer (ISO 17025)
Total Ammonia	Spectrophotometer – EPA approved method (ISO 17025)
Chemical Oxygen Demand	Dr Lange Kit (USEPA approved method)
Conductivity	Conductivity Meter HI9811-0 (EPA approved)
pH /EC/DO/Temperature	Field Meter HI9811-0 (EPA approved)
Major Anions & Cations	Spectrophotometer (ISO 17025) & Flame photometer & ICPMS
VOCs/Organohalogens	Gas Chromatography & Mass Spectroscopy
Colour	Colormetric (Hazen Units)

3 RESULTS

3.1 FIELD PARAMETERS

Table 2: Results of Field Measurements taken at Each Groundwater Monitoring Well[1]

Parameter	Units	Borehole Monitoring Location								Interim EPA Guideline Values for Groundwater
		AGW1		AGW2		AGW3		AGW4		
		Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	
Depth	(mbgl)[2]	4.68	4.67	6.24	6.15	6.95	7.05	N/A	8.27	-
Static water Level	(mbgl)	2.82	2.79	2.51	3.31	4.20	4.00	3.65	4.13	-
Volume Extracted	(litres)	40	20	20	20	30	20	30	24	-
pH	(pH Units)	6.86	6.78	7.24	**5.70**	6.95	6.63	6.71	**6.16**	>6.5 & <9.5
Temp	(^{O}C)	10.4	11.1	13.5	17.0	11.6	13.9	9.50	11.8	<25^{O}C
Conductivity	(µS/cm)	866	785	565	770	747	803	731	962	1000
Dissolved O2	(ppm)	7.73	6.01	3.41	4.54	3.70	3.33	6.36	5.63	No Abnormal Change
Visual Observations		Clear & Odourless	Slightly Cloudy & Odourless	Clear & Odourless	Slightly Cloudy & Odourless	Slightly Cloudy & Odourless	Clear & Odourless	Slightly Cloudy & Odourless	Slightly Cloudy & Odourless	-

Note 1 Figures in bold exceed guideline values
Note 2 mbgl = metres below ground level

3.2 GROUNDWATER CHEMICAL ANALYSIS

Table 3: Results of Groundwater Chemical Analysis[1]

Parameter	Units	Borehole Monitoring Location								Interim EPA Guideline Values (Units as indicated)
		AGW1		AGW2		AGW3		AGW4		
		Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	
Bicarbonate Alkalinity (as CaCO3)	mg/l[2]	130	370	160	150	180	260	190	370	No abnormal change
Carbonate Alkalinity (as CaCO3)	mg/l	40	<1	25	40	35	60	20	<1	-
Hydroxide Alkalinity (as $CaCO_3$)	mg/l	<1	<1	<1	<1	<1	<1	<1	<1	-
Total Alkalinity (as $CaCO_3$)	mg/l	**170**	**370**	185	190	**115**	**320**	210	370	No abnormal change
Aluminum	mg/l	0.018	**0.303**	0.015	**0.415**	0.012	**0.598**	0.010	**2.2**	0.2
Total Ammonia (NH_4)	mg/l	<0.2	**3.8**	<0.2	<0.2	<0.2	<0.2	**0.2**	<0.2	0.15
Ammoniacal Nitrogen	mg/l	<0.2	3.0	<0.2	<0.2	<0.2	<0.2	<0.2	<0.2	-
Boron	mg/l	0.055	0.01	0.031	<0.003	0.028	<0.003	0.02	<0.003	1.0
Calcium	mg/l	124.6	195.0	83.76	97.4	129.1	147.2	137.1	**211.4**	200
Chloride	mg/l	22	20	**36**	17	17	24	23	15	30
COD	mg/l	<15	<15	<15	<15	<15	20	28	<15	No abnormal change
Colour	Hazen units	0	0	0	0	0	1	0	0	No abnormal change
Fluoride	mg/l	0.2	0.2	0.3	0.3	0.3	0.4	0.2	0.2	1.0
Iron	mg/l	<0.010	0.033	<0.055	0.085	<0.079	0.179	<0.084	**0.353**	0.2

Parameter	Units	Borehole Monitoring Location								Interim EPA Guideline Values (Units as indicated)
		AGW1		AGW2		AGW3		AGW4		
		Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	
Lead	mg/l	<0.001	<0.001	0.001	0.002	<0.001	0.002	<0.001	0.003	0.01
Magnesium	mg/l	21.26	22.95	6.23	6.84	15.02	16.59	8.23	13.98	50
Manganese	mg/l	**0.063**	**1.559**	0.005	0.029	**0.056**	**0.139**	0.001	**0.131**	0.05
Nitrate (as NO3)	mg/l	15.2	14.4	1.9	2.4	13.3	13.8	**26.0**	23.0	25
Nitrite (as NO2)	mg/l	<0.05	<0.05	<0.05	<0.05	<0.05	0.05	<0.05	<0.05	0.1
Orthophosphate (as PO4)	mg/l	**0.07**	<0.03	**0.07**	<0.03	**0.09**	<0.03	**0.07**	<0.03	0.03
Potassium	mg/l	1.4	0.6	**6.8**	4.0	1.2	1.6	**7.7**	**5.6**	5
Sodium	mg/l	16.5	15.8	25.5	23.1	12.0	15.9	18.5	14.7	150
Sulphate	mg/l	35	40	45	55	34	32	24	83	200
Potassium:Sodium Ratio		0.08	0.04	0.2	0.1	0.1	0.1	**0.4**	**0.38**	

Note 1 Figures in bold exceed guideline values
Note 2 mbgl = metres below ground level

3.3 HEAVY METALS

Table 4: Results of Heavy Metal Groundwater Analysis[1]

Parameter	Units	Borehole Monitoring Location								Interim EPA Guideline Values (Units as indicated)
		AGW1		AGW2		AGW3		AGW4		
		Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	
Antimony	ug/l	<1	<1	4	<1	<1	<1	<1	<1	-
Arsenic	mg/l	<0.001	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	0.002	0.01
Beryllium	ug/l	<1	<1	<1	<1	<1	<1	<1	<1	-
Cadmium	mg/l	<0.004	<0.004	<0.004	<0.004	<0.004	<0.004	<0.004	<0.004	0.005
Chromium	mg/l	0.005	0.001	0.003	<0.001	0.002	0.002	0.003	0.004	0.03
Cobalt	ug/l	<1	3	<1	<1	<1	<1	<1	<1	-
Copper	mg/l	<0.001	0.002	<0.001	<0.001	<0.001	**0.046**	<0.001	0.003	0.03
Mercury	mg/l	<0.00005	<0.00005	0.00005	<0.00005	<0.00005	<0.00005	<0.00005	<0.00005	0.001
Nickel	mg/l	0.004	0.006	<0.007	0.003	0.003	0.003	0.003	0.005	0.02
Zinc	mg/l	0.027	0.013	0.008	0.015	0.004	0.046	0.005	0.021	0.1

Note 1 Figures in bold exceed guideline values

3.4 VOLATILE ORGANIC COMPOUNDS

Table 5: Results of Volatile Organic Carbon Analysis of Groundwater Samples[1]

Parameter	Laboratory Limit of Detection (µg/l)	Borehole Monitoring Location								Interim EPA Guideline Values
		AGW1		AGW2		AGW3		AGW4		
		Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	
1,1,1,2-Tetrachloroethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,1,1-Trichloroethane	<2	<2	<2	<2	<2	<2	<2	<2	<2	500
1,1,2,2-Tetrachloroethane	<3	<3	<3	<3	<3	<3	<3	<3	<3	-
1,1,2-Trichloroethane	<3	<3	<3	<3	<3	<3	<3	<3	<3	-
1,1-Dichloroethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,1-Dichloroethene	<2	<2	<2	<2	<2	<2	<2	<2	<2	-
1,1-Dichloropropene	<2	<2	<2	<2	<2	<2	<2	<2	<2	-
1,2,3-Trichlorobenzene	<2	<2	<2	<2	<2	<2	<2	<2	<2	-
1,2,3-Trichloropropane	<2	<2	<2	<2	<2	<2	<2	<2	<2	-
1,2,4-Trichlorobenzene[2]	<4	<4	<4	<4	<4	<4	<4	<4	<4	0.4
1,2,4-Trimethylbenzene	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	-
1,2-Dibromo-3-chloropropane	<5	<5	<5	<5	<5	<5	<5	<5	<5	-
1,2-Dibromoethane	<2.5	<2.5	<2.5	<2.5	<2.5	<2.5	<2.5	<2.5	<2.5	-
1,2-Dichlorobenzene	<2	<2	<2	<2	<2	<2	<2	<2	<2	10
1,2-Dichloroethane	<2	<2	<2	<2	<2	<2	<2	<2	<2	3

Parameter	Laboratory Limit of Detection (µg/l)	Borehole Monitoring Location								Interim EPA Guideline Values
		AGW1		AGW2		AGW3		AGW4		
		Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	
1,2-Dichloropropane	<2	<2	<2	<2	<2	<2	<2	<2	<2	-
1,3,5-Trimethylbenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,3-Dichlorobenzene	<2	<2	<2	<2	<2	<2	<2	<2	<2	-
1,3-Dichloropropane	<2	<2	<2	<2	<2	<2	<2	<2	<2	-
1,4-Dichlorobenzene	<3	<3	<3	<3	<3	<3	<3	<3	<3	-
2,2-Dichloropropane	<2	<2	<2	<2	<2	<2	<2	<2	<2	-
2-Chlorotoluene	<2	<2	<2	<2	<2	<2	<2	<2	<2	-
4-Chlorotoluene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
4-Isopropyltoluene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Benzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	1
Bromobenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Bromochloromethane	<2	<2	<2	<2	<2	<2	<2	<2	<2	-
Bromodichloromethane	<3	<3	<3	<3	<3	<3	<3	<3	<3	-
Bromoform	<3	<3	<3	<3	<3	<3	<3	<3	<3	-
Bromomethane	<3	<3	<3	<3	<3	<3	<3	<3	<3	-
Carbon disulphide	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Carbontetrachloride	<1	<1	<1	<1	<1	<1	<1	<1	<1	-

Parameter	Laboratory Limit of Detection (µg/l)	Borehole Monitoring Location								Interim EPA Guideline Values
		AGW1		AGW2		AGW3		AGW4		
		Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	
Chlorobenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	1
Chloroethane	<2	<2	<2	<2	<2	<2	<2	<2	<2	-
Chloroform	<1	<1	<1	<1	<1	<1	<1	<1	<1	12
Chloromethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
cis-1,2-Dichloroethene	<2	<2	<2	<2	<2	<2	<2	<2	<2	-
cis-1,3-Dichloropropene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Dibromochloromethane	<3	<3	<3	<3	<3	<3	<3	<3	<3	-
Dibromomethane	<3	<3	<3	<3	<3	<3	<3	<3	<3	-
Dichlorodifluoromethane	<3	<3	<3	<3	<3	<3	<3	<3	<3	-
Dichloromethane	<2	<2	<2	<2	<2	<2	<2	<2	<2	10
Ethylbenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	10
Hexachlorobutadiene	<1	<1	<1	<1	<1	<1	<1	<1	<1	0.1
Isopropylbenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Naphthalene	<2	<2	<2	<2	<2	<2	<2	<2	<2	1
n-Butylbenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
o-Xylene	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	10
p/m-Xylene	<1	<1	<1	<1	<1	<1	<1	<1	<1	10

Parameter	Laboratory Limit of Detection (µg/l)	Borehole Monitoring Location								Interim EPA Guideline Values
		AGW1		AGW2		AGW3		AGW4		
		Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	
Propylbenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
sec-Butylbenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Styrene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
tert-butyl methyl ether	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
tert-Butylbenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Tetrachloroethene	<0.4	<0.4	<0.4	<0.4	<0.4	<0.4	<0.4	<0.4	<0.4	40
Toluene	<1	<1	<1	<1	<1	<1	<1	<1	<1	10
Trans-1,2-Dichloroethene	<2	<2	<2	<2	<2	<2	<2	<2	<2	-
trans-1,3-Dichloropropene	<2	<2	<2	<2	<2	<2	<2	<2	<2	-
Trichloroethene	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	<1.5	70
Trichlorofluoromethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Vinyl Chloride	<3	<3	<3	<3	<3	<3	<3	<3	<3	-

Note 1 Figures in bold exceed guideline values
Note 2 Laboratories are not currently capable of achieving a detection level below the IGV

3.5 SEMI- VOLATILE ORGANIC COMPOUNDS

Table 6: Results of Semi-Volatile Organic Carbon Analysis of Groundwater Samples[1]

Parameter	Laboratory Limit of Detection (µg/l)	Borehole Monitoring Location								Interim EPA Guideline Values
		AGW1		AGW2		AGW3		AGW4		
		Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	
Phenol	<1	<1	<1	<1	<1	<1	<1	<1	<1	0.5
2-Chlorophenol	<1	<1	<1	<1	<1	<1	<1	<1	<1	200
2-Methylphenol	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
4-Methylphenol	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
2-Nitrophenol	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
4-Nitrophenol	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
2,4-Dichlorophenol	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
2,4-Dimethylphenol	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
4-Chloro-3-methylphenol	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
2,4,6-Trichlorophenol	<1	<1	<1	<1	<1	<1	<1	<1	<1	200
2,4,5-Trichlorophenol	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Pentachlorophenol	<1	<1	<1	<1	<1	<1	<1	<1	<1	2
1,3-Dichlorobenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,4-Dichlorobenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,2-Dichlorobenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	10

Parameter	Laboratory Limit of Detection (µg/l)	Borehole Monitoring Location								Interim EPA Guideline Values
		AGW1		AGW2		AGW3		AGW4		
		Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	
1,2,4-Trichlorobenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	0.4
Nitrobenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	10
Azobenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Hexachlorobenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	0.03
Naphthalene	<1	<1	<1	<1	<1	<1	<1	<1	<1	1
Acenaphthylene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Acenaphthene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Fluorene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Phenanthrene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Anthracene	<1	<1	<1	<1	<1	<1	<1	<1	<1	10000
Fluoranthene	<1	<1	<1	<1	<1	<1	<1	<1	<1	1
Pyrene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Benzo(a)anthracene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Chrysene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Benzo(b)flouranthrene	<1	<1	<1	<1	<1	<1	<1	<1	<1	0.5
Benzo(k)flouranthrene	<1	<1	<1	<1	<1	<1	<1	<1	<1	0.05
Benzo(a)pyrene	<1	<1	<1	<1	<1	<1	<1	<1	<1	0.01

Parameter	Laboratory Limit of Detection (µg/l)	Borehole Monitoring Location								Interim EPA Guideline Values
		AGW1		AGW2		AGW3		AGW4		
		Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	
Indeno(1,2,3-cd)pyrene	<1	<1	<1	<1	<1	<1	<1	<1	<1	0.05
Dibenzo(a,h)anthracene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Benzo(ghi)perylene	<1	<1	<1	<1	<1	<1	<1	<1	<1	0.05
2-Chloronaphthalene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
2-Methylnaphthalene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Carbazole	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Isophorone	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Dibenzofuran	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Dimethyl phthalate	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Diethyl phthalate	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Di-n-butylphthalate	<1	<1	<1	<1	<1	<1	<1	<1	<1	2
Di-n-octylphthalate	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Bis(2-ethylhexyl)phthalate	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Butylbenzylphthalate	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
4-Chloroaniline	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
2-Nitroanaline	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
3-Nitroaniline	<1	<1	<1	<1	<1	<1	<1	<1	<1	-

Parameter	Laboratory Limit of Detection (µg/l)	Borehole Monitoring Location								Interim EPA Guideline Values
		AGW1		AGW2		AGW3		AGW4		
		Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	Biannual 1	Biannual 2	
4-Nitroaniline	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
2,4-Dinitrotoluene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
2,6-Dinitrotoluene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Bis(2-chloroethyl)ether	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
4-Bromophenylphenylether	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
4-Chlorophenylphenylether	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Hexachloroethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Hexachlorobutadiene	<1	<1	<1	<1	<1	<1	<1	<1	<1	0.1
Hexchlorocyclopentadiene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Bis(2-chloroethoxy)methane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
N-nitrosodi-n-propylamine	<1	<1	<1	<1	<1	<1	<1	<1	<1	-

Note 1 Figures in bold exceed guideline values

4 DISCUSSION

The results of groundwater monitoring at the WMI facility for 2008 are presented in Tables 2 - 6 of this report. Discussion of the results and their significance are outlined below.

4.1 GROUNDWATER MONITORING RESULTS

Groundwater field parameters were measured onsite using an EPA approved and calibrated multi-parameter field kit to identify the pH, temperature, electrical conductivity and dissolved oxygen concentrations of the groundwater.

Temperature, Dissolved Oxygen and electrical conductivity were all within the ranges prescribed by the EPA IGVs.

During the 1st biannual monitoring event of 2008, readings for pH were observed to be neutral to slightly alkaline, ranging from 6.71 to 7.24 pH Units and readings for pH were observed to be slightly acidic to neutral ranging from 5.70 to 6.95 pH Units for the 2nd biannual monitoring event of 2008. Future monitoring of pH will determine the persistency of these slightly acidic levels, which appear to be naturally occurring, and not as a result of activities at the WMI site.

Total Alkalinity concentrations ranging between 115 and 370 mg/l were observed across the site for both monitoring events in 2008. The IGV guideline for alkalinity is *"no abnormal change"* which refers to no significant changes with respect to background values. A notable variation of total alkalinity was recorded between biannual 1 and biannual 2 concentrations in monitoring wells AGW1, AGW3 and AGW4 with concentrations recorded between 170 and 370 mg/l respectively in AGW1, 115 and 320 mg/l respectively in AGW3 and 210 and 370 mg/l respectively in AGW4. Future monitoring will determine the persistency of these variations, which appear to be naturally occurring and not as a results of activities at the WMI site. No significant variations were recorded for Total Alkalinity during the 2006 and 2007 monitoring periods.

Aluminium, Iron, Copper and Ammonia recorded significant increases in concentrations with respect to previous monitoring events in at least one borehole during the 2nd biannual monitoring event of 2008 and are discussed in the following paragraphs.

Iron and *aluminium* recorded significantly increased concentrations in all monitoring wells during biannual 2 event with the highest concentrations recorded in the upgradient borehole AGW4. The aluminium concentrations were all in excess of the IGV, iron concentrations for the 2nd biannual round only exceeded the IGV in AGW4. Both iron and aluminium are common naturally occurring compounds within geological formations and naturally elevated concentrations have been recorded

across Ireland. Aluminium is also commonly used as a coagulant in water treatment processes and changes in the oxygen conditions within a water system caused by the breakdown of organic materials (such as septic tank and farmyard waste) can cause the precipitation of iron. These observed increases in concentrations are most likely to be due to changes in aquifer conditions upgradient of the site and not as a result of activities at the site, which are not consistent with the presence of these compounds.

Copper recorded a concentration slightly in excess of the IGV in AGW3 during the 2nd biannual monitoring event. The IGV for copper is hardness dependent and in the absence of hardness data the lowest value has been adopted. The increased concentration of copper is likely to be associated with the change in alkalinity observed within this well and is unlikely to be as a result of activities at the WMI facility.

Ammonia recorded a concentration considerably in excess of the IGV in borehole AGW2 during the 2nd biannual monitoring event. The represents a significant increase in concentrations from previous rounds although slightly elevated concentrations were recorded in AGW4 during the first biannual monitoring event. Ammonia can occur naturally within groundwater and is commonly associated with the release of organic pollutants such as septic tank effluent, livestock manure and leaking sewers. The observed concentrations of ammonia are unlikely to be sourced from the WMI facility, given the nature of operations and the groundwater protection measures in place.

Calcium, manganese and *potassium* recorded concentrations slightly in excess of their respective IGVs during the 2nd biannual monitoring event however these concentrations and the pattern of distribution is broadly similar to that seen in the 1st biannual monitoring event of 2008 and other previous monitoring events and do not represent a significant change. These are naturally occurring compounds and are unlikely to be sourced from the WMI facility. Potassium and manganese in particular can be associated with the presence of organic pollutants and the observed distribution indicates an upgradient source. This is supported by the sodium potassium ratios which were calculated and presented in Table 3 and provide a basic but useful indication of the potential impact of organic waste in groundwater. In general a ratio greater than 0.4 indicates that farmyard organic wastes are likely source of pollution. The potassium sodium ratio has been calculated as 0.38 and 0.4 in the upgradient borehole AGW4 in the first and second monitoring events respectively. In addition, the distribution of concentrations of *nitrate* and *chloride* recorded in the monitoring wells at the WMI site provide supplementary evidence of an upgradient organic pollutant source.

Organo-halogens, namely the US EPA VOC's and SVOC's were all found to be below the relevant limit of detection of laboratory for each compound and below the IGVs, with the exception of 1,2,4 – Trichlorobenzene. The laboratory detection limit for this compound is above the IGV value. This method is UKAS accredited to ISO 17025 and 4ug/l is the lowest level of detection the laboratory can

reach for this VOC. However the general absence of VOCs and SVOCs give confidence that these contaminants are not presenting a risk to groundwater.

5 CONCLUSIONS

Following a review of the groundwater monitoring results of 2008 and groundwater monitoring results from 2006 and 2007, in conjunction with recorded groundwater levels and the interpreted northwesterly groundwater flow direction, the observed elevated concentrations of total ammonia, iron, manganese and potassium in the monitoring wells at the WMI site, appear to indicate an impact on groundwater quality from potential upgradient agricultural and/or septic tank sources in addition to natural background concentrations of the groundwater.

Given that detections of these elevated concentrations were predominantly recorded in the upgradient monitoring well, AGW4, in addition to the other monitoring wells, this would provide strong evidence of an off-site source of organic contamination (*i.e.* to the south and east of the WMI site). Also, the calculated potassium:sodium ratios and distribution of nitrate and chloride detections provides additional supporting evidence to this scenario.

Elevated variations in alkalinity, pH and concentrations of inorganic compounds such as copper and aluminium were recorded during this monitoring period. No notable detections of the IGVs of these compounds were recorded previously. Future monitoring of these parameters will confirm the persistency of these detected compounds.

Given the above, the elevated concentrations of inorganic compounds detected in the groundwater underlying the WMI facility do not indicate the existence of an on-site contamination source given the nature of operation conducted at the site and the groundwater protection measures in place. If the results continue to be elevated in future monitoring rounds then further investigation may be required to determine the likely source.

APPENDIX A

SAMPLING AND ANALYSIS - METHODS AND DETAILS

A.1.1 Location of Sampling

Wyeth Medica Ireland,

Buckley's Cross Roads,

Old Connell,

Newbridge,

Co. Kildare

A.1.2 Date of Sampling

Biannual 1: *12th February 2008*

Biannual 2: *15th July 2008*

A.1.3 Personnel Present During Sampling

Biannual 1 - Joe Hunter, Environmental Consultant, RPS Group, Dublin

Biannual 2 – Ronan Murphy, Environmental Consultant, RPS Group, Dublin

A.1.4 Instrumentation

Honda Purge Pump

Waterra Tubing and ball valves

Dip Meter

Environmental Monitoring Kit – pH, EC, DO and temperature

Appendix 2

Annual Air Monitoring Report - 2008

SiteRIGHT Environmental
Environmental Monitoring and Consultancy

Ballybrew,
Enniskerry,
Co. Wicklow
Ireland

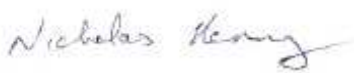
Report No. WYN A1 08c

Air emission compliance monitoring 2008

Licence Register No. P0153-05
Wyeth Medica Ireland, Newbridge, Co. Kildare

Report issue date:- 04/02/09

Report checked and approved:



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Part 1 – Executive summary

Introduction:

Wyeth Medica Ireland Ltd (WMI)., Newbridge, Co. Kildare is required to monitor volumetric flow, total particulate (TP) matter (including Active Pharmaceutical Ingredient (API)), organic species and combustion gases from a number of air emission points at their plant on an annual basis in accordance with the requirements of *Schedule C.1.2 Monitoring of Emissions to Air* of Licence Register No. P0153-05

To fulfil this monitoring requirement Siteright Environmental conducted a series of visits to the WMI site during the course of 2008. Samples were collected and in-situ measurements were carried out using agreed Standard Reference Methods. Laboratory analysis of Total Particulate and Speciated Organic content was conducted by RPS Laboratories Ltd., Salford. Laboratory analysis of Active Pharmaceutical Ingredient content, where required, was conducted by WMI.

This report details the results of air emission monitoring that was completed in 2008 in accordance with the requirements of *Schedule C.1.2 Monitoring of Emissions to Air* of Licence Register No. P0153-05.

Operating information:

The timing of the sample collection was coordinated with WMI staff, to ensure that the relevant process was operating. No further process details were recorded by the sampling staff.

Monitoring deviations:

The monitoring was conducted without difficulty or deviation from the methodologies as stated.

Monitoring results:

Table 1 to Table 4 contain a summary of the monitoring results. Table 5 details the monitoring methodology. Table 6 and Table 7 contain field data relating to Total Particulate sampling and API analysis data respectively.

