Annual Environmental Report 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:	***March 2010***

EXECUTIVE SUMMARY

The following is the Annual Environmental Report (AER) for the period January - December 2009 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 EPA (EPA).

On 15/10/2009, Pfizer Inc., completed its acquisition of Wyeth in the United States, with Wyeth becoming a subsidiary of Pfizer. Because of the merger, Pfizer owns Wyeth and became the ultimate corporate parent of the WMI Newbridge facility. Further to this acquisition, and due to certain planned corporate restructurings (which are subject to change) and the long lead time needed for permit transfer, WMI subsequently submitted a Transfer of a Licence Application to the EPA to account for a technical change in the ownership of the Newbridge facility. Until and unless the Licence transfer is finalised the Newbridge site will continue to trade as *AHP Manufacturing B.V. trading as Wyeth Medica Ireland*.

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. 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 (which are based on Best Available Techniques).

The environmental monitoring carried out over the 2009 reporting period shows no adverse environmental impact on the environmental media into which discharges from the WMI facility are made:

- No exceedance of any emission limit value specified for emissions to sewer (wastewater), emissions to air (including solvent management plan) or noise emissions;
- Storm water emission (surface water) was of good chemical quality with no exceedance of either the Total Organic Carbon warning or action limits;
- Groundwater was of good chemical quality with no indication that the diesel spill that occurred on-site in 2007 has had a significant impact on the receiving groundwater;
- Environmental incidents are detected and responded to appropriately with no significant impact on the environment; 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 2009 were achieved – those that could not be fully implemented or are ongoing as part of the long-term environmental objectives and targets have been incorporated into the 2010 Environmental Management Programme.

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 environmental improvements programme at the site and the continuous improvement requirement of the IPPC licencing process is fully embraced by the WMI Site Leadership Team. 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 Environmental Health & Safety Policy. The success of this policy is reflected by the:

- Unannounced EPA audit and site inspection conducted at the site which were fully compliant; and,
- Ongoing independent certification with ISO14001 and IS393:2005 management system standards, and verification to the EMAS Regulation.

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DECLARATION

The content of the report, including the data (which is based on appropriate sampling and analyses) as presented, is certified as accurate and representative of activities conducted at the site.

Signed: _____

Dr Michael Donlon
Director EHS & Site Services

Date: _____

1. INTRODUCTION

1.1. OVERVIEW

The following is the Annual Environmental Report (AER) for the period January - December 2009 for AHP Manufacturing B.V. trading as Wyeth Medica Ireland (hereafter referred to as 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 EPA (EPA).

WMI is licensed under Section 90(2) of the Environmental Protection EPA 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'.

Summary details for the site are presented as follows:

IPPC Licence Register No.:	P0153-05
Company Name:	AHP Manufacturing B.V. T/A Wyeth Medica Ireland
Address:	Buckley's Cross Roads, Old Connell, Newbridge, Co. Kildare.
Industry Sector (NACE Code):	21.10
National Grid Reference:	2813E, 2156N
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1.2. SITE ACTIVITIES - UPDATE

1.2.1. Wyeth Acquisition by Pfizer

On 15/10/2009, Pfizer Inc., completed its acquisition of Wyeth in the United States, with Wyeth becoming a subsidiary of Pfizer. Because of the merger, Pfizer owns Wyeth and became the ultimate corporate parent of the WMI Newbridge facility.

It was anticipated that a change of assets warranting a change in the IPPC Licence holder for the site would take place after change of ownership. Because of the lead in time for the approval of the Licence transfer, a formal Transfer of Licence Application was submitted to the Agency on 15/12/09. It now appears that subsequent to the change in ownership no change in assets warranting the transfer of the Licence is likely to take place in 2010, and accordingly the IPPC Licence transfer will not be proceeded with. The WMI facility at the Newbridge site will continue to operate as AHP Manufacturing B.V. trading as Wyeth Medica Ireland, and Pfizer Inc will be its parent.

1.2.2. Site Changes

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 which operates on natural gas 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 Wastewater Treatment Plant, engineering workshops, and an administration building with canteen. The following developments were completed at the site in 2009:

- Construction of Pharmaceutical Development Centre (PDC) and Analytical Development Laboratory
- Extension of Microbiology Laboratory.