Table 1 Summary Results and Compliance Status Total Particulate (TP), Active Pharmaceutical Ingredient (API) and Volume Flow (VF)

Emission Point Ref No.	Sample Date	Start time	Duration	Total Part. result (<) mg/Nm3	TP Compliance	Vol flow result Nm3/hr	Vol flow limit Nm3/hr	VF Compliance	Total API Emission result mg/Nm3	API Compliance	Key to notes and acronyms
A2-1	11-Feb-08	15:40:00	30	0.083	c	11575	23472	c	*0.00012*	c	
A2-2	11-Feb-08	14:50:00	30	0.157	c	7773	14256	c	*0.00126*	c	
A2-3	01-May-08	12:20:00	30	0.271	c	6702	10674	c	0.00217	c	
A2-4	17-Jun-08	14:08:00	30	0.181	c	3539	6012	c	0.00144	c	c: Indicates compliance with licence limit
A2-5	03-Feb-08	13:05:00	30	0.122	c	4867	6013	c	*0.00003*	c	
A2-6	03-Apr-08	14:50:00	30	0.442	c	1995	3600	c	*0.00003*	c	nc: indicates non-compliance
A2-7	11-Feb-08	14:05:00	30	0.158	c	4757	6007	c	*0.00004*	c	
A2-8	13-Feb-08	10:12:00	30	0.231	c	12081	14904	c	*0.00014*	c	nmp: no measurement possible
A2-9	13-Feb-08	12:12:00	30	0.172	c	10691	11744	c	*0.00011*	c	
A2-11	11-Feb-08	12:20:00	30	0.131	c	745	2670	c	*0.00003*	c	API results in italics were less than the stated value
A2-12	03-Feb-08	11:50:00	30	0.183	c	732	2670	c	*0.00011*	c	(API level was less than the analytical level of
A2-13	11-Feb-08	10:25:00	30	0.135	c	5201	6007	c	*0.00003*	c	detection)
A2-14	13-Feb-08	11:08:00	30	0.130	c	3066	3067	c	*0.00003*	c	
A2-18	04-Sep-08	15:20:00	30	0.193	c	4049	8496	c	0.00007	c	
A2-20	03-Feb-08	10:40:00	35	0.118	c	404	578	c	*0.00024*	c	
A2-21	03-Apr-08	12:50:00	30	0.935	c	2464	5860	c	0.00021	c	
A2-22	06-Feb-08	14:20:00	30	0.191	c	715	3564	c	*0.00031*	c	
A2-24	16-Jun-08	12:25:00	30	0.145	c	5425	6007	c	*0.00003*	c	
A2-29	06-Feb-08	12:40:00	30	0.313	c	5908	9504	c	*0.00019*	c	
A2-33	24-Jun-08	14:50:00	30	0.157	c	635	1728	c	*0.00126*	c	
A2-34	07-May-08	10:05:00	30	0.148	c	2347	4200	c	0.00022	c	
A2-35	06-Feb-08	13:25:00	30	0.140	c	8534	11744	c	*0.00009*	c	
A2-38	01-May-08	10:50:00	30	0.149	c	1841	4500	c	0.00022	c	
A2-40	30-Apr-08	10:50:00	30	0.196	c	1669	6613	c	0.00029	c	
A2-42	22-Oct-08	17:07:00	30	0.339	c	552	15200	c	0.00051	c	
A2-43	22-Oct-08	15:55:00	30	0.123	c	8226	7916	c	0.00026	c	
A2-77	17-Jun-08	12:25:00	30	0.240	c	3691	578	c	*0.00006*	c	
A2-79	17-Jun-08	09:12:00	30	0.314	c	8069	2350	nc	*0.00008*	c	

Table 2 Summary Results and Compliance Status - Boilers

Air Emision Point (Ref P0153-05)	A1-4	A1-5	A1-6	A1-7	A1-8	A1-10B	A1-11	A1-12
Date	05-Feb	03-Sep	06-Feb	05-Feb	05-Feb	22-Aug	18-Jun	08-Sep
Start time	11:55	11:30:00	09:15:00	13:08	14:10	17:10	11:09	12:30
Duration (min)	30	30	30	30	30	30	30	30
Oxygen	5.31	9.8	9.8	4.7	6.8	10.3	6.6	6.5
NOx (mg/Nm3 @ 5%O_2, dry)	110	134	112	129	55	383	40	68
NOx Licence limit (mg/Nm3 @ 5%O2, dry)	---	---	---	---	---	600	200	200
Compliance	not applicable	not applicable	not applicable	not applicable	not applicable	Compliant	Compliant	Compliant
CO (mg/Nm3 @ 5%O_2, dry)	<10	<10	<10	<10	<10	850	<10	<10
CO Licence limit (mg/Nm3 @ 5%O2, dry)	na	na	---	---	---	2000	100	100
Compliance	not applicable	not applicable	not applicable	not applicable	not applicable	Compliant	Compliant	Compliant
Boiler efficiency (gross)	83.6	80.7	84.9	82.6	82.9	efficiency calc. Not applicable to CHP plant	82.9	80.7

Table 3 Summary Results and Compliance of Quarterly Monitoring at A2-16 and A2-41

Air Emision Point (Ref P0153-05)	A2-16	A2-41	A2-16	A2-41	A2-16	A2-41	A2-41
Quarter	Q1	Q1	Q2	Q2	Q3	Q3	Q4
Sample #	WYN8A16Q1	WYN8A41Q1	wyn8q2a16	wyn8q2a41	wyn8q3a16	wyn8q3a41	wyn8q4a41
Date	12-Feb	12-Feb	16-Apr	08-May	28-Jul	31-Jul	22-Oct
Start time	9:20:00	11:00:00	16:00:00	18:15:00	14:35:00	17:08:00	9:40:00
Duration (min)	60	60	30	30	30	20	30
Duct Volume Flow Nm3/hr	165	165	165	165	165	165	165
TUBE 226-09 Test Cert	WK08-1200 & 8502	WK08-1200 & 8502	wk08-3128 & 8503	wk08-3412 & 8504	wk08-5782 thc	wk08-5782 thc	wk08-7884 thc
Impinger DI water Test Cert	WK08-1199	WK08-1199	WK08-1199	WK08-1199	WK08-1199	WK08-1199	WK08-1199
DCM mg/Nm3	24.45	8.84	8.97	*6.45*	32.68	113.76	9.25
DCM g/hr	4.034	1.459	1.480	1.064	5.392	18.771	1.526
Licence limit R40 Compounds	20 mg/m3 (at mass flows >100g/h)	20 mg/m3 (at mass flows >100g/h)	20 mg/m3 (at mass flows >100g/h)	20 mg/m3 (at mass flows >100g/h)	20 mg/m3 (at mass flows >100g/h)	20 mg/m3 (at mass flows >100g/h)	20 mg/m3 (at mass flows >100g/h)
Compliance	compliant	compliant	compliant	compliant	compliant	compliant	compliant
TA Luft class II mg/Nm3	0.99	0.99	1.76	1.95	2.06	3.08	2.31
TA Luft class II kg/hr	0.0002	0.0002	0.0003	0.0003	0.0003	0.0005	0.0004
Licence limit TA Luft Class II	100 mg/m3 (at mass flows >2kg/h)	100 mg/m3 (at mass flows >2kg/h)	100 mg/m3 (at mass flows >2kg/h)	100 mg/m3 (at mass flows >2kg/h)	100 mg/m3 (at mass flows >2kg/h)	100 mg/m3 (at mass flows >2kg/h)	100 mg/m3 (at mass flows >2kg/h)
Compliance	compliant	compliant	compliant	compliant	compliant	compliant	compliant
MeOH mg/Nm3	992.96	51.87	*49.58*	*59.00*	60.02	90.02	74.44
MeOH kg/hr	0.16	0.01	0.01	0.01	0.01	0.01	0.01
Licence limit TA Luft Class III	150 mg/m3 (at mass flows>3kg/h)	150 mg/m3 (at mass flows>3kg/h)	150 mg/m3 (at mass flows>3kg/h)	150 mg/m3 (at mass flows>3kg/h)	150 mg/m3 (at mass flows>3kg/h)	150 mg/m3 (at mass flows>3kg/h)	150 mg/m3 (at mass flows>3kg/h)
Compliance	compliant	compliant	compliant	compliant	compliant	compliant	compliant
TOC (as C) mg/Nm3	*2.0*	17	1.6	*1.0*	1.3	*1.0*	9.6
Licence limit TOC (as C)	20 mg/m3	20 mg/m3	20 mg/m3	20 mg/m3	20 mg/m3	20 mg/m3	20 mg/m3
Compliance	compliant	compliant	compliant	compliant	compliant	compliant	compliant

Note 1: As the sampling port was unsuitable for velocity measurements, the mass flow results for A2-16 were calculated on the assumption that the volume flow was equal the licence limit of 165 Nm^3/hr (Note: *Schedule B.1 Emissions to Air: Dust Emissions to Air* sets a total combined flow rate of 165m^3/hr for A2-16 and for A2-41). An identical assessment of compliance was used for vent A2-41. This is a worst case volume flow scenario that is based on fan rating, The flow is anticipated to be less due the flow impedance presented by ductwork.

Note 2: No monitoring took place at A2—16 in quarter 4 because the process did not operate.

Table 4 Summary Results and Compliance of Bi-Annual Monitoring at A2-6

Air Emision Point (Ref P0153-05)	A2-6	A2-6
Biannual	BA1	BA2
Sample #	wyn8q2a6	wyn8q4a6
Date	16-Apr	20-Nov
Start time	14:18:00	13:25:00
Duration (min)	10	30
Duct Volume Flow Nm3/hr	1995	1882
TUBE 226-09 Test Cert	3128	8783
Impinger DI water Test Cert	3129	8832
TA Luft Class II mg/Nm3	5	2
TA Luft Class II kg/hr	0.01	0.004
Licence limit TA Luft Class II	100 mg/m3 (at mass flows >2kg/h)	100 mg/m3 (at mass flows >2kg/h)
Compliance	compliant	compliant
TA Luft Class III mg/Nm3	687	391
TA Luft Class III kg/hr	1.37	0.736
Licence limit TA Luft Class III	150 mg/m3 (at mass flows>3kg/h)	150 mg/m3 (at mass flows>3kg/h)
Compliance	compliant	compliant

Part 2 – Supporting information

Methodology:

The following outlines the staff, contractors and methods that were employed.

Site: Sample collection and on site measurements were conducted by Mr Nicholas Kenny, SiteRIGHT Environmental.

Analysis: Gravimetric analysis of Total Particulate conducted by RPS Laboratories Ltd., Waters Edge Business Park, Modwen Road, Salford, M5 3EZ, UK.

API analysis conducted by WMI Environmental Laboratory (refer to Table 7).

Table 5 Monitoring Methodology

Method ID	Determinant	Details
SR102	Volume flow rate	Pitot tube and manometer based on I.S. EN 13284 Part 1.
SR103	Total Particulate	Samples collection using the Sick Gravimat based on I.S. EN 13284 Part 1. Analysis using laboratory practice that is ISO 17025 accredited for gravimetric analysis to I.S. EN 13284 Part 1, (nb. The weighing of the gravimat sampling head is not covered in the scope of the laboratory's accreditation).
SR 104a	Combustion products	Measurements using Horiba PG250 which is MCERTS certified by SIRA (Certificate No: Sira MC 050056/00). A MAK 10 gas conditioning unit with heated line and sintered particulate filter was employed upstream of the PG250. The methodologies were based on the following standard methods and measurement techniques: a. I.S. EN 14789 (to be confirmed) -- Oxygen (Galvanic cell) b. I.S. EN 14792 -- Nitrogen oxides (Chemiluminescence) c. ARM for I.S. EN 14791 -- Sulphur dioxide (NDIR) d. I.S. EN 15058 -- Carbon monoxide (NDIR)
SR 105	Speciated Organics	Samples were adsorbed onto charcoal and into DI water impingers. UKAS accredited analysis of the tube fraction by GCFID was in accordance with I.S. EN 13649. Accredited analysis of the impinger fraction by GCFID.
Summary details and full references for the Irish Standard methods list above are available from www.standards.ie Current details of RPS Laboratories Ltd., ISO 17025 accreditation can be found by searching for laboratory number 0605 on the UKAS website		

Table 6 Field Data - Total Particulate Determination (including sampling location compliance with IS EN 13284)

Emission Point Ref No.	Nozzle ID	Sample Date	Start time	Duration	com file	# pt VT	# pt ext	duct X section m2	Duct flow VT result	ext volume Nm3 dry	Duct flow EXT result	Min Pdyn >.05mb ar	angle gas within 15o of duct axis	No negative flow	ratio high/low velocity < 3	Total dust Lab result (<) mg on filter	Lab report ID	Total Part. result (<) mg/Nm3
A2-1	8, 0332	11-Feb-08	15:40:00	30	wyn8A1	0	1	0.32	10897	1.209	11575	ok	ok	ok	ok	0.1	1193	0.083
A2-2	6, 4330	11-Feb-08	14:50:00	30	wyna8A2	0	1	0.196		0.635	7773	ok	ok	ok	ok	0.1	1193	0.157
A2-3	4,2 331	01-May-08	12:20:00	30	wyn8A35	1	1	0.126	8200	0.369	6702	ok	ok	ok	ok	0.1	3130	0.271
A2-4	5,2 330	17-Jun-08	14:08:00	30	wyn8A4	1	1	0.07	4252	0.554	3539	ok	ok	ok	ok	0.1	4380	0.181
A2-5	6, 4331	03-Feb-08	13:05:00	30	wyn8A5		1	0.095		0.819	4867	ok	ok	ok	ok	0.1	1193	0.122
A2-6	10,0 332	03-Apr-08	14:50:00	30	wyn8A6	1	1	0.08		0.746	1995	ok	ok	ok	ok	0.33	3130	0.442
A2-7	5, 2327	11-Feb-08	14:05:00	30	wyn8A7	1	1	0.08	5063	0.631	4757	ok	ok	ok	ok	0.1	1193	0.158
A2-8	4, 2333	13-Feb-08	10:12:00	30	wyn8A8	0	1	0.196		0.433	12081	ok	ok	ok	ok	0.1	1193	0.231
A2-9	4, 2331	13-Feb-08	12:12:00	30	wyn8A9	0	1	0.126		0.583	10691	ok	ok	ok	ok	0.1	1193	0.172
A2-11	8, 0332	11-Feb-08	12:20:00	30	wyna8A11	0	1	0.018		0.765	745	ok	ok	ok	ok	0.1	1193	0.131
A2-12	8,0 334	03-Feb-08	11:50:00	30	wyn8A12	0	1	0.017		0.547	732	ok	no	ok	ok	0.1	1193	0.183
A2-13	11, 5331	11-Feb-08	10:25:00	30	wyn8A13	1	1	0.196		0.743	5201	no	ok	ok	ok	0.1	1193	0.135
A2-14	10, 331	13-Feb-08	11:08:00	30	wyn8A14	0	1	0.1256		0.767	3066	ok	ok	ok	ok	0.1	1193	0.130
A2-18	6,4 330	04-Sep-08	15:20:00	30	wyn8A18R	4	4	0.126	3829	0.517	4049	ok	ok	ok	ok	0.1	6573	0.193
A2-20	10, 0334	03-Feb-08	10:40:00	35	wyn8A20	0	1	0.049	404	0.845	1058	ok	ok	ok	ok	0.1	1193	0.118
A2-21	11,5 330	03-Apr-08	12:50:00	30	wyn8A21	0	4	0.049		0.706	2464	ok	ok	ok	ok	0.66	3130	0.935
A2-22	11, 5333	06-Feb-08	14:20:00	30	wyn8A22	0	1	0.071		0.523	715	no	ok	ok	ok	0.1	1193	0.191
A2-24	8,0 330	16-Jun-08	12:25:00	30	wyn8A24	0	4	0.196		0.692	5425	ok	ok	ok	ok	0.1	4380	0.145
A2-29	5, 2332	06-Feb-08	12:40:00	30	wyn8A29	0	4	0.126		0.32	5908	ok	ok	ok	ok	0.1	1193	0.313
A2-33	6,4 330	24-Jun-08	14:50:00	30	wyn8a33R	0	1	0.015		0.636	635	ok	ok	ok	ok	0.1	4681	0.157
A2-34	10,0 330	07-May-08	10:05:00	30	wyn8A34	1	1	0.081	2347	0.675		ok	ok	no	ok	0.1	3410	0.148
A2-35	5, 2330	06-Feb-08	13:25:00	30	wyn8A35	0	4	0.196		0.712	8534	ok	ok	ok	ok	0.1	1193	0.140
A2-38	11,5 331	01-May-08	10:50:00	30	wyn8A38	4	4	0.166	1841	0.671	2003	ok	ok	ok	ok	0.1	3130	0.149
A2-40	6,4 332	30-Apr-08	10:50:00	30	wyn8A40	1	1	0.05	1669	0.511	1585	ok	no	ok	ok	0.1	3130	0.196
A2-42	10.0 330	22-Oct-08	17:07:00	30	wyn8A42	1	1	0.05	552	0.295	533	ok	ok	ok	ok	0.1	7883	0.339
A2-43	6,4 331	22-Oct-08	15:55:00	30	wyn8A43	4	4	0.16	8226	0.814	8112	ok	ok	ok	ok	0.1	7883	0.123
A2-77	6,4 331	17-Jun-08	12:25:00	30	wyn8A77	4	4	0.125	3807	0.417	3691	ok	no	ok	ok	0.1	4380	0.240
A2-79	5,2 333	17-Jun-08	09:12:00	30	wynA79	0	4	0.273		0.318	8069	ok	ok	ok	ok	0.1	4380	0.314

Table 7 Analytical Results of Active Pharmaceutical Ingredient Analysis

Emission Point Ref No.	API Lab report ID	Tranquiliser Oxazepam	Tranquiliser Lorazepam	Tranquilsier Lormetazepam	API Congugated Estrogens (ug/filter)	API Venlafaxine (ug/filter)	API Ethinylestradiol (ug/filter)	API Gestodene (ug/filter)	API Norgestrel (ug/filter)	Total API (ug/filter)	Total API Emission result mg/Nm3
A2-1	16/04/2008					*0.15*				*0.150*	*0.00012*
A2-2	16/04/2008	*0.2*	*0.2*	*0.4*						*0.800*	*0.00126*
A2-3	19/06/2008	*0.2*	*0.2*	*0.4*						0.800	0.00217
A2-4	16/09/2008	*0.2*	*0.2*	*0.4*						0.800	0.00144
A2-5	16/04/2008				*0.024*					*0.024*	*0.00003*
A2-6	19/06/2008				*0.024*					*0.024*	*0.00003*
A2-7	16/04/2008				*0.024*					*0.024*	*0.00004*
A2-8	16/04/2008						*0.017*	*0.020*	*0.025*	*0.062*	*0.00014*
A2-9	16/04/2008						*0.017*	*0.020*	*0.025*	*0.062*	*0.00011*
A2-11	16/04/2008				*0.024*					*0.024*	*0.00003*
A2-12	16/04/2008						*0.017*	*0.020*	*0.025*	*0.062*	*0.00011*
A2-13	16/04/2008				*0.024*					*0.024*	*0.00003*
A2-14	16/04/2008				*0.024*					*0.024*	*0.00003*
A2-18R	31/10/2008						*0.004*	0.018	*0.012*	0.034	0.00007
A2-20	16/04/2008					0.2				0.200	*0.00024*
A2-21	19/06/2008					*0.15*				0.150	0.00021
A2-22	16/04/2008					0.16				0.160	*0.00031*
A2-24	16/09/2008				*0.024*					0.024	*0.00003*
A2-29	16/04/2008						*0.017*	*0.020*	*0.025*	*0.062*	*0.00019*
A2-33R	16/09/2008	*0.2*	*0.2*	*0.4*						0.800	*0.00126*
A2-34	19/06/2008					*0.15*				0.150	0.00022
A2-35	16/04/2008						*0.017*	*0.020*	*0.025*	*0.062*	*0.00009*
A2-38	19/06/2008					*0.15*				0.150	0.00022
A2-40	19/06/2008					*0.15*				0.150	0.00029
A2-42	08/12/2008					*0.15*				*0.150*	0.00051
A2-43	08/12/2008					0.215				0.215	0.00026
A2-77	16/09/2008				*0.024*					0.024	*0.00006*
A2-79	16/09/2008				*0.024*					0.024	*0.00008*

Appendix 3

Noise Monitoring Report - 2008

ENVIRONMENTAL NOISE SURVEY

WYETH MEDICA IRELAND

May 2008

REPORT 28126

♦ANV Technology, Clonroad, Ennis, Co. Clare ♦
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ANV Technology **Report 28126**

Environmental Noise Survey - Wyeth Medica Ireland
May 2008

SUMMARY

This noise survey was commissioned by Wyeth Medica Ireland (WMI) to monitor compliance with the noise limits assigned in Licence Register No. P0153-05 from the Environmental Protection Agency.

Schedule B.4 of the licence sets a daytime noise limit of 55 dB(A), and a night-time noise limit of 45 dB(A) at noise sensitive locations. In addition, there shall be no clearly audible tonal or impulsive noise component in the noise emission from the activity at any noise sensitive location. The measured specific noise levels attributable to WMI are presented in Figure 1.

Daytime
At houses N1, N2, N3, the WMI plant noise level was <48, <42 and 43 dB(A) respectively, and in compliance with the daytime noise limit of 55 dB(A).

At house N4, noise from WMI was not audible or detectible, and was determined to be less than 55 dB(A), and in compliance with the daytime limit.

Night-time
At house N1, the component of WMI noise was less than the measured L_{A90} steady noise level of 46 dB(A). The WMI noise was potentially up to 5 dB lower how is this determined – guess estimate?, and consequently in compliance with the 45 dB(A) limit.

At house N2, a steady industrial noise component of 47 dB(A) was detected. However this was due mainly to noise from a neighbouring commercial site. Noise from WMI was audible at a lower level. The component of WMI noise was potentially up to 5 dB lower, and therefore in compliance with the noise limit of 45 dB(A).

The component of WMI noise at houses N3 and N4 were 35 dB(A) and 45 dB(A) respectively, and in compliance with the Night-time noise limit of 45 dB(A).

There was no clearly audible tonal or impulsive component in the noise at the noise sensitive locations.

Boundaries

Boundary noise levels were also measured to identify any significant changes in noise emissions since the previous survey in 2007. Measured specific night-time noise levels at the boundary ranged from <44 dB(A) to 50dB(A). There was no significant change since the previous survey in 2007, apart from boundary B5, where there was an increase of 6dB. This was due to noise from a neighbouring commercial site.

Report Originator: Colin Doyle M.Sc. MIOA
Reviewer: Bridget Ginnity Dip. Acoustics M.Sc. MIOA MFOH MICI
Report issued: 21/05/2008

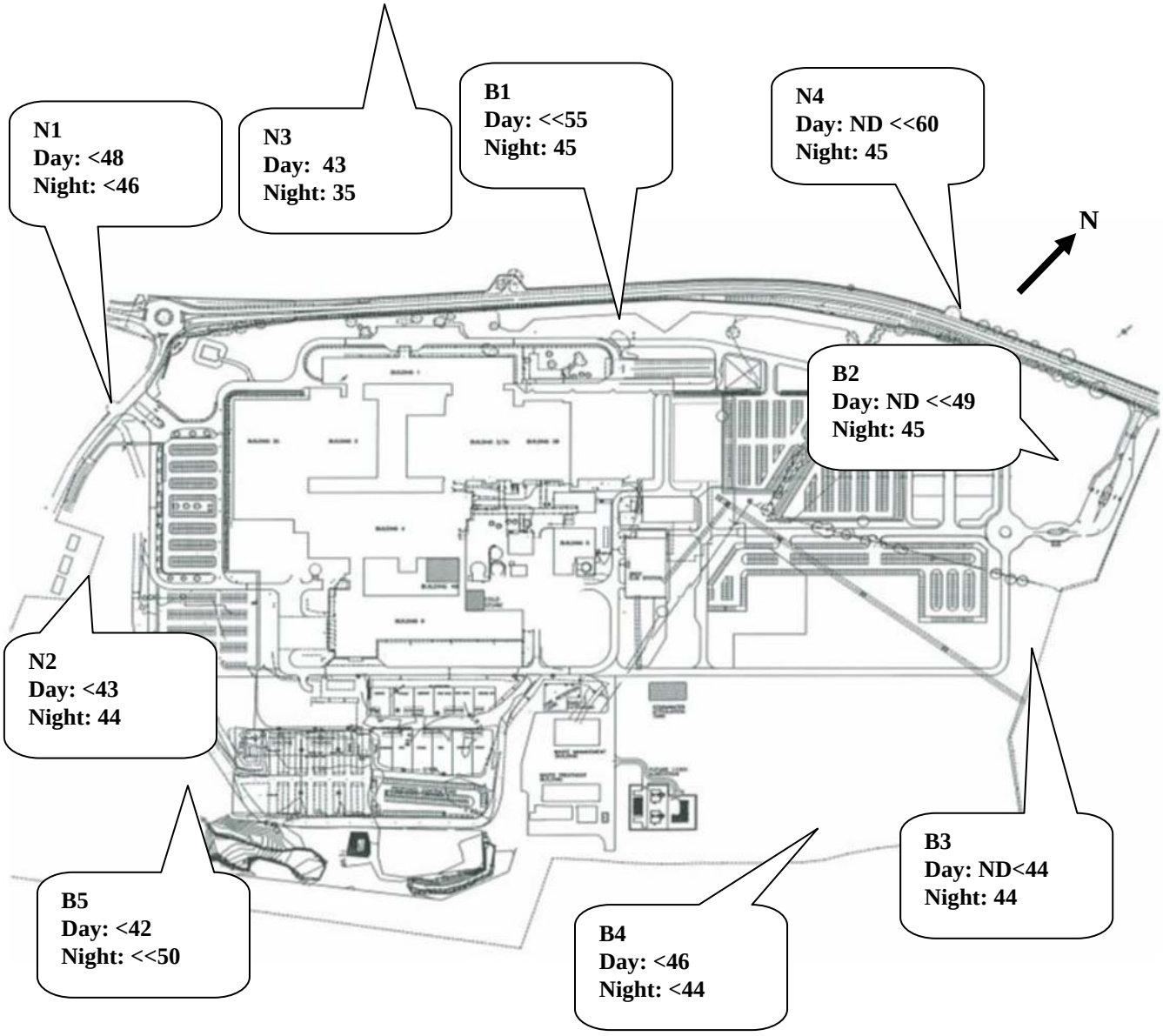

Figure S1. Summary of measured specific noise levels in dB(A), May 2008 **.**
ND = not detectible; B = Boundary location; N = Noise sensitive location - residential dwelling.

ANV Technology Report 28126

Environmental Noise Survey - Wyeth Medica Ireland
May 2008

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TABLES & FIGURES

♦ANV Technology, Clonroad, Ennis, Co. Clare ♦
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Environmental Noise Survey, May 2008
Wyeth Medica Ireland

1 INTRODUCTION

This noise survey was commissioned by Wyeth Medica Ireland (WMI) to monitor compliance with the noise limits set in Integrated Pollution Prevention Control (IPPC) Licence Register No. P0153-05 from the Environmental Protection Agency (EPA).

Schedule B.4 of the licence sets a noise limit of 55dB(A) by day and 45dB(A) by night at noise sensitive locations ($L_{eq,30minutes}$). In addition, there shall be no clearly audible tonal or impulsive noise component in the noise emission from the activity at any noise sensitive location.

The survey consisted of measurement of noise levels at the nearest noise sensitive locations by day and by night. Included also were measurements at plant boundary locations, by day and by night. The daytime survey was carried out on the 07/05/08. The night-time survey was carried out on the 07-08/05/08.

2 MEASUREMENT DETAILS

2.1 METHODOLOGY

The survey methodology followed the EPA "Environmental Noise Survey Guidance Document" (2003), EPA "Guidance Note for Noise in Relation to Scheduled Activities" (2006), and ISO 1996 "Description and measurement of environmental noise".

The measurement duration at each location was 30 minutes during both daytime and night-time. A summary of noise terminology is given in Appendix A.

Noise measurements and reporting were performed by Colin Doyle M.Sc. MIOA of ANV Technology Ltd., and reviewed by Bridget Ginnity M.Sc. MIOA Dip. Acoustics of ANV Technology Ltd.

2.2 MEASUREMENT LOCATIONS

Five boundary measurement locations and four house locations were measured, as indicated in Figure 1, and described in Table 1.

Location	Description
Houses	
N1	House opposite main entrance to WMI site
N2	Adjoining house, near main WMI site entrance, measured inside WMI site at rear boundary wall
N3	Old Connell House, measured at house entrance gate; noise propagation to house calculated
N4	Houses at Old Connell Stud
Boundaries	
B1	North west boundary, opposite Old Connell House entrance
B2	Northern boundary, on WMI embankment adjacent rear site entrance
B3	North east boundary, at WMI embankment in line with farmhouse
B4	Eastern boundary
B5	Southern boundary, rear of WMI plant, near LIDL, at edge of contractors compound

Table 1. Noise measurement locations

2.3 MEASUREMENT AND ASSESSMENT PARAMETERS

At each noise measurement location, the 30-minute average noise level was measured ($L_{Aeq,30mins}$), along with the statistical parameters: $L_{A90,}$ L_{A50}, and L_{A10} . These parameters are defined in Appendix A.