Work on the following projects continued in 2009:

- MHT processing facility - *commissioning and validation ongoing in 2009.*
- OC4B (previously named Levo/EE Continuous Use) processing facility - *commissioning and validation ongoing in 2009.*
- PDC facility - *commissioning and validation ongoing in 2009.*

Amendments made to Licence Register No. P0153-05 in 2009, as approved by the EPA, are summarised in Table 1.1.

Table 1.1: Amendments made to Licence Register No. P0153-05 in 2009

Change Description	WMI Submission Date	EPA Approval Date (Reference)
Air Emissions: ▪ New minor atmospheric emission point: A3-448 ▪ Redundant minor atmospheric emission point: A3-120, A3-121	19/01/2009	30/01/2009 (P0153-05.ap09djm.doc)
General: Introduction of the finished product Tigecycline for secondary packaging at the Newbridge facility	30/01/2009	05/02/2009 (P0153-05.ap09djm.doc)
Air Emissions: ▪ New minor atmospheric emission points: A3-449 (hot air extract from a vial inspection machine associated with the Tigecycline secondary packaging process), A3-450 (General extract from extended Microbiology Laboratory) ▪ Redundant minor atmospheric emission points: A3-187, A3-188	24/03/2009	06/04/2009 (P0153-05/ap11djm.doc)
Groundwater: Relocate Emission Point Reference No. AGW5	24/03/2009	Notification only – no EPA response
Air Emissions: ▪ New minor atmospheric emission points: A3-451 to A3-468 ▪ Decommissioned minor atmospheric emission points: A3-187,A3-188, A3-189 and A3-195 ▪ New potential atmospheric emission points: A4-227 to A4-231	06/04/2009	22/06/2009 (P0153-05/ap15djm.doc)
Waste: Treatment of SRS waste with higher API content	22/04/2009	20/07/2009 (P0153-05.ap16djm.doc)
Air Emissions: PDC Emission Points	27/04/2009	30/06/2009 (Technical Amendment C)
Air Emissions: Decommissioning emission points A1-1 & A1-2	18/05/2009	Notification only – EPA approval not required
Air Emissions: Modify the flow-rates specified Emission Point reference No's A2-20 & A2-39	25/05/2009	Rejected
Waste: Revised Table H	03/06/2009	Notification only – EPA approval not required
Air Emissions: Operation of Emergency Generator (Emission Point Reference No. A4-101, A4-103, A4-105 & A4-123) during load shed testing on the emergency back-up power systems at the site	25/08/2009 (work deferred from 02-03/05/2009)	Notification only – EPA approval not required
Air Emissions: Extend timeline for compliance with ELV for Emission Point Reference No. A2-6	08/09/2009	17/12/2009 (Technical Amendment D)
Air Emissions: Minor atmospheric emissions ▪ New emission points: A3-469 to A3-475 (HVAC & general exhausts from an office development) ▪ Decommissioned Emission Points: A3-87, A3-189.	28/09/2009	15/10/2009 (P0153-05.ap18djm.doc)
General: Introduction of new Active Pharmaceutical Ingredients to the Pharmaceutical Development Centre	07/10/2009	22/10/2009 (P0153-05.ap19djm.doc)
General: Pfizer Acquisition	22/10/2009	Notification
Air Emissions: 24 hour operation of Pharmaceutical Development Centre air emissions	03/11/2009	17/12/2009 (Technical Amendment D)

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 in accordance with the site's objective to limit impact on the environment. Using EPIs may also assist in the identification of further opportunities to:

- prevent potential environmental pollution; and,
- use resources more efficiently thereby minimising waste (in this context waste includes 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 subsequent changes. By setting performance EPIs, the WMI facility is encouraged to monitor what it is doing and then establish targets to help achieve continuous improvement.

The Pfizer Corporate Environmental, Health & Safety (EHS) has set targets for each Pfizer facility for the following 3 No. environmental aspects:

- Carbon Dioxide (CO_2) Emissions (refer to Section 4.7.2).
- Water Usage (refer to Section 4.7.3)
- Waste Arisings (refer to Section 2.7.1)

For the purposes of calculating the reduction targets absolute usage values are used.

2.2. EMISSION TO SEWER

2.2.1. Overview & Results

In 2009 there were no individual exceedances out of 2853 sampling/monitoring determinations and all wastewater flow rates and contaminant concentration levels/ranges were within the emission limit values (ELVs) specified within *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 2009 are presented in Tables 2.1 and 2.2. A comparison of individual parameters expressed as a percentage of the licensed annual mass ELV is presented in Figure 2.1. This graph indicates that, as for 2005 - 2008, the mass emission for the parameters monitored in 2009 continue to be within the IPPC Licence ELVs.