The noise limits in the WMI IPPC licence refer to the noise emitted from the licensed activity. This component of the noise is termed the "specific noise". The measured total noise level includes the specific noise, and also noise from other sources, such as traffic. The other noise sources are termed the "residual noise".

Total Noise = Residual Noise + Specific Noise

L_{Aeq} (total) = L_{Aeq} (residual) + L_{Aeq} (specific)

During the survey the specific noise levels due to noise emissions from WMI were estimated, based on the noise level statistics, and examination of the noise levels logged at 10 second intervals (noise profile). The method of determining the specific noise level is summarised in Table 2.

Description of Noise	**Parameter best representing specific noise from plant**
Plant noise dominant, no other significant noise sources	L_{Aeq}
Intermittent interfering noise (e.g. birds, traffic, wind), with underlying plant noise audible	L_{A50} if plant noise slowly varying and clearly audible, with occasional interference from other noise sources $L_{A90,}$ if plant noise is steady and clearly audible in lulls
Plant barely audible (i.e. not immediately noticeable, unless actively listening)	< L_{A90} (up to 5 dB lower)
Plant not audible	Not Detectible (ND) <<L_{A90} (more than 5 dB lower than L_{A90})
The plant specific noise is established during the survey by correlating the live sound level meter readings with the audible sounds, as described above. The plant specific noise is verified, where necessary, by examining the profile of logged noise levels.	

Table 2. Methodology for determination of plant specific noise

Noise Propagation Calculations

There is no public access to Old Connell House, N3. The plant specific noise level at this house was calculated using a standard noise propagation model, based on the measured WMI plant noise level at the entrance gate to N3.

The propagation calculation was in accordance with ISO 9613 "Attenuation of sound during propagation outdoors", and allowed for noise attenuation due to distance, ground absorption, and atmospheric absorption. The calculated attenuation between the measurement position and the house was 11 dB.

2.4 MEASUREMENT DETAILS AND CONDITIONS

The survey condition and instrumentation used are detailed in Table 3. The sound level meter calibration was checked before and after measurement

Survey Conditions					
Survey period	Daytime	07/05/08			
	Night-time	07/05/08 – 08/05/08			
Weather conditions	Daytime	11:00 - 16.30 Dry, light westerly breeze (Beaufort 2), 24 C, humidity 26%			
	Night-time	22:00 – 01:45 Dry, light southerly breeze (Beaufort 1), 17 C, humidity 40%			
Measurement period	30 minutes at each location				
Plant Operating Conditions	WMI operates on a 24 hour basis, and noise emissions are steady throughout the day and night.				
Survey Personnel	Colin Doyle M.Sc. MIOA of ANV Technology				
Instrumentation Details					
Manufacturer	**Instrument**	**Calibrated by**	**Calibration reference**	**Last Laboratory Calibration**	
Svantek	SLM 947 (Type 1) serial no. 5283	AV Calibration	0611502	13/11/06	
Svantek	SLM 949 (Type 1) serial no. 8183	AV Calibration	No. 0709324	03/09/07	
Castle	Calibrator GA 607 serial no. 040520	AV Calibration	No. 0708323	31/8/07	
In accordance with EPA guidance, sound measurement instrumentation is calibrated at a certified laboratory every two years. Laboratory calibrations for the ANV Technology instrument stock is staggered, so that at any time there is always one instrument which is no more than one year from primary laboratory calibration. Regular comparison calibrations are carried out in-house between instruments to verify that there is no drift in calibration.					

Table 3. Survey Conditions and instrumentation details

3 RESULTS

3.1 NOISE LEVELS AT HOUSES AND BOUNDARIES

The specific noise levels determined at houses and plant boundaries are summarised in Table 4 below. Detailed measurement results are presented in Table 5.

Location	Description	Specific Noise Level [1] dB(A)	
		Daytime	Night-Time
Houses			
N1	House opposite main entrance	<48	<46
N2	Adjoining house, near main entrance	<42	<47
N3	Old Connell House	43	35
N4	Houses at Old Connell Stud	ND <<60	45
Boundaries			
B1	North west, opposite Old Connell House entrance	ND <<55	45
B2	Northern boundary, on embankment adjacent rear site entrance	ND <<49	45
B3	North east, at embankment in line with farmhouse	<44	44
B4	Eastern boundary	<46	<44
B5	Southern boundary, rear of plant, near LIDL. Taken at edge of contractors compound	ND <42	ND <<50

Table 4. Specific Noise Levels, WMI, May 2008.
[1] The Specific Noise Level is the noise level attributable to WMI
ND = not detectable

Location	Date	Time	Measured Noise Level dB(A)					Description of noise environment
			$L_{Aeq\ 30mins}$	L_{A90}	L_{A50}	L_{A10}	Specific [1]	
DAYTIME								
Houses								
N1	07/05/08	15:05	58	48	54	62	**<48**	Traffic, birds, WMI barely audible
N2	07/05/08	12:30	51	42	46	52	**<42**	Birds, traffic, WMI barely audible
N3	07/05/08	15:10	65	54	62	68	**ND 43** [2]	Traffic, WMI not audible
N4	07/05/08	15:40	72	60	69	76	**ND <<60**	Traffic, WMI not audible, L_{Amin}=47 dB(A)
Boundaries								
B1	07/05/08	13:20	61	55	60	64	**ND <<55**	Traffic, lawnmower, WMI not audible
B2	07/05/08	13:35	53	49	52	55	**ND <<49**	Traffic, birds, WMI not audible
B3	07/05/08	13:55	49	44	47	52	**<44**	Birds, plant traffic, distant traffic, WMI barely audible
B4	07/05/08	14:00	49	46	47	50	**<46**	Birds, noise from neighbouring commercial site, WMI barely audible
B5	07/05/08	12:20	45	42	44	47	**ND <42**	Vehicles in construction compound, distant traffic, WMI not audible
NIGHT-TIME								
Houses								
N1	07/05/08	00:10	58	46	49	59	**<46**	Traffic, WMI audible at low level
N2	07/05/08	22:55	50	47	49	51	**<47**	Traffic, noise from neighbouring commercial site, WMI just audible
N3	08/05/08	00:50	57	46	48	59	**35** [2]	Traffic, WMI audible at low level
N4	08/05/08	00:55	66	45	54	68	**45**	Traffic, WMI audible at low level
Boundaries								
B1	07/05/08	23:30	57	45	49	61	**45**	Traffic, WMI audible at low level
B2	07/05/08	23:50	53	45	50	57	**45**	Traffic, WMI audible at low level
B3	07/05/08	22:00	46	44	46	47	**44**	WMI audible at low level, distant traffic, neighbouring commercial site, birds
B4	07/05/08	22:05	46	44	46	48	**<44**	WMI audible at low level, neighbouring commercial site
B5	07/05/08	22:50	52	50	52	53	**<<50**	Noise from neighbouring commercial site, WMI not audible

Table 5. Measured noise levels, WMI, May 2008

[1] specific noise component attributable to WMI. ND = not detectable.

[2] Calculated noise level at Old Connell House in accordance with ISO 9613. The steady WMI noise level at the entrance gate was <<54 dB(A) during daytime, and 46 dB(A) at Night-time. This extrapolates to <43 dB(A) at the house during daytime, and 35 dB(A) at Night-time.

3.2 TONAL AND IMPULSIVE ANALYSIS

Subjectively the noise was broadband in character at all residential locations. There were no audible tones or impulsive sounds audible from WMI. The noise emissions were continuous in character, with no audible impulsive content.

Measured noise spectra (night-time) at site boundaries and at house locations are shown in Appendix B.

The 1/3 octave analysis of the noise at the houses showed no significant peaks. At house N2, there was a spectrum feature at a frequency of 80Hz. This emanated from a neighbouring commercial site, and was not noticeably tonal. At the entrance gate to house N3, there was a spectrum feature at a frequency of 200Hz. This was not noticeably tonal. The house is located approximately 250m to the northwest of the measurement position at the entrance gate. Allowing for the attenuation of sound over the intervening distance, which has been calculated to be 11 dB, there would be no audible tonal noise at the house.

4 COMPLIANCE WITH WMI IPPC LICENCE NOISE LIMITS

Schedule B.4 of the licence Register No. P0153-05 sets a daytime noise limit of 55 dB(A), and a night-time noise limit of 45 dB(A) at noise sensitive locations, and requires that there be no clearly audible tonal or impulsive noise component.

Daytime
At houses N1, N2, N3, the daytime specific WMI plant noise level was <48, <42 and 43 dB(A) respectively, and in compliance with the daytime noise limit of 55 dB(A).

At house N4, noise from WMI was not audible or detectible by measurement, due to interference from traffic noise. The specific noise from WMI was therefore at least (was potentially up to??) 5 dB lower than the measured L_{A90} steady noise level, which was 60 dB(A). This indicates that the noise from WMI was less than 55 dB(A). During the measurement, the minimum noise level noted was 47 dB(A) L_{Amin}. As noise from WMI was not audible on any occasion, it is unlikely to exceed 47 dB(A). The noise from WMI at N4 was therefore in compliance with the daytime limit of 55 dB(A).

Night-time
At Night-time, the specific plant noise levels at the houses N3 and N4 were 35 dB(A) and 45 dB(A) respectively, and in compliance with the Night-time noise limit of 45 dB(A).

At house N1, the component of WMI noise was less than the measured L_{A90} steady noise level of 46 dB(A). The WMI noise was potentially up to 5 dB lower, and consequently in compliance with the 45 dB(A) limit.

At house N2, a steady industrial noise component of 47 dB(A) was detected. However this was due mainly to noise from a neighbouring commercial site. Noise from WMI was audible at a lower level. The component of WMI noise was potentially up to 5 dB lower, and therefore in compliance with the noise limit of 45 dB(A).

Tonality/Impulsiveness
There was no clearly audible tonal or impulsive component in the noise at the noise sensitive locations.

5 COMPARISON WITH PREVIOUS SURVEYS

The results of noise surveys at WMI from 2000 to 2008 are presented in Table 6, and in Figure 1. The historical comparison is confined to Night-time specific noise levels, due to the difficulty detecting plant noise during the daytime surveys.

Changes of a few dB can typically be expected from survey to survey, due to differing wind and atmospheric propagation conditions, measurement precision, and variations in WMI plant production conditions.

Noise levels at the house locations in 2008 were generally similar (+/- 1dB) to the previous ANV survey conducted in 2007, and were consistent with the historical data measured since 2000. However, house location N2 showed an increase in measured industrial noise level of 3 dB. This was due to noise from a neighbouring commercial site. The component of WMI noise was not directly measurable, and was estimated to be less than 47 dB(A).

Specific noise levels at boundary positions B1 to B4 were similar to levels measured in 2007. The noise level at boundary B5 increased by 6 dB to a level of 50 dB(A). This was due to noise from a neighbouring commercial site. Noise from WMI was not audible or detectible at this position, and was consequently significantly less than 50 dB(A).

Location	WMI Specific Noise Level at Night-time dB(A)								
	Nov 2000	May 2001	Jul 2002	Nov 2003	Apr 2004	Feb 2005	Aug 2006	May-2007	May 2008
Houses									
N1	44	44	41	40	44	40	40	38	<46
N2	42	42	40	<38	41	37	<41	44	<47
N3	43	40	34	35	37	36	35	37	35
N4	-	-	-	-	-	-	45	45	45
Boundaries									
B1	-	-	-	46	50	50	45	47	45
B2	55	51	44	52	50	50	45	46	45
B3	-	-	-	51	50	50	<46	46	44
B4	53	52	50	49	46	46	47	45	<44
B5	< 49	< 43	41	<47	<44	<44	48	44	ND <<50

Table 6. Comparison of night-time specific noise levels, 2000 to 2008

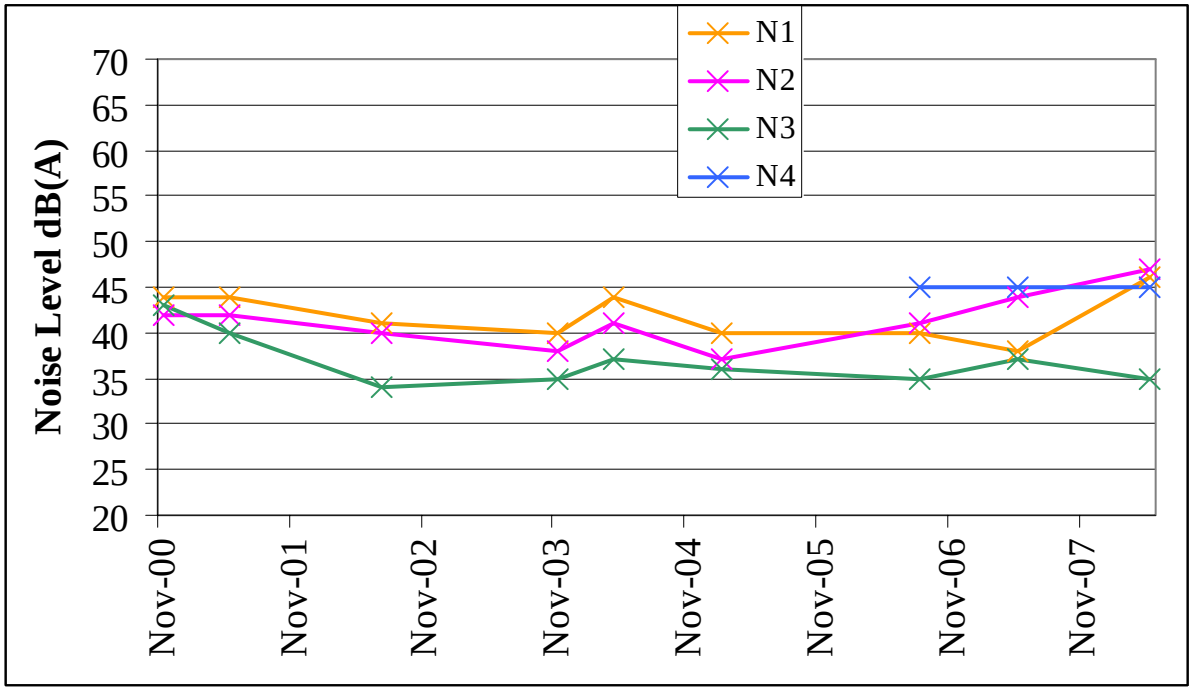


Figure 1. Variation of specific noise levels at nearest houses to WMI, from 2000 to 2008

APPENDIX A - TERMINOLOGY

dB(A) a logarithmic noise scale, called the decibel. The "A" indicates that a frequency weighting has been applied to take account of the variation in the sensitivity of the human ear as a function of frequency.

L_{Aeq} the average noise level during the measurement period. It includes all noise events. The L_{Aeq} value has been found to correlate well with human tolerance of noise, and is the value normally used in setting and monitoring industrial noise limits.

L_{A90} the noise level exceeded for 90% of the time. It is generally taken as being representative of the steady background noise at a location. It tends to exclude short events such as cars passing, dogs barking, aircraft flyovers etc., and provides a good estimation of steady plant noise, when there is significant interference from other noise sources

L_{A50} the noise level exceeded for 50% of the time. This statistical parameter provides a good estimation of plant noise, when there is occasional intermittent interference from other noise sources

L_{A10} the noise level exceeded for 10% of the time, and is a measure of the higher noise levels present in the ambient noise

L_{AS}, L_{AF} the live displayed noise level, updated at 1 second intervals, measured with the instrument's response time set to standardised "Slow" or "Fast" response. The live meter reading provides survey personnel with corroborative data for determining the noise level due to a specific audible sound source. The highest value measured is termed L_{Amax}, and the lowest level detected is termed $L_{Amin.}$

Total Noise the overall noise level (L_{Aeq}), due to all noise noises (also termed ambient noise)

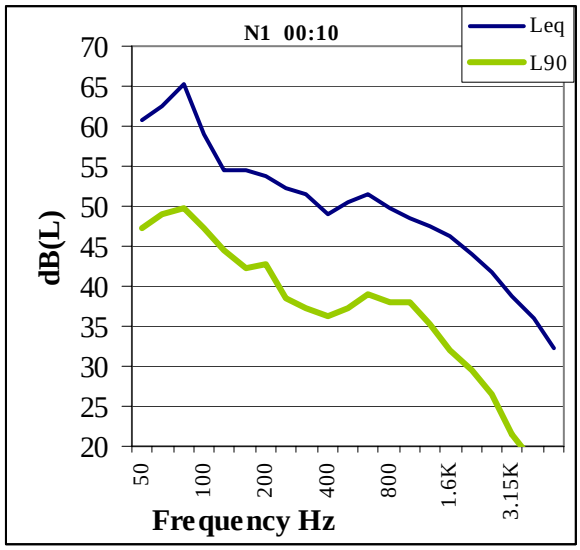
Specific Noise a component of the total noise that can be quantified and attributed to a specific source.

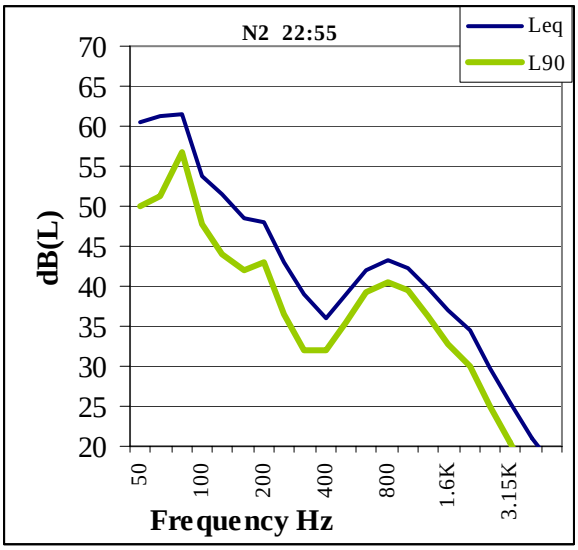
Residual Noise the noise level that would exist in the absence of the specific noise source

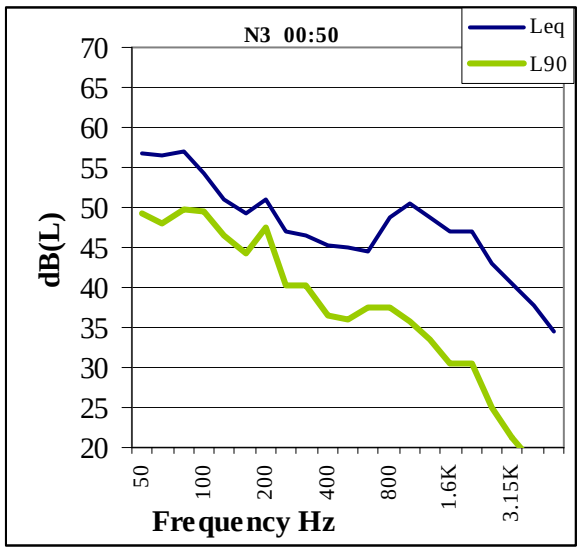
Noise Profile noise level logged at short intervals (10 second intervals in this survey).

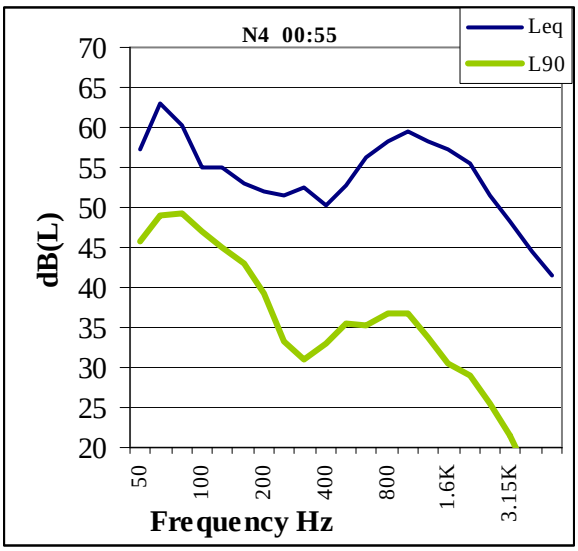
APPENDIX B - ADDITIONAL DATA

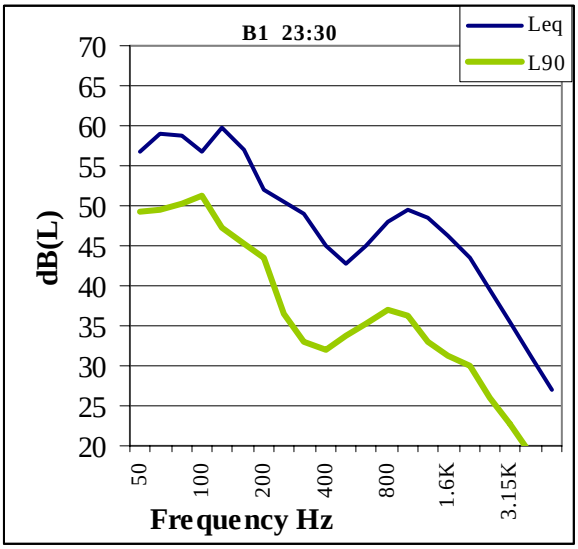
B.1 NIGHT-TIME NOISE SPECTRA

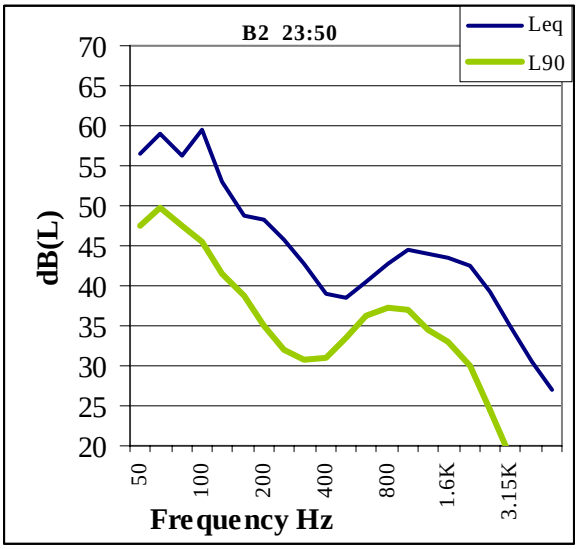


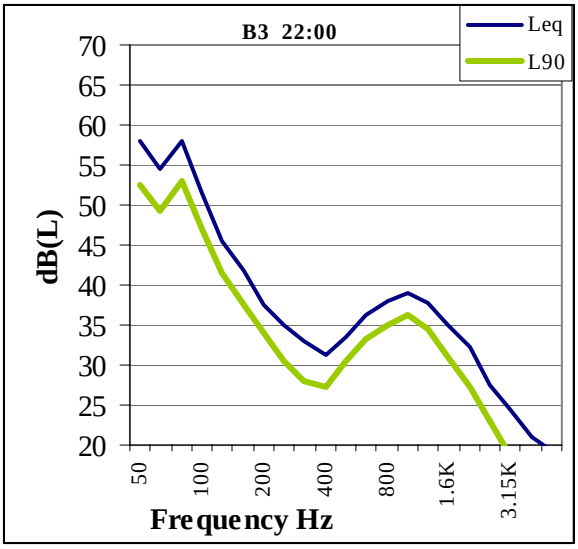


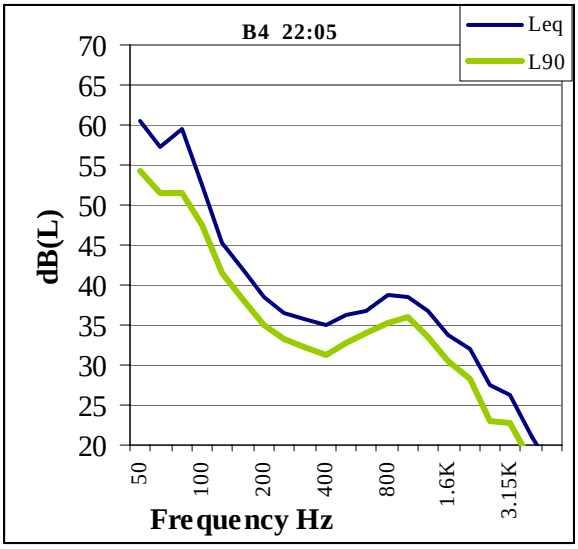


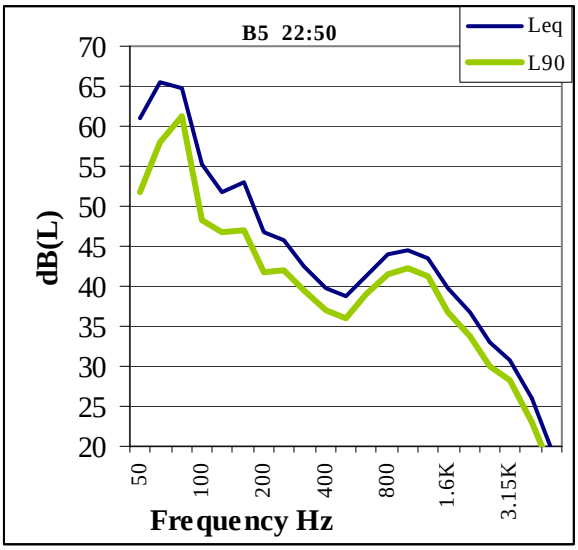



B1 23:30
Leq
L90
dB(L)
70
65
60
55
50
45
40
35
30
25
20
50
100
200
400
800
1.6K
3.15K
Frequency Hz


B2 23:50
Leq
L90
dB(L)
70
65
60
55
50
45
40
35
30
25
20
50
100
200
400
800
1.6K
3.15K
Frequency Hz


B3 22:00
Leq
L90
dB(L)
70
65
60
55
50
45
40
35
30
25
20
50
100
200
400
800
1.6K
3.15K
Frequency Hz


B4 22:05
Leq
L90
dB(L)
70
65
60
55
50
45
40
35
30
25
20
50
100
200
400
800
1.6K
3.15K
Frequency Hz


B5 22:50
Leq
L90
dB(L)
70
65
60
55
50
45
40
35
30
25
20
50
100
200
400
800
1.6K
3.15K
Frequency Hz

B.2 LABELLING SCHEME

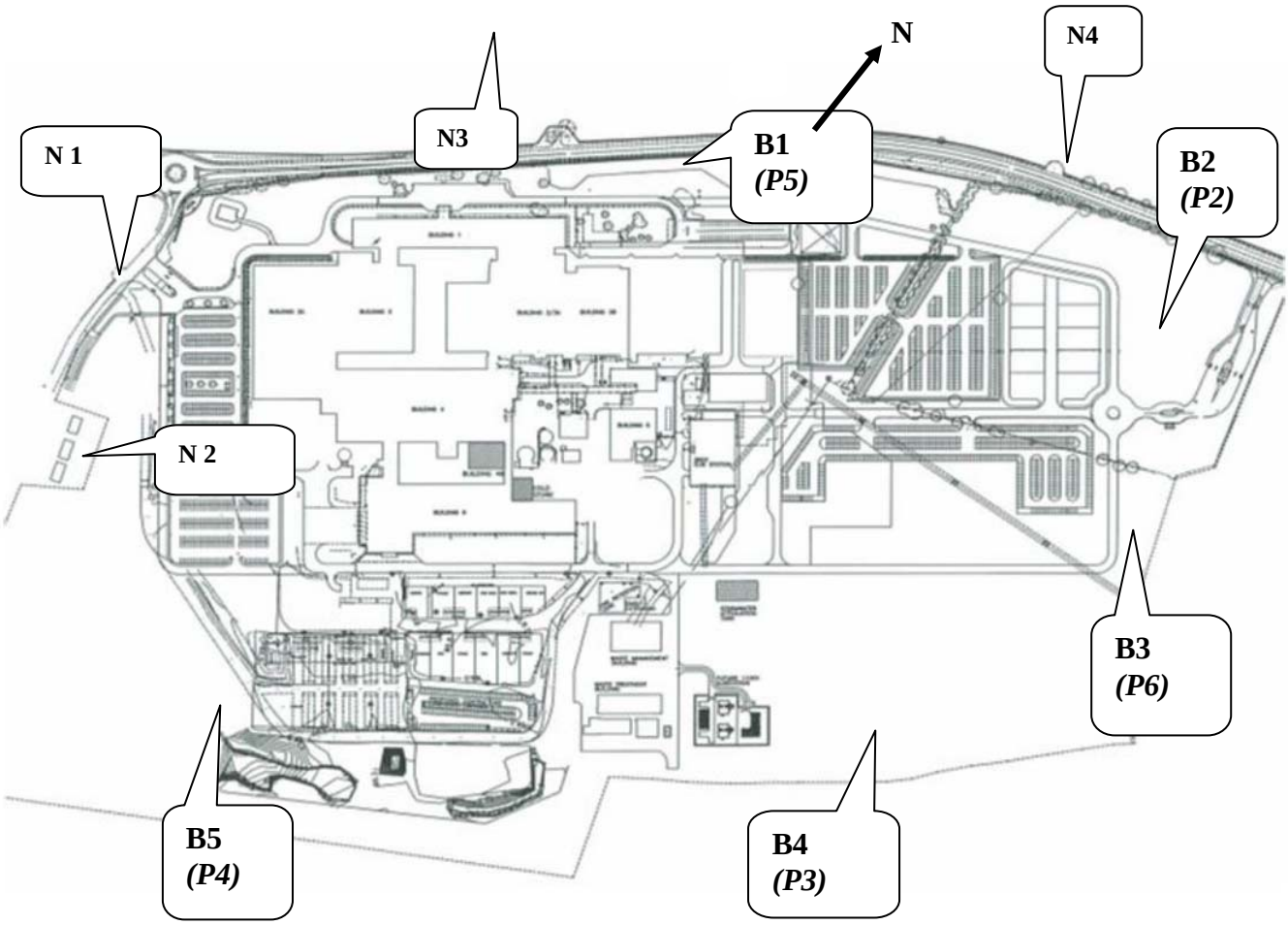


Figure B.1 Noise measurement locations. Houses: N1 to N4. Boundaries: B1 to B5 (labelled P2 to P6 in reports up to 2006)

Noise surveys have been conducted at the site since 1998. Due to building developments at the WMI site over the years, the measurement positions were adjusted as necessary in the annual surveys to best detect noise emissions from the extended plant, and additional positions were also added. This resulted in a non-sequential labelling of the boundary measurement positions. In 2007 the boundary measurement positions were re-labelled B1 to B5, in clockwise sequence around the plant boundary. The labelling of noise sensitive locations N1 to N4 has remained the same.

Appendix 4

Waste Analysis Strategy

A4.1 Analysis Overview

The WMI approach to comply with the requirement of *Schedule C.4 Waste Monitoring* of Licence Register P0153-05 was verbally agreed with the Agency during the Site Inspection of 15/04/2004 and subsequently confirmed in Agency correspondence of 19/08/2005 (EPA Reference: M673/ap16bk). The original sampling strategy, which was submitted in Appendix 5 of the 2005 AER, has been modified as outlined herein to reflect the updated practices adopted in 2008 (text outlined in ***bold italics*** throughout the strategy has been modified from the 2007 waste analysis strategy previously submitted to the Agency in the 2007 AER).

Table A4.1: Waste Characterisation Strategy

Waste Type	Frequency	Parameter	Method
Pharmaceutical Waste – Solid	Per consignment	Full Characterisation	Material Records
Pharmaceutical Waste – Liquid	Bi-annual	Full Characterisation – API Content	Standard Analytical Methods - HPLC
Non-Chlorinated Solvent Waste - Laboratory	Annual	Full Characterisation	Standard Analytical Methods - GC-MS
Chlorinated Solvent Waste - Laboratory Note 1	Annual	Full Characterisation	Standard Analytical Methods - GC-MS
Chlorinated Solvent Waste - SAS Waste Note 1	Per Consignment	▪ DCM, Methanol ▪ Water Content	▪ Standard Analytical Methods - GC-MS ▪ Karl Fisher
Chlorinated Solvent Waste - SRS Note 1,	Per Consignment	▪ DCM, Methanol ▪ Water Content ▪ API Content Note 2	▪ Standard Analytical Methods - GC-MS ▪ Karl Fisher ▪ Standard Analytical Methods - HPLC
Wastewater Pre-Treatment Plant Sludge	Annual	Full Characterisation – API Content	Standard Analytical Methods - HPLC

Note 1: The chlorinated waste has been broken down into chlorinated laboratory waste, SAS and SRS waste
Note 2: All SRS waste sent for recovery is tested for API prior to removal off site as agreed with the Agency on the 31/01/07 (EPA reference: P0153-05/ap02bc.doc)

A4.2 Strategy

Hazardous waste streams for analysis comprise of (refer to Table A5.1):

- Pharmaceutical waste (Solid & Liquid)
- Non-chlorinated solvent waste (Laboratory)
- Chlorinated solvent waste (Laboratory)
- Chlorinated solvent waste (SRS)
- Chlorinated solvent waste (SAS)
- Wastewater pre-treatment plant sludge

The sampling methodologies adopted and laboratory resources used to complete the analysis as per Table A4.2 are described herein.

A4.2.1 Pharmaceutical Waste

A4.2.1.1 Pharmaceutical Solid Waste

Pharmaceutical Solid Waste consists of:

- Solid Waste containing or contaminated with pharmaceutical active ingredient (API) including Controlled Drugs. Controlled drugs include any product listed under the schedules as defined by the International Narcotics Control Board (INCB). These substances are classified controlled substances because of their abuse potential and dependence liabilities. Controlled substances held at WMI are the schedule IV substances Lorazepam, Lormetazepam, Oxazepam and testing standards Bromazepam and Nitrazepam or those products containing these schedule IV substances.
- Solid waste containing or contaminated with API including packaging material, PPE, cleaning materials, vacuumed materials, dust collection material (from HEPA & bag filters, and residual dust).
- Material Records are prepared for all waste loads related to these waste types. The information provided in the material record includes:
  - the number and type of containers [UN approved Boxes, Fibre Kegs, Flexible Intermediate Bulk Containers (FIBCs)]; and,
  - the Product Family (i.e. OCs/HTs etc) contained in each container.

A summary of these Material Records fulfils the 'per consignment' frequency (as Materials Records are provided for all Pharmaceutical Solid Waste arising) and 'Full Characterisation' parameter (as Materials Records indicate the active material type for all of the Pharmaceutical Solid Waste arising) requirement of *Schedule C4 Waste Monitoring* of IPPC Licence Register No. P0153-05.

A4.2.1.2 Pharmaceutical Liquid Waste

Pharmaceutical Liquid Waste consists of:

- Rinsewater containing API which is generated from the manual and automated cleaning of processing equipment.
- Sugar coating solution - sugar and water solution containing MPA and/or additional HT actives.
- Sugar Coating Solution - Environmentally hazardous for transport; HT, OC, BZA-CE.

In order to obtain samples representative of the pharmaceutical liquid wastes generated at WMI the following was considered:

- Given the consistency in the nature of the waste single once-off sampling during the defined period (every 6 months) is considered appropriate i.e. The production process is consistent and relate directly to batch manufacturing procedures which are validated according to defined recipe specifications.
- The strategy employed involves biannual sampling and analysis of IBCs for individual waste types (Rinsewaters and Sugar Coating Solutions from production facilities) for active components as verbally agreed on site inspection of 15/04/2004.

- It is noted that while the content of waste is consistent, the frequency of its generation relates directly to the batch nature of the production process i.e. production depends on the demand for a given product. Accordingly, wastes are sampled as they arise in order to prevent exclusion of a sampling event for a particular waste type (i.e. in the event that the production of a given product does not take place in future within the required biannual monitoring period).
- A grab sampling methodology is employed for pharmaceutical liquid waste (2 Litre sample).

Various analytical laboratories were employed in 2008 to complete the required range of analysis of samples as follows:

- WMI Environmental Laboratory, Newbridge, Co. Kildare, Ireland.
- Bord Na Móna Environmental Ltd., Newbridge, Co. Kildare, Ireland.
- Reading Scientific Services Ltd, RSSL, The Lord Zuckerman Research Centre, White Knights Campus, Pepper Lane, Reading RG6 6LA, United Kingdom.

Where required samples are split and forwarded to the appropriate laboratories for relevant analysis (refer to Table A4.2).

Table A4.2: Pharmaceutical Liquid Waste Analysis

Waste Type	Analysis	Classification	Laboratory
Rinsewater			
Rinsewater containing OC pharmaceutical active (OC PPU)	OC Pharmaceutical Actives	Hazardous	WMI
Rinsewater containing HT pharmaceutical active (HT PPU - General)	HT Pharmaceutical Actives (including MPA)	Hazardous	WMI
Rinsewater containing MHT [Note 1] pharmaceutical active ***(MHT PPU-General)***	***HT Pharmaceutical Actives (including BZA)***	Hazardous	***WMI***
Rinsewater containing Venlafaxine pharmaceutical active (Efexor/Lederle PPU)	Venlafaxine Pharmaceutical Active	Hazardous	WMI
Rinsewater containing Tranquiliser Pharmaceutical Active (CNS PPU)	Venlafaxine and Tranquiliser Pharmaceutical Actives	Hazardous	WMI
Sugar Coating Solution			
Sugar Coating Solution containing HT pharmaceutical active (HT PPU)	HT Pharmaceutical Actives (MPA, Estradiol, Trimegestone)	Hazardous	WMI
Sugar Coating Solution Environmentally hazardous for transport (HT PPU)	Water Content, Sucrose, Povidone, Titanium	Non-Hazardous	RSSL
Sugar Coating Solution Environmentally hazardous for transport (OC PPU)	Water Content, Sucrose, Povidone Calcium Carbonate, Talc	Non-Hazardous	RSSL
Sugar Coating Solution containing ***MHT*** pharmaceutical active ***(MHT PPU)***	MHT Pharmaceutical Actives (BZA) Water Content, Sucrose, Ascorbic Acid, Glucose	Hazardous Non-Hazardous	*WMI* RSSL

Note 1: MHT was previously termed BZA/CE-PNP

A4.2.2 Non-Chlorinated and Chlorinated Solvent Waste

Non-chlorinated and chlorinated solvent streams are subdivided as follows:

- Non-Chlorinated Solvent Waste
  - Laboratory Waste.
- Chlorinated Solvent Waste
  - Process Waste – SRS.
  - Process Waste - SAS.
  - Laboratory Waste

Representative samples (2 Litres) of Non-Chlorinated and Chlorinated laboratory waste drums are sampled by Bord Na Móna Environmental Ltd***.,*** using a sampling thief/rod. Both SAS and SRS waste streams are sampled from individual bulk tankers via an in-line sampling system whereby the representative samples (2 Litres) are collected as the tanker is filled. ***When the SRS is sent for recovery the 2 litre sample is split; with 1 litre sent to Bord Na Móna Environmental Ltd., for solvent and water content testing and the other 1 litre sent to the on-site WMI laboratory for API analysis.***

Samples are forwarded to the relevant laboratories for analysis (refer to Table A4.3).

Table A4.3 Non-Chlorinated and Chlorinated Solvent Waste Analysis

Waste Type	Analysis	Laboratory
Non Chlorinated Solvent Waste		
Non-chlorinated (Laboratory Waste)	Solvents Scan, Water Content	Bord na Móna Environmental Ltd.
Chlorinated Solvent Waste		
Chlorinated Solvent (Laboratory waste)	Solvents Scan, Water Content	Bord na Móna Environmental Ltd.
Chlorinated Solvent Waste (Process Waste - SAS)	DCM, Methanol, Water Content	Bord na Móna Environmental Ltd.
Chlorinated Solvent Waste (Process Waste – SRS).	DCM, Methanol, Water Content ***API content***	Bord na Móna Environmental Ltd. ***WMI***

A4.2.3 Wastewater Pre-Treatment Plant Sludge

The wastewater pre-treatment plant began producing hazardous waste sludges from March 2006. Given the consistency in the nature of the sludges a single once-off sampling event during the defined annual period was considered appropriate. A grab sampling methodology was employed to sample the sludge from the containers. The sludge was analysed after the initial primary coarse screening (with free liquid) and after processing through the wastewater pre-treatment plant, where the sludge has gone through sludge thickening, conditioning and dewatering (without free liquid) for active pharmaceutical ingredients (API). The APIs, analysed for, are reflective of the compounds used in the production processes at WMI. The analysis is completed by WMI.

Table A4.4 Sludge Analysis

Waste Type	Analysis	Laboratory
Wastewater Pre-Treatment Plant Sludge		
Sludge with Free Liquid	Full Characterisation – API content	WMI
Sludge without Free Liquid	Full Characterisation – API content	WMI

A4.2.4 CERES Composting Unit

Trial runs of a CERES composting unit for canteen waste began in 2006. The unit produces compost, which it is planned to spread on the landscaped areas of the WMI facility (as previously approved by the Agency as per correspondence reference M673/GC41bk). ***The CERES composting unit was not used in 2008 and therefore no compost was produced by the unit, therefore no samples were taken for testing.***

Appendix 5

Waste Analysis - 2008

Table A5.1 Pharmaceutical Solid Waste Analysis (Controlled Drugs)

C1/TFS Reference	Pick Up Date	Load Plan [Note 1]	Quantity	Full Characterisation
B453452	5/9/2008	Yes	32 Fibre Kegs 38 Compactor Boxes	Solid Hazardous waste containing: Tranquilliser (CNS) Pharmaceutical Actives -Controlled Drugs
B453451	5/9/2008	Yes	40 FIBCs	Solid Hazardous waste containing: Tranquilliser (CNS) Pharmaceutical Actives -Controlled Drugs
B453454	8/9/2008	Yes	40 FIBCs	Solid Hazardous waste containing: Tranquilliser (CNS) Pharmaceutical Actives -Controlled Drugs
B453455	9/9/2008	Yes	40 FIBCs	Solid Hazardous waste containing: Tranquilliser (CNS) Pharmaceutical Actives -Controlled Drugs
B453456	11/9/2008	Yes	32 Fibre Kegs 38 Compactor Boxes	Solid Hazardous waste containing: Tranquilliser (CNS) Pharmaceutical Actives -Controlled Drugs
311875/1	10/20/2008	Yes	40 FIBCs	Solid Hazardous waste containing: Tranquilliser (CNS) Pharmaceutical Actives -Controlled Drugs

Note 1: The Load Plan identifies each UN Compactor Box/FIBC/Fibre Keg by a unique number recorded in the appropriate logbook e.g. Facilities Solid Hazardous Waste Compactor Log Book

Table A5.2 Pharmaceutical Solid Waste Analysis (Obsolete Pharmaceuticals)

C1/TFS Reference	Pick Up Date	Load Plan [Note 1]	Quantity	Full Characterisation
B396314	10/01/2008	Yes	46 Compactor Boxes, 27 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B396318	15/01/2008	Yes	46 Compactor Boxes, 22 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B396321	22/01/2008	Yes	4 Fibre Kegs, 38 FIBCs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B3963281	28/01/2008	Yes	51 Compactor Boxes, 5 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B396285	31/01/2008	Yes	52 Compactor Boxes	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B396286	31/01/2008	Yes	44 FIBCs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B396295	07/02/2008	Yes	35 Compactor Boxes, 72 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B396298	12/02/2008	Yes	43 Compactor Boxes, 37 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B397915	19/02/2008	Yes	48 Compactor Boxes, 16 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B397923	26/02/2008	Yes	44 Compactor Boxes, 43 Fibre Kegs, 40 FIBCs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B397946	03/03/2008	Yes	48 Compactor Boxes, 15 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B397855	07/03/2008	Yes	40 FIBCs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B397854	07/03/2008	Yes	47 Compactor Boxes, 22 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Lederle/Efexor

C1/TFS Reference	Pick Up Date	Load Plan [Note 1]	Quantity	Full Characterisation
				Pharmaceutical Actives
B397856	10/03/2008	Yes	44 FIBCs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Lederle/Efexor Pharmaceutical Actives
B397862	18/03/2008	Yes	40 Compactor Boxes, 45 Fibre Keg	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Lederle/Efexor Pharmaceutical Actives
B397867	25/03/2008	Yes	49 Compactor Boxes, 13 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Lederle/Efexor Pharmaceutical Actives
B3978677	31/03/2008	Yes	48 Compactor Boxes, 15 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Lederle/Efexor Pharmaceutical Actives
B397888	8/4/2008	Yes	51 Compactor Boxes, 4 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B397890	10/4/2008	Yes	48 FIBCs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B397890	15/04/2008	Yes	43 Compactor Boxes, 37 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B397912	24/04/2008	Yes	40 FIBCs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B397915	28/04/2008	Yes	56 Compactor Boxes, 50 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B397918	2/5/2008	Yes	48 Compactor Boxes, 14 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B397954	13/05/2008	Yes	45 Compactor Boxes, 28Fibre Keg	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B452960	20/05/2008	Yes	48 Compactor Boxes, 19 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B452965	30/05/2008	Yes	52 Compactor Boxes	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B452974	9/6/2008	Yes	49 Compactor Boxes, 11 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B452983	17/06/2008	Yes	45 Fibre Boxes 50Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B452988	19/06/2008	Yes	40 FIBCs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B452931	24/06/2008	Yes	52 Compactor Boxes,	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B452993	2/7/2008	Yes	44 Compactor Boxes, 32 Fibre Kegs, 40 FIBCs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; /Efexor Pharmaceutical Actives
B453000	8/7/2008	Yes	49 Compactor Boxes	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B453479	15/07/2008	Yes	43 Compactor Boxes, 9 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B452940	25/07/2008	Yes	52 Compactor Boxes	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives

C1/TFS Reference	Pick Up Date	Load Plan [Note 1]	Quantity	Full Characterisation
B453481	5/8/2008	Yes	50 Compactor Boxes, 8 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B453484	19/08/2008	Yes	52 FIBCs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B453493	28/08/2008	Yes	49 Compactor Boxes, 17 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B453496	28/08/2008	Yes	40 FIBCs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B453500	4/9/2008	Yes	44 Compactor Boxes, 40 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B453457	15/09/2008	Yes	44 Compactor Boxes, 36 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B453475	22/09/2008	Yes	44 FIBCs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; /Efexor Pharmaceutical Actives
B453461	23/09/2008	Yes	72 Fibre Keg,s, 33 Fibre Boxes	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B452965	25/09/2008	Yes	7 Fibre Kegs, 50 Fibre Boxes	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B453430	30/09/2008	Yes	48 Compactor Boxes 16 Fibre Keg	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B453439	10/9/2008	Yes	28 Compactor Boxes, 72 Fibre Kegs, 2 FIBCs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
IE311664 6/80	6/11/2008	Yes	42 Compactor Boxes 42 Fibre Keg	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
IE311664 7/80	18/11/2008	Yes	45 Compactor Boxes, 29 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
B453801	25/11/2008	Yes	46 Compactor Boxes, 24 Fibre Kegs,40 FIBCs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
IE311664	2/12/2008	Yes	49 Compactor Boxes, 15 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Active; Hormone Replacement Therapy Pharmaceutical Active, Tranquiliser (CNS) Pharmaceutical Active; Efexor Pharmaceutical Active
IE311664	9/12/2008	Yes	44 Compactor Boxes, 60 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Active; Hormone Replacement Therapy Pharmaceutical Active, Tranquiliser (CNS) Pharmaceutical Active; /Efexor Pharmaceutical Active
IE311664 10/80	17/12/2008	Yes	45 Compactor Boxes, 16 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Active; Hormone Replacement Therapy Pharmaceutical Active, Tranquiliser (CNS) Pharmaceutical Active; Efexor Pharmaceutical Active
IE311664 12/80	23/12/2008	Yes	25 Plastic drums Boxes, 140 Fibre Kegs, 13 FIBCs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Active; Hormone Replacement Therapy Pharmaceutical Active, Tranquiliser (CNS) Pharmaceutical Active; Efexor Pharmaceutical Active

Note 1: The Load Plan identifies each UN Compactor Box/FIBC/Fibre Keg by a unique number recorded in the appropriate logbook e.g. Facilities Solid Hazardous Waste RMD Logbook (TMP0346), each unique number will define the waste by product family – Oral Contraceptives, Tranquilliser (CNS), etc.

Pharmaceutical Liquid Waste

Table A5.3: Pharmaceutical Liquid - Rinsewater Waste Analysis

Active	Units	MHT Rinsewater Note 2	CNS Rinsewater		HT Rinsewater		Efexor Rinsewater		OC Rinsewater	
		Biannual I (mg/l) 02/04/08	Biannual I (mg/l) 02/04/08	Biannual II (mg/l)	Biannual I (mg/l) 02/04/08	Biannual II (mg/l)	Biannual I (mg/l) 02/04/08	Biannual II (mg/l) 16/09/08	Biannual I (mg/l) 02/04/08	Biannual II (mg/l)
Oxazepam	mg/l		<LOD	Note 2						
Lorazepam	mg/l		1.5	Note 2						
Lormetazepam	mg/l		<LOD	Note 2						
MPA	mg/l	<LOD			<LOD	Note 2				
Trimegestone	mg/l				<LOD	Note 2				
Bazedoxifene	mg/l	<LOD			<LOD	Note 2				
Venlafaxine HCL	mg/l		1.24	Note 2			712.8	1577.00		
Bisoprolol Fumarate	mg/l						Note 1	Note 1		
Ethinylestradiol	mg/l								<LOD	Note 2
Gestodene	mg/l								<LOD	Note 2
Norgestrel/Levonorgestrel	mg/l								<LOD	Note 2

LOD: Limit of Detection.

Note 1: Sample could not be analysed for Bisoprolol fumarate due to test method interference from Venlafaxine.

Note 2: For Biannual 2 2008 all MHT, CNS, HT, OC rinsewater was treated in the on-site Wastewater Pre-Treatment Plant, as a consequence none of these rinsewaters were sent off site for disposal in the Biannual 2 2008 time-frame.

Note 3: Limits of detection:

Oxazepam	<0.4 mg/l	17-α Estradiol	<0.00030 mg/l	Ethinylestradiol	<0.035 mg/l
Lorazepam	<0.4 mg/l	17-β Estradiol	<0.00030 mg/l	Gestodene	<0.00004 mg/l
Lormetazepam	<0.8 mg/l	17-α Dihydroequilin	<0.00030 mg/l	Norgestrel/Levonorgestrel	<0.05 mg/l
MPA	<0.2 mg/l	Estrone	<.003 mg/l	Trimegestone	<0.0014 mg/l
Venlafaxine HCL	<0.15 mg/l	Equilin	<0.00075 mg/l	Bazedoxifene	<0.13 mg/l

Table A5.4: Pharmaceutical Liquid - Sugar Coating Solutions Waste Analysis

Analyte	MHT Sugar Coating (no active) Coating		MHT Sugar Coating		HT Sugar (no active) Coating		HT Sugar Coating		OC Sugar Coating	
	Biannual I 09/01/08	**Biannual II 28/08/08**	**Biannual I 09/01/08**	**Biannual II 28/08/08 Note [1]**	**Biannual I 09/01/08**	**Biannual II 28/08/08**	**Biannual I 09/01/08**	**Biannual II 28/08/08**	**Biannual I 09/01/08**	**Biannual II 28/08/08**
Pharmaceutical Active - MPA	<LOD	<2 mg/l	<LOD		<LOD	<2	<LOD	62869 mg/l		
Pharmaceutical Active - Trimegestone						<0.14 mg/l	2.2260 mg/l	3179 mg/l		
Pharmaceutical Active - Bazedoxifene	<LOD	<1.3 mg/l	3.8 mg/l		<LOD	<1.3 mg/l	<LOD	4555		
Pharmaceutical Active - Conjugated Estrogens	<LOD	<1.2 mg/l	<LOD		<LOD	<1.2 mg/l	<LOD	5.25 mg/l		
Pharmaceutical Active - Ethinylestradiol									<LOD	<0.04 mg/l
Pharmaceutical Active - Gestodene									<LOD	<0.02 mg/l
Pharmaceutical Active - Norgestrel/ Levonorgestrel									<LOD	<0.2 mg/l
Water Content	95.1 %w/w	86.9 %w/w	91.8 %w/w		72.1 %w/w	74.6 %w/w	81.8 %w/w	45.6 %w/w	40.7 %w/w	49.8 %
Sucrose	0.26 %w/w	49.6 g/kg	1.3 %w/w		23.9 %w/w	247 g/kg	1.3 %w/w	474 g/kg	45.0%w/w	496 g/kg
Glucose		11.5 g/kg	0.08 %w/w		0.10 %w/w	13.2 g/kg	6.4 %w/w	9.5 g/kg	0.01 %w/w	<4 g/kg
Titanium Dioxide	0.0004 %w/w		0.0002 % w/w			0.35 µg/g		<0.05 µg/g		0.2 µg/g
Ascorbic Acid		<0.01%w/w			<0.01%w/w	<1mg/100ml	<0.01%w/w	<0.01%w/w		<0.01%w/w
Fructose		12.5 g/kg	0.09%w/w		0.16 %w/w	8.2g/kg	6.5 %w/w	11 g/kg		<4 g/kg
Maltose		53mg/ kg				92mg/kg		300mg/kg		<20 mg/kg
Lactose		<20mg/kg				<20mg/kg		<20mg/kg		<20 mg/kg
Galactose		<4g/kg				<4g/kg		<4g/kg		<4 g/kg
Providione						0.009%		0.030%	0.001%	0.018%
Talc						<0.01 %w/w		<0.01 %w/w	0.01 %w/w	<0.01 %w/w
Calcium Carbonate						34.8 µg/g		41 µg/g	0.85 %	2508µg/g

LOD: Limit of Detection.