2.2.2. Summary of Impacts

All wastewater (treated) from the WMI facility is discharged to Osberstown municipal wastewater treatment plant (operated by the Local Authority – Kildare County Council) via the on-site wastewater pre-treatment plant (WWTP). Results for 2009 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 or the quality of the downstream River Liffey.

Table 2.1: Emission to Sewer (Emission Point Reference No. SE1) 2005 – 2009 Summary Data **Note 1**

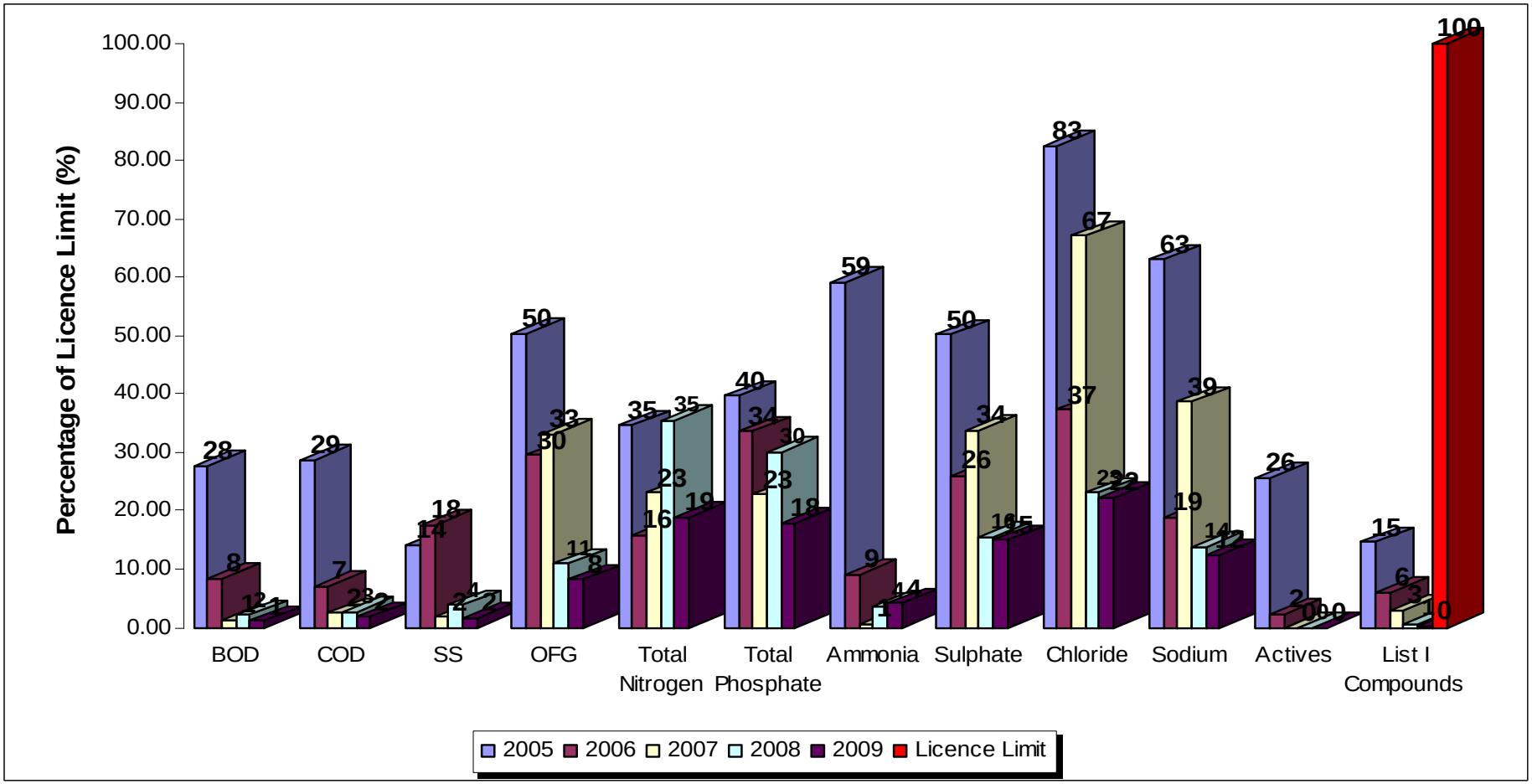
Parameter				Mass Emission							
				2005	Licensed 2005	2006	Licensed 2006	2007	2008	2009	Licensed 2007-2009
				(m^3)							
Total Volume				124844	192850	143398	246521	171688	208888 Note 2	207952	283605
	Concentration (mg/l) 2009			(Kg)							
	Min	Max	ELV								
Suspended Solids	2	10	500	7730	54750	9590	54750	973	2089 Note 3	901	54750
BOD	1	8	800	18144	65700	5485	65700	866	1370 Note 3	749	65700
COD	7	27	2000	46967	164250	11573	164250	3999	4161 Note 3	2907	164250
Total Nitrogen (as N)	1	13	70	2648	7665	1211	7665	1776	2716 Note 3	1441	7665
Total Phosphorus (as P)	0.3	3.9	20	868	2190	735	2190	496	659	390	2190
Oils, Fats & Greases	1	7	50	1654	5475	972	5475	1087	357	268	5475