Oxazepam	<0.4 mg/l	17-α Estradiol	<0.00030 mg/l	Ethinylestradiol	<0.035 mg/l
Lorazepam	<0.4 mg/l	17-β Estradiol	<0.00030 mg/l	Gestodene	<0.00004 mg/l
Lormetazepam	<0.8 mg/l	17-α Dihydroequilin	<0.00030 mg/l	Norgestrel/Levonorgestrel	<0.05 mg/l
MPA	<0.2 mg/l	Estrone	<0.003 mg/l	Trimegestone	<0.0014 mg/l
Venlafaxine HCL	<0.15 mg/l	Equilin	<0.00075 mg/l	Bazedoxifene	<0.13 mg/l

Note 1: MHT Sugar Coating was not disposed of in the second half of 2008, therefore no Biannual II sample was taken for analysis.

Chlorinated & Non-Chlorinated Solvent Waste

Table A5.5: Chlorinated Solvent Waste Analysis (Process Waste - SRS) [Note 1]

	DCM (%)	Methanol (%)	Water (%)	Pharmaceutical Active – Venlafaxine content (mg/l)	Residue content [Note3] (%)
11/01/2008	68.72	30.52	0.76	<0.15 [Note 2]	0.76
25/01/2008	70.74	28.57	0.69	<0.15 [Note 2]	0.80
01/02/2008	75.68	23.43	0.89	<0.15 [Note 2]	0.47
14/02/2008	75.41	23.87	0.72	<0.15 [Note 2]	Note 7
29/02/2008	70.84	28.19	0.97	<0.15 [Note 2]	0.43
14/03/2008	67.97	30.83	1.20	<0.15 [Note 2]	0.35
28/03/2008	72.40	26.65	0.95	<0.15 [Note 2]	0.44
10/04/2008	82.11	17.00	0.89	<0.15 [Note 2]	0.50
18/04/2008	75.86	23.16	0.98	<0.15 [Note 2]	0.42
13/05/2008	72.73	26.46	0.81	<0.15 [Note 2]	0.52
15/05/2008	73.05	26.02	0.93	<0.15 [Note 2]	0.43
22/05/2008	78.44	20.79	0.77	<0.15 [Note 2]	0.39
06/06/2008	68.11	31.03	0.86	<0.15 [Note 2]	0.62
18/06/2008	71.73	27.54	0.73	<0.15 [Note 2]	0.52
30/06/2008	73.18	24.62	2.20	<0.15 [Note 2]	0.46
11/07/2008	71.08	27.69	1.23	<0.15 [Note 2]	0.43
31/07/2008	68.70	30.34	0.96	<0.15 [Note 2]	0.59
08/08/2008	66.29	33.04	0.67	0.16 [Note 2, Note 6]	0.41
22/08/2008	60.50	38.10	1.40	0.18 [Note 2, Note 6]	0.68
18/09/2008	78.36	20.54	1.10	0.19 [Note 2, Note 6]	0.44
19/09/2008	78.03	20.97	1.00	<0.15 [Note 4]	0.45
30/09/2008	70.62	28.56	0.82	<0.15 [Note 4]	0.58
10/10/2008	78.29	20.40	1.31	<0.15 [Note 4]	0.36
22/10/2008	79.89	19.21	0.90	<0.10 [Note 4]	0.21
07/11/2008	68.56	30.54	0.90	<0.10 [Note 5]	0.22
21/11/2008	67.75	31.29	0.96	0.23 [Note 5]	0.53
02/12/2008	79.82	19.28	0.90	0.27 [Note 5, Note 6]	0.50
16/12/2008	65.23	33.67	1.10	0.17 [Note 5, Note 6]	0.60
23/12/2008	65.04	34.06	0.90	0.47 [Note 5, Note 6]	2.70

Note 1: The results given are a percentage of the total organic solvents in the sample

Note2: Pharmaceutical active content reported as <0.15mg/l due to the interference that occurred during the analysis of the sample. The interference was treated as a worst case scenario with the pharmaceutical active content interpreted as Venlafaxine.

Note 3: Residue content consists of microcrystalline cellulose and glycol.

Note 4: From 19/09/08 the limit of detection for pharmaceutical active content was revised to <0.15mg/l due to an improved test method with reduced interference.

Note 5: From 07/11/08 the limit of detection for pharmaceutical active content was revised to <0.0001mg/l due to due to an improved test method with reduced interference.

Note 6: In accordance with information previously submitted to the Agency on which EPA approval P0153-05/ap02bc.doc dated 30/01/07 was based, solvent waste contaminated with pharmaceutical active (i.e. >LOD) was diverted from recovery to incineration.

Note 7: % Residue content inadvertently not measured for sample. No environmental impact as % residue content being determined for information purposes only.

Table A5.6 Chlorinated Solvent Waste Analysis (Process Waste – SAS) [Note 1]

Sample Date	Analysis/Component		
	DCM (%)	Methanol (%)	Water (%)
24/01/2008	15.89	4.29	79.82
21/02/2008	17.09	1.70	81.21
20/03/2008	6.197	1.60	92.20
11/04/2008	5.58	0.85	93.57
13/05/2008	10.89	0.43	88.71
29/05/2008	11.93	0.47	87.61
24/06/2008	1.77	0.33	97.90
18/07/2008	7.706	1.63	90.67
14/08/2008	17.30	1.18	81.52
18/09/2008	7.01	1.09	91.90
14/11/2008	6.96	1.40	91.64

Note 1: The results given are a percentage of the total organic solvents in the sample

Table A5.7 Chlorinated Solvent Waste Analysis (Laboratory Waste) [Note 1]

Sample Date	Analysis	Component	Result	Units (% total organic solvent)
17/01/2008	Water Scan	Water Content	55.390	%
	Solvent Scan (VOCs)	Dimethyl Formamide	1.261	%
		Ethylacetate	0.324	%
		Methanol	17.989	%
		Ethanol	2.504	%
		Acetone	0.507	%
		Dichloromethane	2.634	%
		Chloroform	1.808	%
		Acetonitrile	16.738	%
		1,2-Dichloroethane	0.824	%

Note 1: The results given are a percentage of the total organic solvents in the sample

Table A5.8: Non-Chlorinated Solvent Waste Analysis (Laboratory Waste) [Note 1]

Sample Date	Analysis	Component	Result	Units (% total organic solvent)
17/01/2008	Water Scan	Water Content	64.59	%
	Solvent Scan (VOCs)	Tetrahydrofuran	0.661	%
		Methanol	8.214	%
		Toluene	1.063	%
		Ethanol	2.103	%
		Acetone	0.438	%
		Acetonitrile	20.804	%
		Dichloromethane	0.324	%
		Propan-1-ol	0.207	%
		Dimethylformamide	1.578	%

Note 1: The results given are a percentage of the total organic solvents in the sample

Wastewater Pre-Treatment Plant Sludge

Table A5.9: Waste Water Pre-Treatment Plant Sludge Analysis [Note1]

Pharmaceutical Active	Sample	
	Sludge with free liquid (mg/kg) [Note 2]	Sludge without free liquid (mg/kg) [Note 3]
Oxazepam	0.7	0.8
Lorazepam	<0.1	0.6
Lormetazepam	<0.2	<0.2
Conjugated Estrogens	0.2	3.3
Medroxyprogesterone Acetate	<0.04	<0.04
Trimegestone	<0.004	0.008
Bazedoxifene Acetate	0.08	0.3
Venlafaxine HCL	1.6	1.4
Bisoprolol Fumarate	<0.7	<0.7
Minocycline HCL	<0.03	1.0
Ethinylestradiol	<0.2	<0.2
Gestodene	<0.9	<0.8
Norgestrel/Levonorgestrel	<0.9	<0.8

Note 1: Sampled on 20/08/2008.

Note 2: Screenings from screening units that filter out debris up to a size of 1 millimeter from waste water effluent prior to entering the balancing tanks.

Note 3: Sludge from Biology and MBR tanks which has passed through a disk thickener or centrifuge to separate the sludge from water.

Appendix 6

WMI EHS Policy

Wyeth Newbridge Environmental, Health & Safety Policy

I. SCOPE

This policy governs all activities carried out at the Wyeth Newbridge facility and is the responsibility of all staff to ensure all activities are undertaken in accordance with this policy.

II. POLICY STATEMENT

It is the policy of Wyeth, its divisions and subsidiaries to conduct business in a responsible way and in a manner designed to protect the health and safety of our employees, customers, the public and the environment.

As a good corporate citizen, we must be conscious of the effects of our operations on the environment. We, therefore, will continually evaluate and assess our products and processes in order to reduce adverse environmental and safety impacts as we strive toward being a more sustainable Company and fulfilling our vision of “leading the way to a healthier world.”

Wyeth will act responsibly in addressing environmental impacts caused by releases and past practices and will endeavour to return impacted properties to productive use.

The Company is committed to providing a healthy and safe workplace for our employees, contractors, visitors and neighbours by operating our facilities in a manner that is harmonious with the communities in which the facilities are located.

Wyeth will continue to comply with the spirit as well as the letter of the national and local laws relating to the protection of employees, the public and the environment. We will supplement compliance with local laws and regulations with our own Environmental, Health and Safety Guidelines that provide a framework for all of our facilities worldwide.

III. ROLES AND RESPONSIBILITIES

The Company has assigned qualified corporate, division and facility staff to ensure that this Policy is implemented globally. However, it is the responsibility of all employees to accept accountability for following this Policy, our Environmental, Health and Safety Guidelines, and all specific safety and environmental laws and regulations in order to protect themselves, their co-workers, their community and the environment.

IV. PROCESS

The Company shall carry out the policy as follows:

- Develop and maintain Environmental, Health and Safety (EHS) Guidelines that provide direction and demonstrate commitment to all of our employees. Our facilities shall follow the more stringent of the EHS Guidelines or the applicable local requirements.
- Develop and maintain an EHS assessment program to ensure that the Company Policy is being implemented and that the Guidelines are being followed.
- Provide a healthy and safe environment for all employees, contractors, visitors and neighbours with an ultimate goal of zero incidents.
- Prevent or reduce adverse environmental impacts with an ultimate goal of elimination of these impacts.
- Establish appropriate forums for facilitating communication and disseminating environmental, health and safety information throughout the Company and to the general public.
- Conduct training for EHS personnel within the Company.
- Evaluate the performance through periodic review of the Company's EHS programs in order to promote continuous improvement.
- Create products and processes that are inherently safe and that incorporate the principles of pollution prevention, waste minimization and process safety.
- Conduct due diligence investigations and remediation of properties in a responsible manner.
- Develop EHS objectives and targets to ensure the site continually improves its environmental, health and safety performance.
- Review this and related policies frequently (at least biennially) and update following changes to legislation, key personnel and industry best practice.
- Understand and consider stakeholder points of view in the development of EHS policy.
- Add value to the Company by coordinating EHS initiatives with business objectives.
- Participate in trade associations and professional organizations regarding EHS issues.

Signed 

Robert Vincent
Managing Director
Wyeth Newbridge

Signed 

Michael Donlon
Associate Director
Environmental Health & Safety
Wyeth Newbridge

Appendix 7

Environmental Management Programme - 2009

Environmental Management Programme 2009

Company:	***AHP Manufacturing B.V. T/A Wyeth Medica Ireland***
Address:	***Buckley's Cross Roads, Old Connell, Newbridge, Co. Kildare***
Licence Register No:	***P0153-05***
Date:	***January 2009***

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OBJECTIVE 1: COMPLIANCE

To achieve compliance with all WMI IPPC Licence (Licence Register No. P0153-05), and Wyeth Corporate EHS environmental policy requirements.

Target

- To achieve compliance with the requirements of current WMI IPPC Licence (in particular Emission Limit Values, and *Conditions 2.2.2.2, 3.9, 5.1, 6.1, 6.11.3*), and where possible improve compliance on previous years. Ensure the site, at all times, can demonstrate compliance for regulator/cEHS audit.
- To measure site environmental performance in accordance with Wyeth Corporate EHS environmental indicators & associated targets.

Why

To comply with all conditions of the current WMI IPPC Licence and Wyeth Corporate EHS environmental policies, and to implement year on year continuous improvement where possible.

How & When

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
Monitoring Programme (IPPC Condition 5.1, 6.1)									***Project Manager: M Gallagher***			
Develop monitoring schedule	■											
Implement monitoring programme	■	■	■	■	■	■	■	■	■	■	■	■
Prepare & submit AER to EPA												■
Environmental Performance Indicators (IPPC Condition 2.2.2.2)									***Project Manager: R Cully***			
Data												
Process 2008 data for cEHS EPIs	■	■										
Submit report to EPA for review (AER)			■									
Monitoring												
Monitor site performance against 2009 cEHS EPI targets			■			■			■			■
Implement corrective action where required for any significant deviation to cEHS EPI targets				■	■	■	■	■	■	■	■	■
Process Effluent (IPPC Condition 6.11.3)									***Project Manager: R Cully***			
Complete process validation of WWTP (Efexor)												
Implement Programme Proposal				■	■	■	■					
Produce report on findings								■	■			
Submit report to EPA for review										■		
Fire Water Retention (IPPC Condition 3.9)									***Project Manager: R Cully***			
Implement further studies as per 2005 Firewater Retention Study	■	■	■									
Produce report(s) on findings of further studies			■	■								
Submit report(s) on findings of further studies to EPA for approval					■							
Efficiency of Raw Materials Use – Efexor/OC (Condition 7.4)									***Project Manager: E Molyneaux***			
Revisit previous processes reviews (Efexor - 2005; OC - 2006) - Identify progress on implementation of opportunities identified	■	■	■									
Produce report on findings		■	■									
Submit report to EPA for assessment			■									

Who

WMI EHS, WMI Processing, WMI Packaging, WMI Engineering, External Consultants.

OBJECTIVE 2: ENVIRONMENTAL TRAINING & AWARENESS

Continue to develop on-site environmental training and awareness programmes.

Target	▪ To achieve compliance with the requirements of the current WMI IPPC Licence (Licence Register No. P0153-05), in particular *Condition 2.2.2.6*.												
Why	▪ To maintain ongoing environmental training on site with particular focus on delivery through different media. ▪ To implement an ongoing environmental awareness campaign in order to further heighten environmental awareness on site (in particular waste management).												
How & When		**Jan**	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**	**Sept**	**Oct**	**Nov**	**Dec**
	Environmental Training – General (IPPC Condition 2.2.2.6)												***Project Managers: R Cully / E Molyneaux***
	Review existing training master kits												
	Update existing training master kits to CBT (including environmental training for new employees)												
	Roll out revised/new training master kits												
	Environmental Awareness (IPPC Condition 2.2.2.6)												***Project Manager: E Molyneaux / AM Flynn***
	Develop Programme Proposal (with particular focus on waste management)												
	Draw up short-list of proposed ideas/projects												
	Implement ideas/projects												
Who	WMI EHS, WMI Training, External Consultants.												

OBJECTIVE 3: ENERGY EFFICIENCY

Continue to reduce energy and water consumption associated with on-site operations.

Target	To reduce energy and water consumption associated with on-site operations thereby achieving compliance with the requirements of WMI IPPC Licence (Licence Register No. P0153-05), in particular *Conditions 7.1, 7.2, 7.3.* : ▪ Energy Usage – Decrease energy usage by 2% of 2008 baseline. ▪ Water Usage – Decrease water usage by 2% of 2008 baseline.
Why	This project is being undertaken to introduce a programme of minimising energy and water usage at the WMI facility. It is expected that assessment of the feasibility of projects for improvements in energy and water usage will result in both financial benefits (i.e. reduced energy costs) and environmental benefits (i.e. increased energy efficiency).

How & When

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
Energy Usage (Condition 7.1, 7.2)												***Project Manager: M Dullaghan***
Identify ideas/projects												
Draw up short-list of proposed ideas/projects												
Implement programme ideas/projects (subject to receiving capital approval)												
Review progress quarterly												
Water Usage – General (Condition 7.3)												***Project Manager: M Dullaghan***
Identify ideas/projects												
Draw up short-list of proposed ideas/projects												
Implement programme ideas/projects (subject to receiving capital approval)												
Review progress quarterly												
Water Usage – WWTP / Cooling Towers (Condition 7.3)												***Project Manager: R Butler***
Continue baseline information gathering (to continue until WWTP performance verification is completed in June 2009)												
Evaluate data												
Assess viability of project												
Energy Management System (Condition 7.1, 7.2)												***Project Managers: E Molyneaux / M Dullaghan***
Simplification & rationalisation of site energy management procedures												

Who	WMI Engineering, WMI EHS, External Consultants.

OBJECTIVE 4: WASTE MANAGEMENT

Continue to examine options for reduction & recycling of hazardous and non-hazardous waste, and improving on-site waste logistics.

Target

- Waste Reduction/Recycling – Increase hazardous / non-hazardous waste recycling rate by 2% of 2008 baseline.
- Waste Logistics – To assess feasibility of implementing an electronic labelling and tracking system (Indascan) for management of waste logistics at the site (i.e. labeling/logging of waste and tracking of waste movement).

Why

WMI's long-term objective is, where possible, to reduce the quantities of waste requiring disposal.

How & When

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
Waste Reduction/Recycling – Hazardous Waste (Efexor)												
Waste audit of Efexor process												
In association with hazardous waste contractor identify ideas/projects												
Draw up short-list of proposed ideas/projects with Efexor management												
Implement programme ideas/projects												
Review progress quarterly												
Waste Reduction/Recycling -Non-Hazardous Waste												
In association with non-hazardous waste contractor identify ideas/projects												
Draw up short-list of proposed ideas/projects with area management												
Implement programme ideas/projects												
Review progress quarterly												
Waste Logistics – Waste Tracking												
In association with Wyeth Grangecastle confirm operational suitability of Indascan waste tracking software												
Develop programme for implementation of electronic waste tracking system at Wyeth Newbridge												
Implement programme (subject to receiving capital approval)												

Project Managers: AM Flynn / E Molyneaux

Project Managers:AM Flynn / E Molyneaux

Project Manager: AM Flynn

Who

WMI Engineering, WMI Processing, WMI SAP, WMI Compliance, WMI EHS, External Consultants.

Revision History

Number	Date	Objective	Change	Reference	Contact	EHS
1						
2						
3						
4						

Appendix 8

Review of Residuals Management Plan

Wyeth Medica Ireland

Residuals Management Plan (RMP)

DOCUMENT CONTROL SHEET

Client	Wyeth Medica Ireland					
Project Title	Wyeth Medica, Residuals Management Plan (RMP)					
Document Title	Residuals Management Plan Report					
Document No.	MDE0856Rp0001					
This Document Comprises	DCS	TOC	Text	List of Tables	List of Figures	No. of Appendices
	1	1	26	1	1	-

Rev.	Status	Author(s)	Reviewed By	Approved By	Office of Origin	Issue Date
D01	Draft	Martin Doherty	Esther Villoria	Shane Herlihy	West Pier	27/02/09
D02	Draft	Martin Doherty	Esther Villoria	Shane Herlihy	West Pier	06/03/09
F01	Final	Martin Doherty	Esther Villoria	Shane Herlihy	West Pier	23/03/09
F02	Final	Martin Doherty	Esther Villoria	Shane Herlihy	West Pier	31/03/09

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1 INTRODUCTION

1.1 FACILITY AND LICENCE DETAILS

Wyeth Medica Ireland (WMI) is a pharmaceutical manufacturing company operating in Newbridge, Co. Kildare. The site is licensed *[Integrated Pollution Prevention Control (IPPC) Licence Register No. **P0153-05]*** by the Environmental Protection Agency (EPA) to carry out the following activities:

"the surface treatment of products using organic solvents, in particular for printing, coating, with a consumption capacity of more than 200 tonnes per year".

In accordance with Condition 10 of Licence Register No. P0153-05, a Residuals Management Plan is required. The specific requirement is as follows:

Condition 10. Decommissioning & Residuals Management.

10.1 Following termination, or planned cessation for a period greater than six months, of use or involvement of all or part of the site in the licensed activity, the licensee shall, to the satisfaction of the Agency, decommission, render safe or remove for disposal/recovery, any soil, subsoils, buildings, plant or equipment, or any waste, materials or substances or other matter contained therein or thereon, that may result in environmental pollution.

10.2 The Residuals Management Plan.

The Residuals Management Plan previously agreed by the Agency shall be reviewed annually and proposed amendments thereto notified to the Agency for agreement as part of the AER. No amendments may be implemented without agreement of the Agency.

10.3 The Residuals Management Plan shall include as a minimum, the following: -

- *(i) A scope statement for the plan.*
- *(ii) The criteria, which define the successful decommissioning of the activity or part thereof, which ensures minimum impact on the environment.*
- *(iii) A programme to achieve the stated criteria.*
- *(iv) Where relevant, a test programme to demonstrate the successful implementation of the decommissioning plan.*
- *(v) Details of costings for the plan and the financial provisions to underwrite those costs.*

10.4 A final validation report to include a certificate of completion for the residuals management plan, for all or part of the site as necessary, shall be submitted to the Agency within three months of execution of the plan. The licensee shall carry out such tests, investigations or submit certification, as requested by the Agency, to confirm that there is no continuing risk to the environment.

The original RMP for the WMI site was completed in 2002. Reviews were carried out annually and the most recent was in 2008. All RMP reports have been submitted to the Agency in compliance with Condition 10 of Licence Register No. P0153-05.

1.2 METHODOLOGY AND SCOPING

The EPA guidance document entitled '*Guidance on Environmental Liability Risk Assessment, Residuals Management Plans and Financial Provisions'* (hereafter referred to as EPA 2006) has been used as the basis for the methodology in preparing this report.

Section 3.1 of the document makes reference to the IPPC Directive (96/61/EC), Codified (2008/1/EC), which states that '*the necessary measures are taken upon definitive cessation of activities to avoid pollution risk and return the site of the operation to a satisfactory state'.*

The initial step involved is to scope the requirements of the closure and assess whether aftercare management is likely to be required. An Environmental Liabilities Risk Assessment report was previously prepared for the WMI facility by RPS to assess the potential risks associated with *unknown liabilities* for the site (Report Ref. No. MDE0598Rp0001), which was submitted to the Agency on 18/10/2007, in accordance with Condition 12.2 *Environmental Liabilities* of Licence Register No. P0153-05.

This report (Residuals Management Plan) will focus on the *Known Liabilities* of the WMI site i.e. the planned and or anticipated liabilities associated with facility closure, decommissioning and aftercare management.

1.3 SCREENING AND OPERATIONAL RISK ASSESSMENT

EPA 2006 sets out the methodology for assessing the requirement for a wide range of IPPC facilities under three risk categories (1-3). The risk category is determined by assessing the following facility specific information.

- Complexity: The complexity band is determined with reference to the 'Look-Up Table' in Appendix B of EPA 2006. A facility with Complexity G4 or G5 is automatically classified as Risk Category 3. According to the EPA 2006 'Look-Up Table', WMI is classified as G4 and is therefore a Category 3 facility.

- Environmental Sensitivity: This considers 6 environmental receptors and by assigning scores to each an environmental attributes score is obtained.

- Compliance Record: A score is assigned for compliance record. The scores vary depending on the level of non-compliance (administrative, minor, major or repeat).

Although EPA 2006 states that activities with complexity band G4 or G5 are classified as Category 3, for completeness the Environmental Sensitivity and Compliance Record are assessed here.

Environmental Sensitivity

EPA 2006 classifies the environmental sensitivity using the scoring system presented in Table 1.1. The WMI environmental sensitivity is scored using the environmental attributes listed in Table 1.2.

Table 1.1 Environmental Sensitivity Classifications

Total Attributes Score	Sensitivity Classification
Low < 7	1
Moderate 7-12	2
High > 12	3

Table 1.2 Environmental Attributes Score

Environmental Attribute	WMI Environmental Attribute Score
Human Occupation	
Within 50m of site	5
Groundwater Protection	
Regionally Important Aquifer	2
Vulnerability Rating- High	2
Sensitivity of Receiving Waters	
Class A	3
Air Quality and Topography	
Simple Terrain	0
Protected Ecological Sites and Species	
No protected ecological sites/species	0
Sensitive Agricultural Receptors	
<50m from site boundary	2
WMI Environmental Attribute Total	**14**

The WMI Environmental Attributes score is greater than 12 so the environmental sensitivity classification is 3.

Compliance Record

At WMI only minor non-compliances have occurred in the past five years. A diesel spill (discussed in more detail in Section 2.3), which occurred on site in 2007, was investigated and a detailed quantitative risk assessment concluded that the spill was not significant and did not pose a long-term liability to the environment or to human health.

Overall WMI has a good compliance record and is proactive in dealing with environmental protection at the site, and on the one occasion where contamination occurred (i.e. 2007 diesel spill incident referred to previously) WMI responded rapidly and effectively. A compliance record score of 3 (minor non-compliance) is reflective of conditions at the WMI facility.

Table 1.3 Operational Risk Assessment Score

Site Specific Detail		WMI Score
Complexity		4
Environmental Sensitivity		3
Compliance Record		3
Overall Risk Score (Complexity x Environmental Sensitivity x Compliance Record)	4x3x3	36
RISK CATEGORY		**Category 3**

WMI is classified in Risk Category 3 and the requirements for assessing Category 3 facilities detailed in the EPA 2006 must therefore be followed.

The RMP will be based on a 'Clean Closure' scenario as it is considered that ground and site conditions are such that upon definitive closure, there would be no long-term environmental liabilities. However, a provision for aftercare monitoring of the diesel spill that occurred at the WMI site in 2007 is included.

The decontamination procedure for process equipment and plant will follow WMI site policy. It is considered that these procedures will "*render safe buildings, plant or equipment, contained therein or thereon, that may result in environmental pollution".* This RMP applies a worst-case approach to contaminated equipment disposal and assumes that all contaminated process equipment cannot be cleaned to API non-detect levels and will require disposal as hazardous waste.

As stated in Section 7 of this RMP, it is also likely that during the closure planning stage, Wyeth Corporate will identify opportunities to migrate production to alternative Wyeth locations. Therefore high value plant and equipment may be removed from Newbridge as part of any product transfer. With regard to timeframe, it is estimated that the closure of the WMI facility will take between 4 to 6 months. There are numerous factors that may influence the timeframe and it is proposed that prior to definitive cessation of activities, WMI will present the EPA with a detailed Closure Plan timeframe for review.

2 SITE EVALUATION

2.1 THE FACILITY

Wyeth Medica Ireland (WMI) was established in Newbridge, Co. Kildare in 1992. The site occupies over 120 acres (48.56 ha), with over 1300 people employed at the 1,000,000 sq ft (92,900sqm) facility. WMI operates on a twenty-four hour, 5 days per week shift basis, with some production at weekends.

The manufacture of solid dose pharmaceutical products at WMI are based on formulation activities, consisting of blending of raw materials, granulation, drying and coating processes, with subsequent filling and packaging operations and product distribution from the site. The production facilities comprise packaging and processing buildings, solvent recovery plant, combined heat & power (CHP) plant and laboratories.

Other facilities include warehousing of raw materials / intermediates / finished goods, external materials storage, services including steam, compressed air, nitrogen, cooling water and process water, wastewater treatment plant, waste management centre, an engineering workshop, and an administration building with canteen.

2.2 INVENTORY OF SITE BUILDINGS, PLANT, RAW MATERIALS AND WASTE

The main WMI facility buildings and associated services are itemised in Table 2.1.

Table 2.1 List of WMI Site Buildings and Plant

Building/Plant Area	Function
Building 1	Administration services (accounting, purchasing, HR etc), Canteen
Building 2	Packaging
Building 3	Production
Building 3A	Production
Building 3B	Production
Building 3C & associated Central Utilities Building	Production –– *vaildation ongoing*
Building 4	Warehouse/ Production (OC4B) – *vaildation ongoing* / R&D (Pharmaceutical Development Centre) – *construction ongoing* / Solvent Storage Area / Waste Staging Areas
Building 5	Central Utilities Building (boilers, CHP, cooling towers etc.)
Building 9	AS/RS automated warehouse
Solvent Tank Farm	Raw Material / Waste Solvent storage in 7 No. 30m^3 bunded tanks.
Waste Management Centre	Solid waste storage prior to dispatch from the site
Waste Water Pre-Treatment Plant (WWTP)	Treatment plant for all trade and foul waste water prior to discharge from the site
Oils, Fats & Greases (OFG) Waste Water Treatment Plant	Treatment unit for canteen waste water
Temporary Liquid Waste Storage area	Storage of liquid waste in bunded units prior to dispatch from the site
Fire-Water Retention Tank	Retention tank (1000m^3) for any contaminated fire-water
Surface Water Attenuation Tank	Below ground attenuation tank (2,200m^3) which attenuates surface water flow discharge from the site
Overhead solvent lines	Transport of Dichloromethane and Methanol from Solvent Tank Farm to Building 3 production area

A description of each of the areas and a summary of their processes are outlined below.

Packaging Buildings

Packaging operations for all pharmaceutical products manufactured at the WMI facility are based in Building 2.

Production Buildings

There are four main primary processing units (PPUs) at WMI, which perform a variety of operations required for the manufacture of pharmaceutical products. The production buildings are 3, 3A, 3B, 3C and 4B. The WMI facility formulates and blends pharmaceutical products used in the areas of:

- Anti-depressant treatment (Efexor).
- Hormone Therapy (HT) and Menopausal Hormone Therapy (MHT).
- Oral Contraception (OC).
- Central Nervous System (CNS) treatment.

A new Pharmaceutical Development Centre (PDC) is currently undergoing construction and is housed in building 4. The primary function of the PDC is to accommodate the increased demand for new products through process optimisation at a development scale. The PDC facility will also be able to manufacture clinical batches and provide on-going process development support for products post-launch.

In order to minimise the potential for environmental damage at each stage of the process, WMI operates under strict procedures, which include:

- Solvents are predominantly hard piped from the Solvent Tank Farm direct to the Efexor 3B process for charging. All solvent to building 3A is manually handled through dewers.
- Raw materials are brought in on a demand basis to avoid stockpiling within all production buildings.
- The processes are fully enclosed and all dust emissions to air are extracted by the air extraction system, which are subsequently routed to a series of HEPA filters for each production unit.
- Solvent emissions are vented to atmosphere via a Solvent Recovery System (SRS) and Solvent Abatement System (SAS), which recovers a minimum of 99.97% of solvent input.

Solvent Tank Farm

The Solvent Tank Farm is located adjacent to Building 3, and contains 6 No. 30m^3 solvent tanks [4 No. raw material tanks (2 x 30m^3 DCM; 2 x 30m^3 methanol) and 2 No. aqueous/solvent-rich waste)] and 1 No. 30m^3 spill containment tank.

The Solvent Tank Farm including the tanker loading/unloading area is bunded and sloped to feed drains (which drain to the Fire-Water Retention Tank) in the event of spillages. The capacity of each bund is as per the requirements of Condition 3.6.2 of Licence Register No. P0153-05 and the bunds are integrity tested every three years in compliance with Condition 3.6.5. To date there have been no integrity failures for the Solvent Tank Farm bunds.

All bunds are subject to weekly housekeeping checks and all pipes are stainless steel and are routed to the process buildings via an overhead gantry. The integrity of the pipes on this gantry undergo regular inspection, as part of the routine preventive maintenance plan.

DCM and Methanol are mainly used as a carrier agent for the coating material used in the Efexor tablet coating process. An on-site solvent recovery system (SRS) removes solvent from the air stream through a cooling and condensation process. The recovery system has a recovery efficiency of 98.5%. The gas stream is then vented to a dedicated solvent abatement system (SAS), where any remaining solvent is removed by absorption, discharging to atmosphere with VOC levels less than 0.005kg/hour.

The installation of the SAS/SRS system is designed to provide a minimum recovery efficiency of 99.97% of the process input of both DCM and Methanol. All waste solvent produced from the SRS/SAS systems is transferred (using a totally automated and closed loop solvent transfer system) to the solvent waste tanks and removed off site via road tanker for distillation (recovery) and/or incineration (disposal) by an EPA approved Waste Management Contractor.

Automated Storage Retrieval System (ASRS)/Warehouse

A large ASRS for the storage of dry raw materials, intermediates and products is located in Building 9 in the centre of the site. All materials are initially stored in a quarantine area before sampling and approval by Incoming Quality (IQ). Materials are stored on a vertical pallet shelving system. Any dry spillages from the warehouse areas are swept and placed into designated hazardous waste storage bins in the area. There are no liquid materials stored in this area and all drains are sealed.

The warehouse area located in Building 4 is also used for storage of dry raw materials, intermediates and products as well as detergents. Solid materials are stored on a vertical pallet shelving system and detergents are stored on bunded containers as per the site's requirements.

Waste Storage Areas

There are two waste storage areas on the site, a purpose built Waste Management Centre and a temporary liquid hazardous waste storage area.

Waste Management Centre

The Waste Management Centre (to the rear of Building 9 adjacent to the WWTP) has been constructed so that WMI can better manage on-site waste management practices. In the waste management centre there are dedicated separate hazardous and non-hazardous waste storage areas. This waste management facility is suitably contained (bunded) in accordance with IPPC licence requirements and environmental best practice.

Temporary Liquid Hazardous Waste Storage Area

The temporary liquid hazardous waste storage area (hazardous waste compound) is located adjacent to building is used to store Intermediate Bulk Containers (IBCs) containing liquid wastes not suitable for treatment in the on-site WWTP, prior to collection for incineration off-site. This is an open area located on a tarmac compound and surrounded by security fencing.

Storage of all liquid material is on bunds and there are spill kits located in the area. Any loading of this waste is carried out under the supervision of the site EHS team with a frequency of 1-2 loads per week.

Waste Water Pre-Treatment Plant (WWTP)

The WWTP is located to the south east of the site and was commissioned in January 2006 and commenced full operation in 2007. The WWTP is used to treat both foul sewer and trade effluent and both networks serve the entire site through a series of underground drains and lift stations draining to the WWTP to the north west of the site. The trade effluent line is double lined high-density polyethylene (HDP) and the foul network is single lined HDP. Passive leak detection is installed on all double lined effluent lines and the lines are subject to an annual Preventative Maintenance check (i.e. visual inspection of drip points). A new wastewater conveyance system associated with the new WWTP was installed in 2005 and is integrity tested in accordance with Condition 3.6.5 of Licence Register P0153-05.

Wastewater from the foul sewer and trade effluent networks, enter the WWTP through influent wet well. Initial treatment is with a drum screen (1mm screen) to remove larger solids. Following screening the wastewater enters one of two balance tanks. The balance tanks are equipped with propellers and agitators where the dissolved oxygen content is continually monitored.

Following physical treatment the wastewater undergoes biological treatment in one of two biological tanks followed by a membrane tank and a permeate tank. The sludge from the initial screening and the sludge following drying and thickening at the plant are transported off-site by EPA approved waste management contractors for incineration off site. At this stage the wastewater is treated with ozone in the contact tank and a degas vessel (to remove the excess ozone) followed by discharge through the final effluent sump.

Final discharge is at Emission Point Reference No. SE1, which is continually monitored for pH, volume and temperature. Approximately 550m^3 of wastewater is treated per day at the plant. The balance and biological tanks are constructed of reinforced concrete and lined with polyethelene. With the exception of the influent and effluent sumps all structures are above ground.

In addition to the WWTP, there is a second treatment system installed to treat oils, fats and greases generated in the waste water from the canteen, prior to treatment in the main WWTP. This system is located in a designated compound to the north west of the site.

Storm Water Drainage Network

Storm water arises from rainwater run-off from roofed and paved areas (roads and car parking areas) around the site. The storm water flows by gravity through two underground drainage lines (North and South drainage lines) which combine at the main entrance gate at the WMI site before discharging under licence (Emission Point Reference No. SW1) to the Kildare County Council storm water drainage network which ultimately outfalls to the River Liffey.

On the south line, Storm water generated from the MHT area during a heavy rainfall event is attenuated using a below ground attenuation tank. This attenuation ensures that the net increase in

storm water runoff during such a rainfall event will be in line with the Dublin Corporation 'Storm water Management Policy for Developers', (January 1999). [1]

Each of these two drainage lines has a dedicated penstock valve. These 2 lines subsequently combine and a Total Organic Carbon (TOC) Analyser and a third penstock valve have been installed at this point (emission point reference No SW1).

WMI have designated TOC warning and action limits set at 20 mg/l and 30 mg/l respectively, which have been approved by the EPA. In the event of the site attaining the action limit for TOC, a penstock valve will be closed off automatically and will not be opened until the investigation into the cause of the elevated TOC warning is complete and approved by the WMI EHS Department. Additionally the penstock valves will automatically close off during a sprinkler test or during a fire alarm. In addition, the discharge to the SW1 can be manually restricted through two penstocks located adjacent to the discharge point

For selected areas around the site the storm water drainage system is further protected through shut off valves to close the storm water system. These areas include the loading bay between the Waste Management Centre and the WWTP. In the event of a fire or major spill these valves can be operated through an emergency switch on the wall of the Waste Management Centre building shutting down any potential discharges to surface water and diverting to the Fire-Water Retention Tank where the water can be tested and disposed off-site as per site procedures.

Air Emissions

There are 14 No. licensed boilers, 94 licensed major emission points (A2-1 to A2-94) and over 400 minor emission points located throughout the site. The emission sources associated with these discharge points are varied from coatings, vacuums, dust collectors and dryers across the plant.

The equipment used for such processes are enclosed and fitted with air extraction and filtration systems to collect any particulate matter that arises. Particulate matter also arises from general activities such as cleaning of equipment and work areas and is collected by the central house vacuum systems. In the main extraction systems are fitted with combined cartridge/ HEPA filters which have minimum collection efficiencies of 99.97% at 0.3 μm. The HEPA filters are fitted with pressure sensors. These pressure sensors are fitted with alarms with high and low level pressure settings whereby the emissions can be shut down. The pressure sensors undergo annual routine inspection and maintenance

VOC's emissions are produced as a result of the use of solvent in processing. Significant solvent usage (based on annual usage figures) is limited to DCM, Methanol, IPA, IMS, Pharmaglaze and a number of printing inks, which contain solvents. The three solvents used in the processing building include DCM, Methanol and IMS and account for the majority (>96%) of total organic solvent usage on-site.

The bulk of solvents used in processing (DCM/ Methanol) are recovered through the SRS and SAS abatement system, which recovers 99.9% of the solvent. A full mass balance tracking of the solvents used on site is carried out annually as part of the Solvent Management Plan and submitted within the Annual Environmental Report (AER).

[1] To enable attenuation, all of the storm water from MHT flows through a Hydrobrake, which attenuates the flow in accordance with current Local Authority requirements

Fire Water Retention (FWR) Tank

The firewater retention tank is located at the southeast corner of the site. The tank is constructed of concrete and was empty at the time of the audit. The tank has a capacity designed to meet the requirements of site operations at the time of installation (approx. 1,000m^3). The firewater retention capacity of the site was investigated in June 2005 and found that there was scope for increasing the size of the existing tank to meet the calculated shortfall for retention on the site (shortfall of approx 1,300m^3). This shortfall in retention was noted as being a direct effect of the significant increase in the volume of hard standing areas (car parks, etc) on the site.

Since 2007 (when the Agency formally approved the 2005 Fire-water Retention Study (FRS)) WMI have engaged with external consultants in assessing the implementation of the recommendations of the study. Phase 1 of this review involved the following scope:

a) Review the pervious and impervious areas used in the FRS report. Consideration to be made of any developments to the site, since the date of issue of the report.

b) Review the WMI suggestion (based on specialist consultant's advice) to reduce the rainfall intensity value currently set at 68mm in the FRS report. If deemed appropriate, reduce this figure provided that formal acceptance of same is received from the Agency.

c) Review the rainfall/runoff factors used in the FRS report based on comments received by WMI from JE. If necessary, revise the factors accordingly.

d) Review the Firewater containment figures used in the FRS report. Consideration to be made of any additional storage, installed since the date of issue of the report.

e) Review the catchment areas for both the north and south storm water drainage pipe runs to establish what, if any, overall firewater storage deficiency exists.

f) If deemed necessary during the above stages, advise on 'cost effective' engineering solutions to resolve any infrastructural deficits, including temporary above ground firewater hoses.

Following Phase 1 and in agreement with the FRS, it does appear that there is a nett firewater storage deficit at the WMI facility. Based on the available information and in the absence of 'building by building' based reviews, the extent of the deficit is unknown but it is envisaged to be in the region of 3,000m^3.

As part of Phase 2 of this study It is proposed that a 'system by system' or 'building by building' based approach is now carried out to progress the FRS and take account of developments on site since 2005. This approach will support a global assessment of the sites overall firewater retention needs and ultimately determine the level of deficiency currently present on the site. The proposed review should also validate the methodologies and assumptions that form the basis of the FRS.

Contractors Compound

There are a series of individual contractors bays located within one overall compound to the south of the site adjacent to Building 9. Each contractor has a designated area and is responsible for all environmental and waste management in their compound. The Wyeth EHS team carries out weekly inspections where the work practices in each contractor compound are audited.

Utilities

There is an 110kV sub station located south east of the site adjacent to the WWTP. There is also a CHP plant on the site to supplement the energy provided by the boilers. The CHP provides power and hot water to the site in addition to the national grid. The CHP is fuelled by natural gas. The boilers are also fuelled by natural gas with diesel only used if there is a shortage in the natural gas supply (diesel is piped underground feeding the boilers).

In addition to these systems there are emergency generators for short-term power supply to individual building areas located on the site (selected generators or fire pumps have localised storage of diesel in bunded areas). The emergency generators are tested on a weekly basis. Diesel refuelling is carried out using a bowser to refuel these tanks with the bowser pipeline located within the bund, which the diesel tank is located.

2.3 SOIL & GROUNDWATER CONDITIONS

A detailed soils and groundwater investigation was undertaken at the WMI site to determine the impact of an oil spill on surrounding soils and groundwater following the leakage of an oil storage tank, located adjacent to the pump house (building 6) (as first notified to the Agency on 02/03/2007). A Detailed Quantitative Risk Assessment (DQRA) was subsequently completed by RPS Group Ltd (submitted to the Agency on 14/02/2008) to assess the risk posed to sensitive receptors.

The site investigation report, localised groundwater pumping and the subsequent DQRA concluded that the although free phase diesel product had entered the underlying shallow aquifer, regular monitoring and analysis of the groundwater since 2007 has indicated that the material is very localised in extent, is likely to remain within 100m of the spill area and does not pose a risk to the Curragh sand and gravel aquifer. Biannual groundwater monitoring is currently undertaken within groundwater monitoring wells at this location and a provision for continuing this monitoring after closure of the WMI site is included in this Residual Management Plan.

2.4 GENERAL COMMENTS AND ASSUMPTIONS

A number of assumptions have been made when preparing this report.

According to EPA 2006 Clean Closure is defined as- *'upon cessation of operations and subsequent decommissioning at the facility, there are no remaining environmental liabilities*.'

- The closure considered most suited to the WMI site is a 'Clean Closure', with a provision for some post closure monitoring in the area of the historic diesel spill (the requirement for post closure monitoring will decided in conjunction with the EPA at the time of closure).

- The strict environmental policies implemented at the WMI site ensure that any cessation of operations at the facility will be a well-managed and resourced closure i.e. production schedules, raw materials purchasing, and storage will be planned with the shutdown already factored in.

- As any closure of the WMI facility will be well planned and resourced, the timeframe involved for closure activities is likely to range from 4-6 months.

- This Closure Plan assumes that the WMI facility will be decontaminated and decommissioned and sold for future industrial use, i.e. the costs for complete dismantling of buildings, etc., is not considered under this plan.

- Given that WMI operates using Good Manufacturing Practice (GMP) and has well defined cleaning and decontamination procedures in place, it is assumed that these practices will be employed throughout the planned closure.

- The Environmental Management System (EMS) will be maintained during closure.

2.5 CRITERIA FOR SUCCESSFUL CLOSURE

In order to achieve 'Clean Closure' the following benchmark set of criteria will need to be met as per EPA 2006 document.

- Full decontamination (in line with GMP and WMI Standard Operating Procedures) and decommissioning of all production buildings, including ancillaries and tank farms with shipping records for dispatch (if exported).

- All end products dispatched off site.

- All excess raw materials removed from site.

- All warehouse and storage buildings fully emptied and stored material transported or disposed of.

- All waste (hazardous and non-hazardous) disposed or recovered in a manner that complies with regulatory requirements.

- All site services fully decontaminated and decommissioned, and verified using analytical testing and certification.

- All relevant records relating to waste and materials movement, and transfer or disposal, managed and retained throughout the closure process.

- Independent documented verification that any asbestos is rendered safe and if necessary removed from site.

- Independent documented verification and removal of any PCB/PCT materials

- Removal by Radiological Protection Institute of Ireland (RPII) licensed contractor of any radioactive sources e.g. from laboratories, etc.

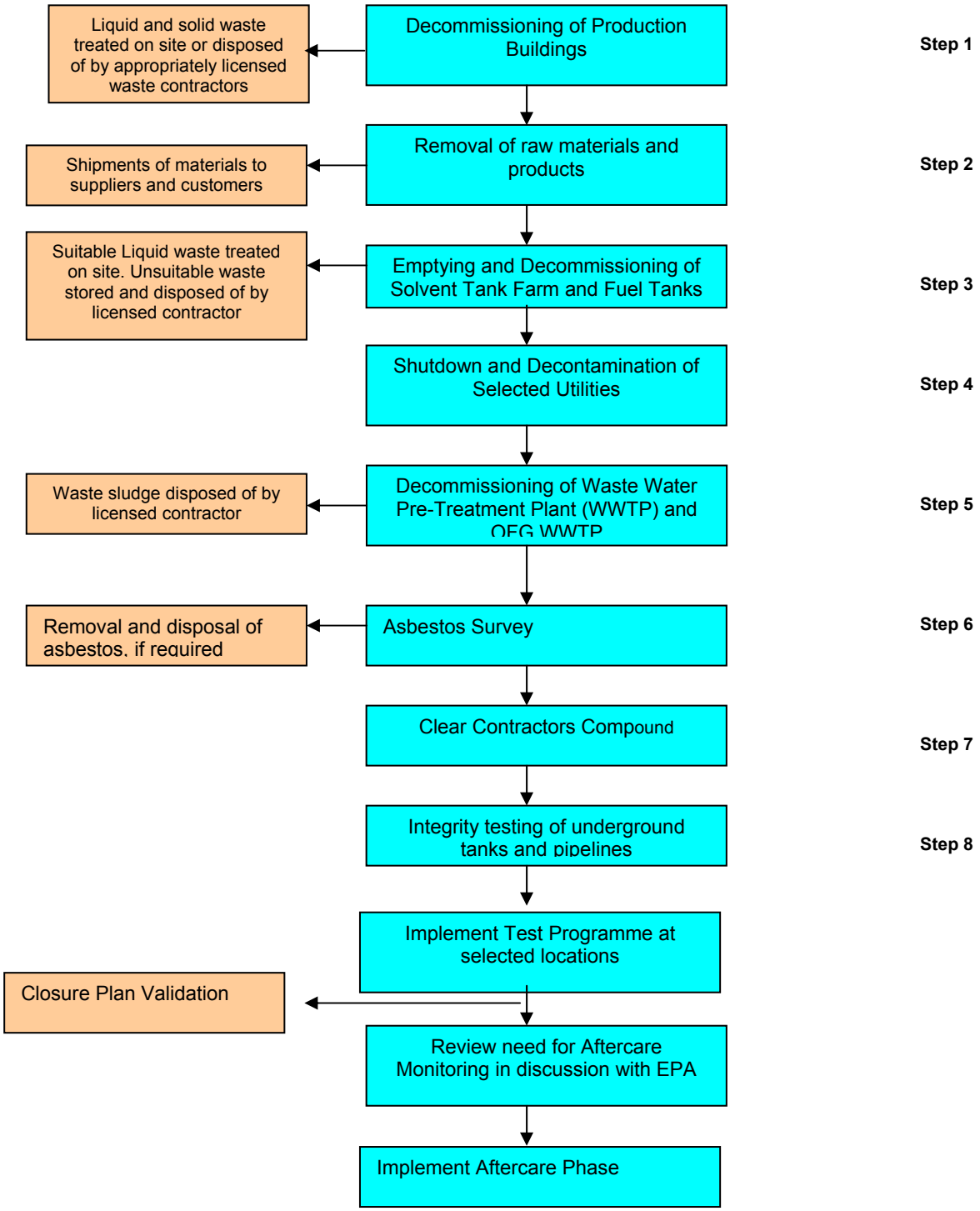
- Independent verification that no soil or groundwater contamination exists on the site upon closure through additional site investigation.

- Independent verification and certification of 'Clean Closure' status.

2.6 PLAN IMPLEMENTATION

Figure 2.1 illustrates the proposed programme for full WMI site closure. Each step is discussed in further detail in the section below.

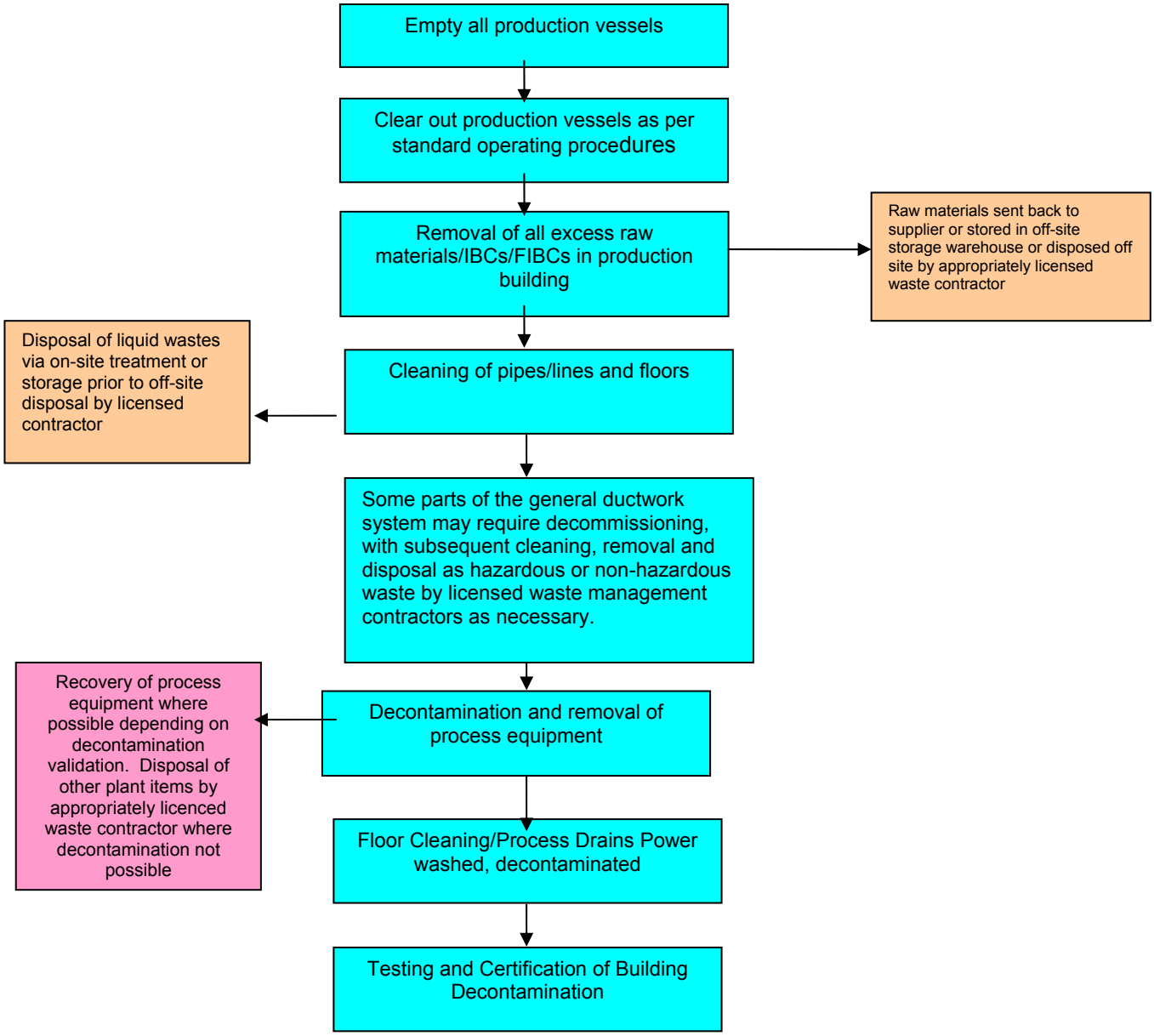
Figure 2.1 lustration of Programme of Closure for WMI facility.



Step 1: Decommissioning of Production Buildings

Decontamination of production equipment buildings will follow existing WMI Policies, Procedures (such as site change control) and Guidelines (PPG's). This is part of regular day-to-day practice in the WMI plant and therefore would not incur significant additional costs, resources or time to undertake. Figure 2.2 illustrates the likely sequence and methodology employed in fully decommissioning and decontaminating a production building at the WMI site.

Figure 2.2 Flow Diagram of Likely Order of Decommissioning of a WMI Production Building



The stages involved in Production Building closure are described in further detail below. These steps are presented in outline only here. For each step the relevant WMI PPG or programme will be consulted by site staff and subsequently implemented.

Step 1, Phase 1: Emptying & decontamination of all production vessels

Assume final product in the production building has been processed. Raw materials/intermediates/solvents will be removed and vessels will be cleaned and decontaminated as per WMI PPG's.

Step 1, Phase 2: Removal of excess raw materials/IBCs/FIBCs in production building

Any production liquid wastes not suitable for treatment in the on-site WWTP will be collected in appropriate UN approved containers (IBCs/drums) and transferred to the temporary liquid hazardous waste storage area awaiting collection prior to transport off site by EPA approved waste management contractor for disposal. Solid hazardous and non-hazardous waste will be transported to the appropriate on-site storage area, prior to transportation off site by appropriately licensed waste management contractors for disposal.