Ammonia (as N)	0.2	6.4	30	1945	3285	298	3285	22	118	135	3285
Sulphate	33	96	300	5496	10950	6078	23360	7885	11355 Note 3	10976	73000
Chloride	84	230	500	13554	16425	14447	38690	25942	29528 Note 3	28471	127750
Sodium	80	177	800	15533	24660	11697	62050	23993	27632 Note 3	24933	200750
List I Compounds	0.000	0.004	0.2	5.3	36.5	2.2	36.5	1.1	0.6 Note 3	0.3	36.5
Copper	0.009	0.028	N/A	N/A	N/A	0.73	N/A	6.44	4.58	3.78	N/A
Nickel	0.000	0.004	N/A	N/A	N/A	0.19	N/A	0.32	0.59	0.34	N/A
Zinc	0.036	0.069	N/A	N/A	N/A	1.39	N/A	8.69	9.48 Note 3	9.87	N/A
Arsenic	0.000	0.004	N/A	N/A	N/A	0.06	N/A	0.48	0.00 Note 3	0.27	N/A
Chromium	0.000	0.005	N/A	N/A	N/A	0.06	N/A	0.37	0.76 Note 3	0.28	N/A
Fluoride	0.759	0.932	N/A	N/A	N/A	18	N/A	124	149	176	N/A
Total Alkalinity	65	190	N/A	N/A	N/A	2728	N/A	19903	33856 Note 3	24506	N/A
Pharmaceutical Active – Efexor Note 4	<LOD	<LOD	1	491.4	164.3	3.7	164.3	<LOD	<LOD	<LOD	N/A
Pharmaceutical Active – CNS Note 5	<LOD	<LOD	0.5	85.5	547.5	1.5	54.8	<LOD	<LOD	<LOD	N/A
Pharmaceutical Active – HTs Note 4	<LOD	<LOD	0.02	<LOD	32.9	0.2	3.3	<LOD	<LOD	<LOD	N/A
Pharmaceutical Active – OCs Note 4	<LOD	<LOD	0.02	0.9	32.9	<LOD	3.3	<LOD	<LOD	<LOD	N/A