Step 1, Phase 3: Cleaning of overhead lines/floors & removal of air filters

Overhead pipes/ducts will be cleaned using vacuum cleaners and suitable detergent on hard surface areas. Once cleaned, swab testing will be undertaken. The acceptance criteria for the cleaning process and the subsequent classification of equipment as non-hazardous material for recycling/disposal are that the level of API must be below the limits of detection for the test method for individual APIs.

All HEPA filters will be bagged, labelled and transported off-site by appropriately licensed waste management contractors for disposal. Ducts will be cleaned and certified as decontaminated using WMI analytical testing procedures.

Step 1, Phase 4: Removal of plant items

All process equipment and plant will be removed from the building. This RMP assumes a worst-case scenario that all equipment cannot be cleaned to API non-detect levels and will require disposal as hazardous waste.

Step 1, Phase 5: Walls, floors and process drains flushed

This final stage of building decontamination will involve a complete power wash of walls, ceilings and process drains. Any waste generated will be suitably stored in UN approved containers prior to transportation off site by appropriately licensed waste management contractors for disposal.

Documentation relating to production buildings decontamination will be maintained as per existing procedures.

Budget Cost Estimate:

It is assumed that the shut down of production buildings is a well-planned and resourced event and most costs in terms of manpower will be allocated to normal plant running costs for the period in question with the exception of hired cleaning company and materials/equipment where necessary. Whilst the majority of the costs will be absorbed into normal operating costs, there may be exceptional additional costs for some equipment disposal. The resource value of various high-grade steel plant items can be recovered through sale of this material and possible shipment overseas. For these reasons a provisional sum of **€250,000** is proposed for the closure and decontamination of all Production Buildings at the WMI site.

Step 2: Removal of raw materials and products

The AS/RS warehouse and general warehouse will be emptied on a phased basis depending on the closure of the production buildings. It is assumed that the shut down of production buildings is a well-planned event, therefore ensuring that there is not an excess of raw materials or products stored on site.

All raw materials will be sent back to suppliers where possible. In the event where this is not possible, these will be stored in appropriate UN approved containers for collection by appropriately licensed waste management contractors for recovery/disposal off-site.

All non-hazardous waste will be segregated and sorted for recycling/reuse or disposal by appropriately licensed waste management contractors. Liquid waste, which is suitable for treatment at the on-site WWTP, will be directed to the process drains and treated and discharged under the terms of the WMI IPPC licence. Liquid wastes not suitable for release to the WWTP will be stored in appropriate UN approved containers (IBCs/drums) and transferred to the temporary liquid hazardous waste storage area awaiting collection prior tor transport off site by appropriately licensed waste management contractor for disposal.

Significant additional costs will not be incurred for this step. However, a provisional sum of **€20,000** is proposed for contract cleaning.

Step 3: Emptying and Decommissioning of Solvent Tank Farm and Fuel Tanks

The planned shut down of the WMI facility and Solvent Tank Farm will ensure excess solvent raw materials are not in storage at the time of shut down.

All solvent lines will be isolated from associated tanks and tanks fully emptied. All bunded solvent storage areas (External – Solvent Tank Farm; Internal – Solvent Storage Area) and solvent/process drains will be flushed and cleaned. All liquid waste generated during cleaning processes, which is suitable for treatment at the on-site WWTP will be directed to the process drains and treated and discharged under the terms of the WMI IPPC licence. Liquid wastes not suitable for release to the WWTP will be stored in appropriate UN approved containers (IBCs/drums) and transferred to the temporary liquid hazardous waste storage area awaiting collection prior to transport off site by appropriately licensed waste management contractor for disposal.

Fuel tanks (5 No. diesel tanks) will be emptied by appropriately licensed contractors Where possible fuel will be returned to supplier. If this is not possible the fuel will be disposed of by an appropriately licensed contractor. If required all fuel tank bunds will be cleaned. All other site bunds will be cleaned and the 3 oil interceptors and 5 wastewater lift stations will be cleaned during this stage.

A specialised contractor will be appointed to carry out the above cleaning and WMI engineering staff will oversee the process. All documentation relating to the cleaning process will be available on-site. All wastes will be stored in appropriate UN approved containers (IBCs/drums) and transferred to the temporary liquid hazardous waste storage area awaiting collection prior to transport off site by appropriately licensed waste management contractor for disposal.

The cost of specialist cleaning contractor will require a provision of **€100,000**. This includes cleaning of all tanks, bunds, sumps, lift stations and oil interceptors.

Step 4: Shutdown and Decontamination of Selected Utilities

- Cooling towers and chiller units will be shutdown and decommissioned. Appropriately licensed waste contractors will dispose of contact water. Refrigerant will be collected for re-processing by appropriately licensed contractors.

- A specialist contractor (service contractors) will decommission boilers and associated systems.

- The process and potable water systems will be decommissioned and any chemicals will be removed off site by appropriately licensed contractors.

- A specialist contractor will clean the Solvent Abatement System and Solvent Recovery System.

- The Combined Heat and Power plant will be decommissioned and rendered safe by the service contractors.

- Contractor will decommission compressed air units.

- The Firewater Retention tank is not expected to contain hazardous residuals. The tank will be washed through with clean water and the contents drained to the site surface water drainage system.

- The Surface Water Attenuation Tank will be flushed with clean water and the contents drained to the site surface water drainage system.

- Laboratories and administration building will be cleared and all waste recorded and stored prior to disposal. Laboratory chemicals and equipment will be returned to supplier or may be sold on where appropriate. If this is not feasible the chemicals will be disposed of off-site by an appropriately licenced waste management contractor. All Waste Electrical and Electronic Equipment will be removed off site for recycling by an appropriately licenced waste management contractor.

The main costs associated with decommissioning utilities will be contractor costs. There may be disposal costs associated with some equipment and waste. There may also be resale value attached to some equipment and plant. A provision of **€75,000** should be sufficient for contractor costs and equipment disposal.

Step 5: Decommissioning of Waste Water Pre-Treatment Plant (WWTP) and OFG WWTP

The WWTP and OFG WWTP will be one of the last items of plant to be fully decommissioned. The operational WWTP will be required throughout the decommissioning and decontamination stages of the closure to treat any suitable wastewater generated. The WWTP and OFG WWTP systems will be shutdown according to standard procedures. The WWTP ozone treatment tanks will be decommissioned and all tanks will be washed through and the de-watering facilities will be decommissioned. Any chemicals will be sent back to supplier. A licensed contractor will dispose of waste sludge off site.

It is estimated that a sum of **€100,000** will be required for decommissioning of the WWTP and OFG WWTP.

Step 6: Asbestos Survey

An asbestos (Type 1 and Type 2) survey undertaken in 2008 by Occupational Hygiene Safety Services (OHSS) concluded that firedoors, rope gaskets and underground cement piping on site are likely to be asbestos containing. In 2008 WMI disposed of waste containing asbestos (this waste originated from decommissioned fire doors).

For the purposes of this RMP it is assumed that a UK Health and Safety Executive Guideline "MDHS 100", Type 3 Asbestos Survey (full access sampling and identification survey – pre-demolition/major refurbishment survey) will be carried out at a cost of €10,000. A provisional and contingency sum of sum of **€30,000** has been included for the management of asbestos if required. Any activities involving asbestos will be properly documented (e.g. removal and disposal).

Step 7: Contractors Compound

The contractor's compound will be used throughout the closure process. Closure of this area of the site will involve dismantling of cabins, removal and safe disposal of wastes, paints to be collected by an appropriately licenced waste management contractor. All non hazardous waste will be segregated for recycling/recovery or disposal and will be collected by appropriately licensed waste contractors. The costs associated with waste disposal for the entire WMI site closure are detailed in Section 2.7

Step 8: Integrity Testing of underground tanks and pipelines

WMI will include for the integrity testing of underground tanks and pipelines prior to decommissioning of the site. However this testing will only be carried out if the site is decommissioned after 1 year of completion of the scheduled 3 year testing as required by Condition 6.9 of Licence Register No. P0153-05. In this instance, contract specialists will perform a CCTV inspection on pipelines. A cost of **€20,000** has been included to account for the sewer inspection (including any associated required cleaning and disposal of waste to landfill) and a contingency sum of **€50,000** has been included to allow for any required repairs.

2.7 WASTE ARISINGS

Throughout the closure process the majority of liquid waste will be routed through the WWTP for treatment and discharge in compliance with WMI IPPC licence conditions. There will, however, be solid and liquid hazardous waste and some plant and equipment waste, which cannot be treated on-site or re-sold or transferred to Wyeth sister sites.

Table 3.1 details the total waste arisings for the WMI site in 2007. It is estimated that the Closure Plan will take 4-6 months to implement. As an estimate, it is assumed that 4 months of hazardous and non-hazardous waste will be generated during the Closure Plan implementation.

Table 3.1: 2008 Off Site Waste Disposal.

Type	Amount(1) (tonne)	Methods of Disposal
Hazardous	3451	Licensed waste management contractor
Non-hazardous	503	Licensed waste management contractor

(1) Figure taken from 2008 AER

Table 3.2 RMP Off Site Waste Disposal Costs.

Type	Amount(1) (tonne)	Approximate Cost per tonne (€)	Cost (€)
Hazardous	1150	1000	1,115,000
Non-hazardous	168	300	50,400
Total			**1,165,400**

(1) Based on 4 months of waste generation.

2.8 TEST PROGRAMME

A test programme will be required to verify the full decontamination of ducting, drains, pipelines, underground tanks, etc. All test results for API decontamination will be recorded and records kept on-site.

It is proposed that a final inspection/integrity test of underground structures, bunds and process lines is undertaken upon final wash down. In the event of any failure of structures, a soil and ground water investigation may be required to assess potential ground contamination beneath structures (requirement or otherwise for such investigation will be based on appropriate risk assessment methodologies). All tested structures will require certification of full integrity. During full operations at the facility it is not possible to investigate soil conditions beneath certain structures. Once decommissioned, these areas can be investigated for possible contamination. Examples of areas which may require certification of uncontaminated status include:

- Fire Water Retention Tank
- Waste Water Treatment Plant
- Fuel Oil Tanks Bunds
- Solvent Storage Area
- Solvent Process Drains
- Solvent Bund Drains
- Underground sewer network (foul and trade effluent lines, lift stations etc).
- Surfacewater attenuation tank

The costs associated with bund cleaning are included in Step 3.

A planned programme of ground investigation could be implemented in the areas as described above. Budget cost estimates for ground investigation of the site involving up to 30 borehole wells or soil cores at all key potential areas of contamination are as follows:

(a) installation of monitoring wells: **€20,000**

(b) soil sampling programme: **€20,000**

(c) reporting €**12,000**

2.9 AFTERCARE MANAGEMENT

In the event that during the post-closure investigation, significant soil contamination is found to be present, appropriate additional measures will be implemented.

A sum of **€50,000** is provided for monitoring and reporting of groundwater in the area of the diesel spill for a period of three years after closure. This provision is dependent on the assessment of the need for such monitoring once closure is announced. At time of some future closure it may not be necessary to continue monitoring at this location. However, as a precaution it is proposed to continue the monitoring programme in the area of the diesel spill for a period of three years after closure.

3 SUMMARY OF CLOSURE PLAN COST ESTIMATES

Step 1 Shutdown and decommissioning of Production Buildings	**€250,000**
Step 2 AS/RS & Warehouse cleaning	**€20,000**
Step 3 Solvent Tank Farm and diesel fuel tanks cleaning	**€100,000**
Step 4 Utilities decommissioning	**€75,000**
Step 5 WWTP and OFG WWTP decommissioning	**€100,000**
Step 6 Asbestos Survey and disposal (if required)	**€40,000**
Waste Arisings	**€1,165,400**
Process Equipment Hazardous Waste Disposal	**€30,000,000**[(1)]
Sewer network investigation and repair (if required)	**€70,000**
Ground Investigation	**€52,000**
Monitoring in area of diesel spill	**€50,000**
Independent Verification Audit	**€10,000**
Total	**€31,932,400**

Note [(1)]: It is estimated that up to €30,000,000 for hazardous waste disposal of all equipment that cannot be cleaned to API non-detect levels will be required. This is based on worst-case assumptions and from previous decommissioning of plant and equipment carried out at WMI.

4 CLOSURE PLAN UPDATE AND REVIEW

In accordance with the WMI IPPC licence '*the plan shall be reviewed annually and proposed amendments thereto notified to the Agency for agreement as part of the AER'.* It is proposed therefore that this report is subject to review as required by the licence and will reflect any process changes on the site.

5 CLOSURE PLAN IMPLEMENTATION

As part of the Closure Plan implementation, a series of requirements must be met;

Notification to EPA

WMI management will notify the EPA, as soon as is reasonably practicable, of all plans to cease operations with full closure of the site. A detailed time frame for the Closure Plan will be agreed with the EPA prior to any cessation.

Other statutory Notifications:

Other statutory bodies including the local authority (Kildare County Council) will be notified of plans to cease operation and proposed closure time frame.

6 CLOSURE PLAN VALIDATION

Upon completion of implementation of the Closure Plan, WMI will conduct a validation audit to demonstrate to the EPA that the Closure Plan has been implemented.

7 FINANCIAL PROVISIONS

WMI is committed to ensuring the highest level of environmental performance and environmental protection in its operations, and regards this as an integral part of its normal business practice. This includes a commitment to safe and responsible residuals management where required including the provision of central funding to implement and progress any required residuals management.

WMI is a component site of Wyeth Corporate. Wyeth Corporate operates a global network of manufacturing sites, including both bulk manufacture and final dosage formulation facilities, together with logistics facilities, and technical support functions.

Wyeth Corporate is a global leader in pharmaceuticals, consumer health care products, and animal health care products. Global revenues for 2007 were US$48.4 billion with net income, after tax of US$19.3 billion. The WMI manufacturing site in Newbridge is a cost centre within the Wyeth Corporation and is therefore centrally funded from Wyeth Corporate in the US. The site operates to an agreed annual budget which is set in advance and which is intended to cover projected expenditure related to site operations for that financial year. This budget is typically of the order of several hundred million US dollars.

Wyeth Corporate, in common with many large multinational companies, provides central funds to its operating units through standard financial mechanisms. Because of the likely lengthy interval between a decision to close the WMI site and its actual closure, adequate time would be available to ensure that an allowance for central Wyeth Corporate funding would be incorporated into the site budget to implement the RMP.

Consequent upon a decision to decommission all or part of the WMI site, an estimate would be prepared of projected closure costs, including those costs which may be incurred under RMP activities as outlined herein (this RMP cost estimate would include those activities required to effect closure in the short-term and also any longer term remediation and monitoring activities if required). A detailed dossier would then be prepared for submission to Wyeth Corporate central management and central funding would be released by Wyeth Corporate to cover both short-term and longer-term costs as required. Such central funding may be structured by Wyeth Corporate to stretch over several years as required to cover longer-term activities.

Wyeth Corporate would take a decision to decommission all or part of the WMI site centrally under a coordinated review. Any such decision would be announced by Wyeth Corporate sufficiently in advance of implementation to allow adequate opportunity to migrate production to alternative locations, to explore divestiture options, to address legal and regulatory requirements, and to complete decommissioning activities where required.

Any closure decision would therefore be taken significantly in advance of implementation. In the event of such a decision, the site RMP as outlined herein would be prepared for activation. The actions detailed in the RMP would begin upon cessation of manufacturing and preparation for closure.

It is therefore a valid assumption that any permanent or long-term shutdown of the WMI site will be a well-planned and well-resourced process. This implies that the shutdown date will be known well in advance and that both production schedules and raw materials purchasing will be planned with the shutdown already factored in.

It also implies that the WMI site will have the resources in terms of financial inputs to implement the RMP through to completion, with no requirement for external financing. WMI reviews its insurance and financial arrangements on a regular basis to ensure ongoing and continued adequacy. Any changes or updates to such arrangements shall be described in RMP reviews to be submitted to the Agency.

Appendix 9

Bund Integrity Testing 2008

ID	Test Date	Test Result	ID	Test Date	Test Result	ID	Test Date	Test Result
PE 01	08/10/08	Pass Note 1	TP010a	30/07/08	Pass Note 1	TP038	07/07/08	Pass Note 1
PE 02a	08/10/08	Pass Note 1	TP010b	15/10/08	Pass Note 1	TP039	18/06/08	Pass Note 1
PE 02b	08/10/08	Pass Note 1	TP011a	11/07/08	Pass Note 1	TP040	07/07/08	Pass Note 1
PE 03	08/10/08	Pass Note 1	TP011b	11/07/08	Pass Note 1	TP041	10/07/08	Pass Note 1
PE 04	08/10/08	Pass Note 1	TP012a	17/06/08	Pass Note 1	TP042	10/08/08	Pass Note 1
PE 05	27/08/08	Pass Note 1	TP012b	17/06/08	Pass Note 1	TP043	07/07/08	Pass Note 1
PE 06	27/08/08	Pass Note 1	TP013a	17/06/08	Pass Note 1	TP045	18/08/08	Pass Note 1
PE 07	27/08/08	Pass Note 1	TP013b	17/06/08	Pass Note 1	TP046	26/08/08	Pass Note 1
PE 13	27/08/08	Pass Note 1	TP014a	18/06/08	Pass Note 1	TP047	16/10/08	Pass Note 1
PE 14	08/08/08	Pass Note 1	TP014b	18/06/08	Pass Note 1	TP048	16/10/08	Pass Note 1
PE 15	08/08/08	Pass Note 1	TP015a	17/06/08	Pass Note 1	TP049	30/07/08	Pass Note 1
PE 17	02/10/08	Pass Note 1	TP015b	17/06/08	Pass Note 1	TP050	30/07/08	Pass Note 1
PE 18	02/10/08	Pass Note 1	TP016a	17/06/08	Pass Note 1	TP051	30/07/08	Pass Note 1
PE 19	08/08/08	Pass Note 1	TP016b	17/06/08	Pass Note 1	TP052	15/05/08	Pass Note 1
PE 20	08/08/08	Pass Note 1	TP017a	09/07/08	Pass Note 1	TP053	07/08/08	Pass Note 1
PE 21	14/08/08	Pass Note 1	TP017b	09/07/08	Pass Note 1	TP054	30/07/08	Pass Note 1
PE 22	15/10/08	Pass Note 1	TP018a	09/06/08	Pass Note 1	TP057	16/10/08	Pass Note 1
PE 23	15/05/08	Pass Note 1	TP018b	09/06/08	Pass Note 1	TP058	18/07/08	Pass Note 1
PE 24	15/05/08	Pass Note 1	TP019a	01/06/08	Pass Note 1	TP059	10/07/08	Pass Note 1
PE 26	02/10/08	Pass Note 1	TP019b	05/06/08	Pass Note 1	TP060	15/05/08	Pass Note 1
PE 36	15/10/08	Pass Note 1	TP020a	05/06/08	Pass Note 1	TP061	01/08/08	Pass Note 1
PE 37	25/11/08	Pass Note 1	TP020b	05/06/08	Pass Note 1	TP062	01/08/08	Pass Note 1
PE 38	25/11/08	Pass Note 1	TP021a	29/11/08	Pass Note 1	TP063	28/11/08	Pass Note 1
PE 39	10/10/08	Pass Note 1	TP021b	29/11/08	Pass Note 1	TP064	28/07/08	Pass Note 1
PE 40	25/11/08	Pass Note 1	TP022a	30/07/08	Pass Note 1	TP065	24/07/08	Pass Note 1
PE 43	01/10/08	Pass Note 1	TP022b	30/07/08	Pass Note 1	TP066	16/10/08	Pass Note 1
PE48	10/01/08	Pass Note 1	TP022c	30/07/08	Pass Note 1	TP068	01/08/08	Pass Note 1
PE65	24/07/08	Pass Note 1	TP023	21/07/08	Pass Note 1	TP069	04/08/08	Pass Note 1
PE 68	01/12/08	Pass Note 1	TP024	21/07/08	Pass Note 1	TP072	10/07/08	Pass Note 1
PE 71	22/03/08	Pass Note 1	TP025	01/08/08	Pass Note 1	TP075	10/07/08	Pass Note 1
TP003a	22/07/08	Pass Note 1	TP026	08/08/08	Pass Note 1	TP078	28/08/08	Pass Note 1
TP003b	22/07/08	Pass Note 1	TP027	11/07/08	Pass Note 1	TP081	18/07/08	Pass Note 1
TP004a	22/07/08	Pass Note 1	TP028	10/07/08	Pass Note 1	TP082	10/07/08	Pass Note 1
TP004b	22/07/08	Pass Note 1	TP029	21/07/08	Pass Note 1	TP083	01/08/08	Pass Note 1
TP005a	22/07/08	Pass Note 1	TP030	21/07/08	Pass Note 1	TP084	28/11/08	Pass Note 1
TP005b	22/07/08	Pass Note 1	TP032	21/07/08	Pass Note 1	TP086	13/08/08	Pass Note 1
TP006a	10/07/08	Pass Note 1	TP034	10/07/08	Pass Note 1	TP087	15/10/08	Pass Note 1
TP006b	10/07/08	Pass Note 1	TP035	18/06/08	Pass Note 1	TP088	21/07/08	Pass Note 1
TP007a	10/07/08	Pass Note 1	TP036	18/06/08	Pass Note 1	TP089	21/07/08	Pass Note 1
TP007b	10/07/08	Pass Note 1						

ID	Test Date	Test Result	ID	Test Date	Test Result	ID	Test Date	Test Result
TP093	16/10/08	Pass Note 1	TP121	18/08/08	Pass Note 1	TP199	15/10/08	Pass Note 1
TP094	16/10/08	Pass Note 1	TP122	31/07/08	Pass Note 1	TP198	15/10/08	Pass Note 1
TP095	10/07/08	Pass Note 1	TP123	30/07/08	Pass Note 1	TP200	28/11/08	Pass Note 1
TP096	10/07/08	Pass Note 1	TP124	30/07/08	Pass Note 1	TP201	28/11/08	Pass Note 1
TP097	10/07/08	Pass Note 1	TP153	23/07/08	Pass Note 1	TP202	03/06/08	Pass Note 1
TP098	01/08/08	Pass Note 1	TP154	09/07/08	Pass Note 1	TP 270	11/01/08	Pass Note 1
TP100	10/07/08	Pass Note 1	TP155	17/06/08	Pass Note 1	TP 271	11/01/08	Pass Note 2
TP101	10/07/08	Pass Note 1	TP156	28/08/08	Pass Note 1	TP 272	09/01/08	Pass Note 2
TP102	10/07/08	Pass Note 1	TP163	28/11/08	Pass Note 1	TP 273	09/01/08	Pass Note 2
TP105	09/07/08	Pass Note 1	TP164	28/11/08	Pass Note 1	TP 275	21/04/08	Pass Note 2
TP106	16/10/08	Pass Note 1	TP165	28/11/08	Pass Note 1	TP 276	03/06/08	Pass Note 2
TP107	13/08/08	Pass Note 1	TP167	01/10/08	Pass Note 1	TP 284	16/05/08	Pass Note 1
TP108	09/07/08	Pass Note 1	TP174	28/08/08	Pass Note 1	TP 285	16/05/08	Pass Note 2
TP109	10/07/08	Pass Note 1	TP175	15/10/08	Pass Note 1	TP 298	16/09/08	Pass Note 2
TP112	29/07/08	Pass Note 1	TP177	16/10/08	Pass Note 1	TP 299	16/09/08	Pass Note 2
TP113	25/11/08	Pass Note 1	TP178	16/10/08	Pass Note 1	TP 300	16/09/08	Pass Note 2
TP114	15/10/08	Pass Note 1	TP179	16/10/08	Pass Note 1	TP 301	16/09/08	Pass Note 2
TP115	15/10/08	Pass Note 1	TP180	28/11/08	Pass Note 1			
TP117	18/08/08	Pass Note 1	TP192	15/10/08	Pass Note 1			
TP118	18/08/08	Pass Note 1	TP196	15/10/08	Pass Note 1			
TP120	18/08/08	Pass Note 1	TP197	15/10/08	Pass Note 1			

Note 1: The Integrity testing methodology employed is based on BS8007;1987, Section 9.2
Note 2: New, Supplier provided the Integrity Certificate

ID	Test Date	Test Result	ID	Test Date	Test Result	ID	Test Date	Test Result
PE41	03/06/2008	Fail Note 1	TP022d	30/07/2008	Fail ***Note 2***	TP031	01/06/2008	Fail Note 3
TP056	01/08/2008	Fail **Note 3**	TP067	10/07/2008	Fail **Note 3**	TP071	10/07/2008	Fail Note 3

Note 1: An Incident report has been filed and remediation works have been scheduled
Note 2: The Failed bunds have been decommissioned and removed from use
Note 3: The Failed bunds have been decommissioned and removed from site

Appendix 10

Boiler Maintenance Programme 2008

Wyeth **Wyeth Medica Ireland**

Newbridge, Co. Kildare, Ireland. Telephone (045) 447000 Facsimile (045) 434113

Internal Memorandum

To: **Ray Cully, EHS**

From: **Roy Serviss, Utilities Planning Engineer**

Date: **18/03/09**

Subject: **Boilers – Service and Maintenance**

Boilers on site are maintained on a regular basis through maintenance contracts with two companies. This maintenance is in the form of four quarterly maintenance checks per year by Saacke, and one annual service visit from Boiler House Services. This includes (Medium Temperature Hot Water) MTHW and Steam boilers.

Signed _____ **Date** 18/03/09

Roy Serviss
Utilities Planning Engineer

Signed _____ **Date** 18/03/09

Paul O'Brien
Utilities Supervisor

Appendix 11

European Pollutant Release and Transfer Register

Environmental Protection Agency

AER Returns Worksheet

Version 1.1.02

REFERENCE YEAR	2008

1. FACILITY IDENTIFICATION

Parent Company Name	AHP Manufacturing B.V. Trading As Wyeth Medica Ireland
Facility Name	AHP Manufacturing B.V. Trading As Wyeth Medica Ireland
PRTR Identification Number	P0153
Licence Number	P0153-05

Waste or IPPC Classes of Activity

No.	class_name
12.2.1	The surface treatment of substances, objects or products using organic solvents, in particular for dressing, printing, coating, degreasing, waterproofing, sizing, painting, cleaning or impregnating, with a consumption capacity of more than 150 kg per...

Address 1	Buckley's Cross Roads
Address 2	Old Connell
Address 3	Newbridge
Address 4	County Kildare
Country	Ireland
Coordinates of Location	28162157
River Basin District	
NACE Code	211
Main Economic Activity	Manufacture of basic pharmaceutical products
AER Returns Contact Name	Michael Donlon
AER Returns Contact Email Address	donlonm@wyeth.com
AER Returns Contact Position	Environmental, Health & Safety Associate Director
AER Returns Contact Telephone Number	045 447000
AER Returns Contact Mobile Phone Number	
AER Returns Contact Fax Number	045 434113
Production Volume	837954.0
Production Volume Units	Kg
Number of Installations	0
Number of Operating Hours in Year	0
Number of Employees	1300
User Feedback/Comments	
Web Address	www.wyeth.ie

2. PRTR CLASS ACTIVITIES

Activity Number	Activity Name
9c	Installations for surface treatment of substances,objects or products using organic solvents,in particular dressing,printing,coating,degreasing,waterproofing,sizing,painting,cleaning or impregnating

3. SOLVENTS REGULATIONS (S.I. No. 543 of 2002)

Is it applicable?	No
Have you been granted an exemption ?	No
If applicable which activity class applies (as per Schedule 2 of the regulations) ?	
Is the reduction scheme compliance route being used ?	

SECTION A : SECTOR SPECIFIC PRTR POLLUTANTS

RELEASES TO AIR

POLLUTANT		METHOD									QUANTITY		
			Method Used		CHP	A1-11	A1-12	A1-1-A1-9	A1-1 to A1-8 A1-10(a)(b) A1-11 A1-12 A3-317 A3-324 A3-325 A3-335 A3-336 A4-101 to A4-105 A4-121 to A4-125 A4-140	A2-16 & A2-41			
No. Annex II	Name	M/C/E	Method Code	Designation or Description	Emission Point 1	Emission Point 2	Emission Point 3	Emission Point 4	Emission Point 5	Emission Point 6	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
02	Carbon monoxide (CO)	M	Siteright Environmental I.S. EN 15058; Analysis - Flue gas Analyser	-	30913.91	359.44	303.23	1036.62	0.0	0.0	32615.2	0.0	0.0
08	Nitrogen oxides (NOx/NO2)	M	Siteright Environmental I.S. EN 14792; Analysis - Flue gas Analyser	-	13929.44	1437.76	2061.58	10582.79	0.0	0.0	28011.99	0.0	0.0
03	Carbon dioxide (CO2)	C	-	Guidelines for the monitoring and reporting of greenhouse gas emissions pursuant to Directive 2003/87/EC (2007/589/EC)	0.0	0.0	0.0	0.0	22120000.0	0.0	22120000.0	0.0	0.0
35	Dichloromethane (DCM)	C	Siteright Environmental test method based on EN 13649; Analysis by GCFID	-	0.0	0.0	0.0	0.0	0.0	32.73	362.23	0.0	329.5

* Select a row by double clicking on the Pollutant Name (Column B) then click the delete button

SECTION B : REMAINING PRTR POLLUTANTS

RELEASES TO AIR

POLLUTANT		METHOD			QUANTITY			
			Method Used					
No. Annex II	Name	M/C/E	Method Code	Designation or Description	Emission Point 1	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
					0.0	0.0	0.0	0.0

* Select a row by double clicking on the Pollutant Name (Column B) then click the delete button

SECTION C : REMAINING POLLUTANT EMISSIONS (As required in your Licence)

RELEASES TO AIR

POLLUTANT		METHOD			A2-1-A2-94	A2-16,A2-41	A2-6, A2-16 and A2-41	QUANTITY		
			Method Used							
Pollutant No	Name	M/C/E	Method Code	Designation or Description	Emission Point 1	Emission Point 2	Emission Point 3	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
210	Dust	C	Siteright environmental method based on I.S. EN 13284 Part 1; Analysis using laboratory practice that is ISO 17025 accredited for gravimetric analysis	-	132.04	0.0	0.0	132.04	0.0	0.0
227	TA Luft inorganic dust particles class 1	C	Siteright Environmental method based on IS EN 13649; Analysis by GCFID	-	0.0	39.58	0.0	39.58	0.0	0.0
228	TA Luft inorganic dust particles class 2	C	Siteright Environmental method based on IS EN 13649; Analysis by GCFID	-	0.0	0.0	34.33	34.33	0.0	0.0
229	TA Luft inorganic dust particles class 3	C	Siteright Environmental method based on IS EN 13649; Analysis by GCFID	-	0.0	0.0	1282.68	1282.68	0.0	0.0
351	Total Organic Carbon (as C)	C	Siteright Environmental method based on IS EN 13649; Analysis by GCFID	-	0.0	6.92	0.0	6.92	0.0	0.0

* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

Additional Data Requested from Landfill operators

For the purposes of the National Inventory on Greenhouse Gases, landfill operators are requested to provide summary data on landfill gas (Methane) flared or utilised on their facilities to accompany the figures for total methane generated. Operators should only report their Net methane (CH4) emission to the environment under T(total) KG/yr for Section A: Sector specific PRTR pollutants above. Please complete the table below:

Landfill: AHP Manufacturing B.V. Trading As Wyeth Medica Ireland

Please enter summary data on the quantities of methane flared and / or utilised	T (Total) kg/Year	M/C/E	Method Used: Method Code	Method Used: Designation or Description	Facility Total Capacity m3 per hour	
Total estimated methane generation (as per site model)	0.0				N/A	
Methane flared	0.0				0.0	(Total Flaring Capacity)
Methane utilised in engine/s	0.0				0.0	(Total Utilising Capacity)
Net methane emission (as reported in Section A above)	0.0				N/A	

SECTION A : SECTOR SPECIFIC PRTR POLLUTANTS

Data on ambient monitoring of storm/surface water or groundwater, conducted as part of your licence requirements, should NOT be submitted under AER / PRTR Reporting as this only concerns Releases from your facility

RELEASES TO WATERS								
POLLUTANT			Method Used			QUANTITY		
No. Annex II	Name	M/C/E	Method Code	Designation or Description	Emission Point 1	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
					0.0	0.0	0.0	0.0

* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

SECTION B : REMAINING PRTR POLLUTANTS

RELEASES TO WATERS								
POLLUTANT			Method Used			QUANTITY		
No. Annex II	Name	M/C/E	Method Code	Designation or Description	Emission Point 1	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
					0.0	0.0	0.0	0.0

* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

SECTION C : REMAINING POLLUTANT EMISSIONS (as required in your Licence)

RELEASES TO WATERS								
POLLUTANT			Method Used			QUANTITY		
Pollutant No.	Name	M/C/E	Method Code	Designation or Description	Emission Point 1	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
					0.0	0.0	0.0	0.0

* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

SECTION A : PRTR POLLUTANTS

OFFSITE TRANSFER OF POLLUTANTS DESTINED FOR WASTE-WATER TREATMENT OR SEWER										
POLLUTANT		METHOD			QUANTITY					
			Method Used							
No. Annex II	Name	M/C/E	Method Code	Designation or Description	Emission Point 1	Emission Point 2	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
17	Arsenic and compounds (as As)	M	SLS TM 128 by Hydride Generation Atomic Absorpt		0.2	0.0	0.2	0.0	0.0
27	Atrazine	M	Part of a group testing for triazine/Herbicides by GC		0.2	0.0	0.2	0.0	0.0
79	Chlorides (as Cl)	M	SLS TM 097 based on USEPA Method 525.1/2		29502.0	0.0	29502.0	0.0	0.0
19	Chromium and compounds (as Cr)	M	SLS TM 152 by ICPMS		0.75	0.0	0.75	0.0	0.0
20	Copper and compounds (as Cu)	M	SLS TM 152 by ICPMS		4.59	0.0	4.59	0.0	0.0
22	Nickel and compounds (as Ni)	M	SLS TM 152 by ICPMS		0.59	0.0	0.59	0.0	0.0
51	Simazine	M	Part of a group testing for triazine/Herbicides by GC		0.2	0.0	0.0	0.0	0.0
12	Total nitrogen	M	SLS TM 102 D based on AWWA/APHA 20th Edition		2713.0	0.0	2713.0	0.0	0.0
13	Total phosphorus	M	SLS TM 100 based on BS 2690:Part 105:1983		659.0	0.0	659.0	0.0	0.0
82	Cyanides (as total CN)	M	GLS TM 134 by Steam Distillation		0.07	0.0	0.07	0.0	0.0
83	Fluorides (as total F)	M	SLS TM 104		149.3	0.0	149.3	0.0	0.0
35	Dichloromethane (DCM)	M	SLS TM 116 by Headspace A Autosampler and Gas		0.33	0.0	0.33	0.0	0.0
23	Lead and compounds (as Pb)	M	SLS TM 152 by ICPMS		0.2	0.0	0.2	0.0	0.0
21	Mercury and compounds (as Hg)	M	SLS TM 127 by Cold Vapour Atomic Absorption Spe		0.089	0.0	0.089	0.0	0.0
73	Toluene	M	SLS TM 116 by Headspace A Autosampler and Gas		0.07	0.0	0.07	0.0	0.0
78	Xylenes	M	SLS TM 116 by Headspace A Autosampler and Gas		0.07	0.0	0.07	0.0	0.0
24	Zinc and compounds (as Zn)	M	SLS TM 152 by ICPMS		9.47	0.0	9.47	0.0	0.0
06	Ammonia (NH3)	M	SLS TM 099 based on BS2690 Part 7:1968/ BS 60E		117.7	0.0	117.7	0.0	0.0

* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

SECTION B : REMAINING POLLUTANT EMISSIONS (as required in your Licence)

OFFSITE TRANSFER OF POLLUTANTS DESTINED FOR WASTE-WATER TREATMENT OR SEWER								
POLLUTANT		METHOD			QUANTITY			
			Method Used					
Pollutant No	Name	M/C/E	Method Code	Designation or Description	Emission Point 1	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
337	Pharmaceutical actives	M	-	Wyeth Medica Ireland (HPLC/GC-MS)	0.0	0.0	0.0	0.0
341	Sodium	M	-	Alcontrol Laboratories: Flame Photometer	27609.0	27609.0	0.0	0.0
					0.0	0.0	0.0	0.0

* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

SECTION A : PRTR POLLUTANTS

RELEASES TO LAND							
POLLUTANT		METHOD				QUANTITY	
			Method Used				
No. Annex II	Name	M/C/E	Method Code	Designation or Description	Emission Point 1	T (Total) KG/Year	A (Accidental) KG/Year
					0.0	0.0	0.0

* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

SECTION B : REMAINING POLLUTANT EMISSIONS (as required in your Licence)

RELEASES TO LAND							
POLLUTANT		METHOD				QUANTITY	
			Method Used				
Pollutant No.	Name	M/C/E	Method Code	Designation or Description	Emission Point 1	T (Total) KG/Year	A (Accidental) KG/Year
					0.0	0.0	0.0

* Select a row by double-clicking on the Pollutant Name (Column B) then click the delete button

Transfer Destination	European Waste Code	Hazardous	Quantity T/Year	Description of Waste	Waste Treatment Operation	Method Used		Location of Treatment	Name and Licence / Permit No. of Recoverer / Disposer / Broker	Address of Recoverer / Disposer / Broker	Name and Address of Final Destination i.e. Final Recovery / Disposal Site (HAZARDOUS WASTE ONLY)	Licence / Permit No. of Final Destination i.e. Final Recovery / Disposal Site (HAZARDOUS WASTE ONLY)
						M/C/E	Method Used					
Within the Country	07 05 01	Yes	148.41	aqueous washing liquids and mother liquors	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	AVG Abfalls-Verwertungs-Geselleschaft GMBH, Borsigstrasse 2, D-22112 Hamburg, Germany	E2310/AVG-GENB
Within the Country	07 05 01	Yes	1640.18	aqueous washing liquids and mother liquors	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver NV, Industriele Afvalverwerking, Poldervlietweg, B-2030 Antwerpen 3, Belgium.	MLAVI/9800000485/MV/bd
Within the Country	07 05 03	Yes	519.79	Organic halogenated solvents, washing liquids and mother liquors	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	AVG Abfalls-Verwertungs-Geselleschaft GMBH, Borsigstrasse 2, D-22112 Hamburg, Germany	E2310/AVG-GENB
Within the Country	07 05 03	Yes	308.45	Organic halogenated solvents, washing liquids and mother liquors	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver NV, Industriele Afvalverwerking, Poldervlietweg, B-2030 Antwerpen 3, Belgium.	MLAVI/9800000485/MV/bd
Within the Country	07 05 03	Yes	90.18	Organic halogenated solvents, washing liquids and mother liquors	R2	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Solvent Resource ManagementLtd.,Middleton Road, Morecambe, Lancashire, LA 3JW	BL7302ID
Within the Country	07 05 04	Yes	7.39	Other organic solvents, washing liquids and mother liquors	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	AVG Abfalls-Verwertungs-Geselleschaft GMBH, Borsigstrasse 2, D-22112 Hamburg, Germany	E2310/AVG-GENB
Within the Country	07 05 04	Yes	31.18	Other organic solvents, washing liquids and mother liquors	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver NV, Industriele Afvalverwerking, Poldervlietweg, B-2030 Antwerpen 3, Belgium.	MLAVI/9800000485/MV/bd
Within the Country	07 05 10	Yes	0.67	Other filter cakes and spent absorbents	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver NV, Industriele Afvalverwerking, Poldervlietweg, B-2030 Antwerpen 3, Belgium.	MLAVI/9800000485/MV/bd
Within the Country	07 05 11	Yes	31.38	Sludges from on-site effluent treatment containing dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	AVG Abfalls-Verwertungs-Geselleschaft GMBH, Borsigstrasse 2, D-22112 Hamburg, Germany	E2310/AVG-GENB
Within the Country	07 05 11	Yes	140.4	Sludges from on-site effluent treatment containing dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver NV, Industriele Afvalverwerking, Poldervlietweg, B-2030 Antwerpen 3, Belgium.	MLAVI/9800000485/MV/bd
Within the Country	07 05 13	Yes	190.09	Solid Hazardous Waste (Containing or Contaminated with Pharmaceutical Actives)	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	TRV, Thermische Ruckstandsverwertung Gmbh & Co. KG, Rodenkirchener Str, 50289 Wesseling, Germany	55.8851.8.1-73/94-koln
Within the Country	07 05 13	Yes	16.68	Solid Hazardous Waste (Containing or Contaminated with Pharmaceutical Actives)	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	AVG Abfalls-Verwertungs-Geselleschaft GMBH, Borsigstrasse 2, D-22112 Hamburg, Germany	E2310/AVG-GENB
Within the Country	07 05 13	Yes	274.59	Solid Hazardous Waste (Containing or Contaminated with Pharmaceutical Actives)	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver NV, Industriele Afvalverwerking, Poldervlietweg, B-2030 Antwerpen 3, Belgium..	MLAVI/9800000485
Within the Country	07 05 13	Yes	34.78	Solid Hazardous Waste (Containing or Contaminated with Pharmaceutical Actives)	D5	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	IAG, Ihlenberger, Abfallentsorgungsgeselischaft mbH, Ihlenberg 1, 23923 Selmsdorf, Germany	M58SAD001

Within the Country	07 05 13	Yes	31.1	Solid Hazardous Waste (Containing or Contaminated with Pharmaceutical Actives) Controlled drugs	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	TRV, Thermische Ruckstandsverwertung Gmbh & Co. KG, Rodenkirchener Str, 50289 Wesseling, Germany...	55.8851.8.1-73/94-koln
Within the Country	07 05 14	No	3.56	solid waste other than those mentioned in 07 05 13	R3	M	None	Abroad	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin		
Within the Country	07 05 14	No	2.64	solid waste other than those mentioned in 07 05 13 (capsugels)	R3	M	None	Abroad	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin		
Within the Country	07 05 99	No	8.98	Waste not otherwise specified (lactose)	R3	M	None	Abroad	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin		
Within the Country	07 05 99	No	75.32	Waste not otherwise specified (sugar coating)	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1		
Within the Country	07 05 99	No	64.45	Waste not otherwise specified (sugar coating)	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1		
Within the Country	08 03 18	No	2.6	waste printing toner other than those mentioned in 08 03 17	R5	M	None	Abroad	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin		
Within the Country	13 01 13	Yes	2.86	Other hydraulic oils	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver NV, Industriele Afvalverwerking, Poldervlietweg, B-2030 Antwerpen 3, Belgium..	MLAVI/9800000485
Within the Country	13 01 13	Yes	1.6	Other hydraulic oils	R9	M	None	Onsite in Ireland	Enva Ireland Ltd. / W0184-01	Clonminam Industial Estate, Portlaoise, Co. Laois	Enva Ireland Ltd., Clonminam Industial Estate, Portlaoise, Co. Laois	W0184-01
Within the Country	13 05 08	Yes	0.05	Mixtures of wastes from grit chambers and oil water separators	R9	M	None	Offsite in Ireland	Enva Ireland Ltd. / W0184-01	Clonminam Industial Estate, Portlaoise, Co. Laois	Enva Ireland Ltd., Clonminam Industial Estate, Portlaoise, Co. Laois	W0184-01
Within the Country	13 07 03	Yes	0.5	other fuels including mixtures	R9	M	None	Offsite in Ireland	Enva Ireland Ltd. / W0184-01	Clonminam Industial Estate, Portlaoise, Co. Laois	Enva Ireland Ltd., Clonminam Industial Estate, Portlaoise, Co. Laois	W0184-01
Within the Country	15 01 10	Yes	7.59	packaging containing or contaminated by dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	AVG Abfalls-Verwertungs-Geselleschaft GMBH, Borsigstrasse 2, D-22112 Hamburg, Germany	E2310/AVG-GENB
Within the Country	15 01 10	Yes	0.25	packaging containing or contaminated by dangerous substances	R9	M	None	Offsite in Ireland	Enva Ireland Ltd. / W0184-01	Clonminam Industial Estate, Portlaoise, Co. Laois	Enva Ireland Ltd., Clonminam Industial Estate, Portlaoise, Co. Laois	W0184-01
Within the Country	15 01 10	Yes	35.01	packaging containing or contaminated by dangerous substances	R4	M	None	Offsite in Ireland	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Rilta Environmental Limited, Block 402, Greenogue Businness Park, Rathcoole, Co. Dublin	W0192-02
Within the Country	15 01 10	Yes	25.81	packaging containing or contaminated by dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver NV, Industriele Afvalverwerking, Poldervlietweg, B-2030 Antwerpen 3, Belgium..	MLAVI/9800000485
Within the Country	15 02 02	Yes	0.01	absorbents, filter material, contaminated by dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	AVG Abfalls-Verwertungs-Geselleschaft GMBH, Borsigstrasse 2, D-22112 Hamburg, Germany	E2310/AVG-GENB
Within the Country	15 02 02	Yes	2.14	absorbents, filter material, contaminated by dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver NV, Industriele Afvalverwerking, Poldervlietweg, B-2030 Antwerpen 3, Belgium..	MLAVI/9800000485

Within the Country	16 02 13	Yes	18.36	discarded equipment containing hazardous component	R12	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	AppaRec, Baeckelmansstraat 125, 2830 Tisselt-Willbroek, Belgium	MLAV1/0200000470/GVDA/I s
Within the Country	16 02 13	Yes	13.0	discarded equipment containing hazardous component	R12	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	TechRec Ireland Limited, Unit 51, Park West Industrial Estate, Nangor Road, Dublin 12; 3. COD International Ltd (Tech Rec), Trewmount Road, Killyman, Dungannon,Northern Ireland.	1. W02333-01 2. LN/004/07/A
Within the Country	16 05 04	Yes	0.07	gases in pressurised containers containing dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Chemogas N.V., B1850,Grimbergen, Belgium	WL D/PMVC/05F09/03933
Within the Country	16 05 04	Yes	0.01	gases in pressurised containers containing dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver NV, Industriele Afvalverwerking, Poldervlietweg, B-2030 Antwerpen 3, Belgium..	MLAVI/9800000485
Within the Country	16 05 04	Yes	1.87	gases in pressurised containers containing dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	AVG Abfalls-Verwertungs-Gesellschaft GMBH, Borsigstrasse 2, D-22112 Hamburg, Germany	E2310/AVG-GENB
Within the Country	16 05 06	Yes	1.79	laboratory chemicals, consisting of or containing dangerous substances, including mixtures of dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	AVG Abfalls-Verwertungs-Gesellschaft GMBH, Borsigstrasse 2, D-22112 Hamburg, Germany	E2310/AVG-GENB
Within the Country	16 05 06	Yes	2.91	laboratory chemicals, consisting of or containing dangerous substances, including mixtures of dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver NV, Industriele Afvalverwerking, Poldervlietweg, B-2030 Antwerpen 3, Belgium..	MLAVI/9800000485
Within the Country	16 05 07	Yes	2.65	discarded organic chemicals consisting of or containing dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	AVG Abfalls-Verwertungs-Gesellschaft GMBH, Borsigstrasse 2, D-22112 Hamburg, Germany	E2310/AVG-GENB
Within the Country	16 05 07	Yes	3.205	discarded organic chemicals consisting of or containing dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver NV, Industriele Afvalverwerking, Poldervlietweg, B-2030 Antwerpen 3, Belgium..	MLAVI/9800000485
Within the Country	16 05 08	Yes	1.26	discarded inorganic chemicals consisting of or containing dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	AVG Abfalls-Verwertungs-Gesellschaft GMBH, Borsigstrasse 2, D-22112 Hamburg, Germany	E2310/AVG-GENB
Within the Country	16 05 08	Yes	0.63	discarded inorganic chemicals consisting of or containing dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver NV, Industriele Afvalverwerking, Poldervlietweg, B-2030 Antwerpen 3, Belgium..	MLAVI/9800000485
Within the Country	16 06 01	Yes	4.01	lead batteries	R4	M	None	Abroad	Enva Ireland Ltd. / W0184-01	Clonminam Industial Estate, Portlaoise, Co. Laois	Campine Recycling N.V., Nijverheidsstraat 2, B-2340 Beerse, Belgium.	MLAV/05-173GVDA
Within the Country	16 06 02	Yes	0.33	Nickel-Cadmium Batteries	R4	M	None	Abroad	Enva Ireland Ltd. / W0184-01	Clonminam Industial Estate, Portlaoise, Co. Laois	Accurec Recycling GmbH, Wiehagen 12-14, 45472 Mulheim, Germany	ZUUM-054-0499-45-40-1103 and 52.03.06.06 Accu-9/09
Within the Country	17 05 03	Yes	1.94	Soils and stones containing dangerous substances	R5	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Enva Ireland Ltd., Clonminam Industial Estate, Portlaoise, Co. Laois	W0184-01
Within the Country	17 06 01	Yes	4.94	Insulation materials containing asbestos	D5	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	IAG, Ihlenberger, Abfallentsorgungsgesellscha lt mbH, Ihlenberg 1, 23923 Selmsdorf, Germany	M58SAD001
Within the Country	19 09 04	No	0.49	Spent activated carbon	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1		

Within the Country	20 01 21	Yes	1.22	Flourescent tubes and other mercury containing waste	R13	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Irish Lamp Recycling Co. Limited, Woodstock Industrail Estate, Kilkenny Road, Athy,Co. Kildare	02/2000B
Within the Country	20 01 21	Yes	0.03	Flourescent tubes and other mercury containing waste	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	AVG Abfalls-Verwertungs-Geselleschaft GMBH, Borsigstrasse 2, D-22112 Hamburg, Germany	E2310/AVG-GENB
Within the Country	20 01 21	Yes	0.01	Flourescent tubes and other mercury containing waste	R4	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver Relight NV, Haven, 1940 Molenweg B39130, Doel Bevern Belgium	46003/44/A11
Within the Country	20 01 25	No	34.3	Edible oil and fat	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1		
Within the Country	20 01 26	Yes	0.37	Oils and fat other than those mentioned in 20 01 25	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver NV, Industriele Afvalverwerking, Poldervlietweg, B-2030 Antwerpen 3, Belgium..	MLAVI/9800000485
Within the Country	20 01 27	Yes	11.76	Paints, inks, adhesives and resins containing dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	Indaver NV, Industriele Afvalverwerking, Poldervlietweg, B-2030 Antwerpen 3, Belgium..	MLAVI/9800000485
Within the Country	20 01 27	Yes	4.9	Paints, inks, adhesives and resins containing dangerous substances	D10	M	None	Abroad	Indaver Ireland Ltd. / W0036-02	Tolka Quay Rd., Dublin Port, Dublin 1	AVG Abfalls-Verwertungs-Geselleschaft GMBH, Borsigstrasse 2, D-22112 Hamburg, Germany	E2310/AVG-GENB
Within the Country	15 01 01	No	213.4	Cardboard	R3	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin		
Within the Country	15 01 01	No	33.08	Cardboard	R3	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin		
Within the Country	15 01 02	No	10.95	Plastic Packaging	R5	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin		
Within the Country	15 01 02	No	66.76	Plastic Packaging	R5	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin		
Within the Country	15 01 03	No	230.32	Wood	R3	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin		
Within the Country	15 01 03	No	1.56	Wood	R3	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin		
Within the Country	15 01 04	No	0.65	Foil	R4	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin		
Within the Country	15 01 04	No	15.95	Foil	R4	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin		
Within the Country	15 01 05	No	59.32	Blister packs	R4	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin		
Within the Country	15 01 06	No	25.63	mixed packaging	R12	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin		

Within the Country	15 01 07	No	4.7	glass packaging	R5	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	15 01 07	No	1.15	glass packaging	R5	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	16 01 17	No	4.48	Foil	R4	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	16 01 17	No	42.16	Ferrous metal	R4	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	16 01 17	No	2.19	Ferrous metal	R4	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	17 01 07	No	2558.92	Mixtures of concrete,bricks, tiles and ceramics other than those mentioned in 17 01 06	R12	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	17 08 02	No	6.9	Gypsum based construction material other than those mentioned in 17 08 01	R12	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 01 01	No	51.09	cardboard	R3	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 01 01	No	1.54	cardboard	R3	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 01 01	No	4.35	Paper	R3	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 01 01	No	27.54	Paper	R3	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 01 01	No	204.77	Paper	R3	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 01 08	No	6.04	Biodegradable Canteen and kitchen waste	R3	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 01 38	No	101.78	Wooden	R3	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 01 40	No	3.68	Foil	R4	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 01 40	No	198.22	metals	R4	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin

Within the Country	20 01 40	No	3.71	metals	R4	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 02 01	No	1.56	biodegradable waste	R4	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 03 01	No	174.12	Mixed municipal waste	D5	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 03 01	No	4.96	Mixed municipal waste	D5	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 03 07	No	136.47	Bulky waste	D5	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 03 07	No	318.43	Bulky waste	D12	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 03 07	No	0.43	Bulky waste	D5	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 03 07	No	0.99	Bulky waste	R12	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 03 07	No	11.58	Bulky waste	D5	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 03 99	No	19.21	Blister packs	R4	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin
Within the Country	20 03 99	No	3.56	Blister packs	R4	M	None	Offsite in Ireland	Greenstar Ltd. / W0188-01	Unit 14B Grants Way, Greenogue Industrial Estate, Rathcoole, Co. Dublin

* Select a row by double-clicking on the Description of Waste then click the delete button

Raymond Cully - AER Electronic Reporting System - Licence Register No. P0153-05

From: Raymond Cully
To: aerreturns@epa.ie
Date: 30/03/2009 17:08
Subject: AER Electronic Reporting System - Licence Register No. P0153-05

We are having difficulty uploading the XML file. The following message appears:

An error occurred while attempting to upload the XML file - The error is : An error occurred while parsing EntityName. Line 88, position 31.

Please advise of appropriate way forward to resolve

Ray Cully

Ray Cully

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