N/A Not Applicable
<LOD Less than Limit of Detection
Note 1: Refer to previous AERs for notes on 2005-2008 data.
Note 2: Increase in flow figure required following EMAS verification of emissions data in December 2009.
Note 3: Mass emissions increased due to increase in flow figure (see Note 2).
Note 4: Refer to previous AERs for limits of detection for Pharmaceutical Actives.
Note 5: Limits of detection for the CNS method improved on 01/11/2009 due to changes to the testing methods: 0.4µg/ml Oxazepam, 0.4µg/ml Lorazepam and 0.4µg/ml Lormetazepam.

Table 2.2: Emission to Sewer (SE1) Respirometry Testing Results 2005 - 2009

Parameter	Toxic Units				
	2005	2006	2007	2008	2009
180 min EC_{50}	<2	<2	<2	<2	<2

Figure 2.1 Emission to Sewer Yearly Mass Emissions (2005-2009) as a Percentage of IPPC Licence Limit



Note 1: 2009 data is compared to ELVs based on Licence Register No. P0153-05 ELVs.
Note 2: Refer to previous AERs for notes on 2005-2008 data.

2.3. STORM WATER EMISSION

2.3.1. Overview & Results

Surface water discharge (surface water run-off from hard-standing areas following a storm water event) from the site (Emission Point Reference No. SW1) is monitored in accordance with *Schedule C.2.3 Monitoring of Storm Water Emission* of Licence Register No. P0153-05. Results for surface water discharge monitoring for 2009 are outlined in Table 2.3.

Table 2.3: Surface Water Discharge 2009 Summary Data

Date	pH (pH Units)	Temperature (°C)	COD Note 1 (mg/l)	Conductivity (µS/cm @25°C)	Organic Solvents		Pharmaceutical Actives (mg/l) Note 3 , 4
					USEPA 524.2 List Substances (µg/l)	Solvents (mg/l) Note 2	
21/01/2009	7.66	15.2	<15	0.75	-	0.1	-
11/02/2009	7.50	16.5	<15	0.76	-	-	-
25/02/2009	-	-	-	-	-	-	<LOD
02/03/2009	-	-	-	-	<0.001	-	-
11/03/2009	7.70	9.3	<15	0.91	-	-	-
08/04/2009	7.70	10.6	13	0.30	-	-	-
06/05/2009	8.19	10.6	<7	0.68	-	-	-
03/06/2009	7.93	11.5	<7	0.72	-	-	-
15/07/2009	8.04	12.6	<7	0.67	<0.001	0.1	-
12/08/2009	8.00	11.1	<7	0.56	-	-	-
09/09/2009	8.18	10.4	<7	0.58	-	-	-
07/10/2009	8.34	10.1	<7	0.64	-	-	-
04/11/2009	8.35	9.5	11	0.61	-	-	-
02/12/2009	7.92	9.7	<7	0.49	-	-	-
10/12/2009	-	-	-	-	-	-	<LOD

LOD: Limit of Detection
Note 1: Limits of detection for COD improved from <15mg/l to <7mg/l due to improvements on 01/04/2009 to the test method
Note 2: Compounds screened for are Methanol, Ethanol, Acetone, Acetonitrile and Iso-Propyl Alcohol.
Note 3: Refer to previous AERs for limits of detection for Pharmaceutical Actives.
Note 4: Limits of detection for the CNS method improved on 01/11/2009 due to changes to the testing methods: 0.4µg/ml Oxazepam, 0.4µg/ml Lorazepam and 0.4µg/ml Lormetazepam.

A daily visual inspection of surface water discharges is carried out in accordance with Condition 6.12.1 of Licence Register No. P0153-05 and no issues were noted in 2009. Also, 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. Neither of the designated TOC warning (20 mg/l) and action (30 mg/l) limits were exceeded in 2009.

2.3.2. Summary of Impacts

Results for 2009 indicate that the surface water discharge from the WMI facility is of good chemical quality and unlikely to impact on the receiving waters into which it ultimately discharges (i.e. River Liffey).

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 the site. The following groundwater wells are monitored on a bi-annual basis:

- For Emission Point Reference No. AGW1, AGW2, AGW3, AGW4; and,
- For Emission Point Reference No. AGW5a, AGW6, AGW7, AGW8, AGW9, AGW10, AGW11, AGW12 - *installed in 2007 for the purpose of a hydrogeological investigation conducted in order to assess the impacts of a diesel oil spill.*

Groundwater monitoring methodology and results for 2009:

- Emission Point Reference No. AGW1, AGW2, AGW3, AGW4 are outlined in Appendix 1 and Table 2.4; and,
- Emission Point Reference No. AGW5a, AGW6, AGW7, AGW8, AGW9, AGW10, AGW11, AGW12 were submitted separately to the EPA on 07/08/2009 and 30/11/2009 (results are summarised in Table 2.4).

2.4.2. Summary of Impacts

Results for Emission Point Reference No. AGW1, AGW2, AGW3 and AGW4 indicate groundwater of a good quality, with no pharmaceutical actives detected (Appendix 1 & Table 2.4). In addition to natural background concentrations of the groundwater, the elevated concentrations of iron, manganese, calcium, iron, lead, aluminium, chloride and manganese across the site are attributed to a combination of natural variations in groundwater geochemistry and a potential up gradient off-site source of contamination 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 (secondary containment).

Results of ongoing monitoring of groundwater monitoring wells installed for the purpose of the diesel spill investigation (Emission Point Reference No. AGW5a, AGW6, AGW7, AGW8, AGW9, AGW10, AGW11 and AGW12) indicate that free phase product appears to have significantly reduced over time, with no detections observed in selected monitoring wells (Emission Point Reference No. AGW5a, AGW7, AGW8), and slight thicknesses of free phase product detected in other wells [Emission Point Reference No. AGW6, AGW9, AGW10, AGW11, AGW12 (refer to Table 2.4)]. These levels represent significant reductions since initiation of the groundwater-monitoring programme in 2007 and confirm the limited migration of the original diesel spill. It is also noted that free phase diesel, dissolved phase levels of DRO, VOC's or mineral oil was not detected in Emission Point Reference No. AGW1, AGW2, AGW3 and AGW4 (refer to Table 2.4). This indicates that the original diesel spill has had a limited, if any, impact on the receiving groundwater. 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 EPA 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.

Table 2.4: Groundwater Monitoring 2009 – Pharmaceutical Actives Analysis & Diesel Spill Summary Data

Emission Point Reference No.		Parameter				
		Pharmaceutical Actives Note 1,2	Free Phase Diesel Oil Note 3	TPH Note 4	VOC Note 4	sVOC's Note 4
AGW1	Biannual 1 19/02/09	<LOD	-	<LOD	<LOD	<LOD
	Biannual 2 16/07/09	<LOD	-	<LOD	<LOD	<LOD
AGW2	Biannual 1 19/02/09	<LOD	-	<LOD	<LOD	<LOD
	Biannual 2 16/07/09	<LOD	-	<LOD	<LOD	<LOD
AGW3	Biannual 1 19/02/09	<LOD	-	<LOD	2 Note 6	<LOD
	Biannual 2 16/07/09	<LOD	-	<LOD	3.7 Note 6	<LOD
AGW4	Biannual 1 19/02/09	<LOD	-	<LOD	<LOD	<LOD
	Biannual 2 16/07/09	<LOD	-	<LOD	<LOD	<LOD
AGW5	Biannual 1 19/02/09	N/A	Note 5	<LOD	<LOD	<LOD
	Biannual 2 16/07/09	N/A	<1	13	<LOD	<LOD
AGW6	Biannual 1 19/02/09	N/A	1-2	<LOD	<LOD	<LOD
	Biannual 2 16/07/09	N/A	2	<LOD	<LOD	<LOD
AGW7	Biannual 1 19/02/09	N/A	<1	<LOD	1.1 Note 6	<LOD
	Biannual 2 16/07/09	N/A	<1	<LOD	<LOD	<LOD
AGW8	Biannual 1 19/02/09	N/A	<1	<LOD	1.4 Note 6	<LOD
	Biannual 2 16/07/09	N/A	<1	13	<LOD	<LOD
AGW9	Biannual 1 19/02/09	N/A	<1	<LOD	6.1 Note 6	<LOD
	Biannual 2 16/07/09	N/A	1	69	1.3 Note 6	<LOD
AGW10	Biannual 1 19/02/09	N/A	<1	<LOD	1.2 Note 6	<LOD
	Biannual 2 16/07/09	N/A	1	13	1.3 Note 6	<LOD
AGW11	Biannual 1 19/02/09	N/A	1-2	500	1.3 Note 6	<LOD
	Biannual 2 16/07/09	N/A	1	1250	<LOD	<LOD
AGW12 Note 7	Biannual 1 19/02/09	N/A	1	-	-	-
	Biannual 2 16/07/09	N/A	Dry	-	-	-

LOD: Limit of Detection
Note 1: Refer to previous AERs for limits of detection for Pharmaceutical Actives.
Note 2: Limits of detection for the CNS method improved on 01/11/2009 due to changes to the testing methods: 0.4µg/ml Oxazepam, 0.4µg/ml Lorazepam and 0.4µg/ml Lormetazepam.
Note 3: Determinations are measured in mm
Note 4: All parameters are measured in µg /l
Note 5: Emission Point Reference No. AGW5 Replaced by AGW5a as per notification to the EPA on 24/03/09
Note 6: Limit of detection for Chloroform <1ug/l
Note 7: Emission Point Reference No. AGW 12 is a shallow piezometer installed to assess water levels and product thickness within the associated excavation. As repeated monitoring over 2 years has demonstrated that this well is too shallow to serve as a groundwater monitoring well, this installation will be decommissioned as approved by the EPA (Ref: P0153-05/ap20djm.doc dated 04/02/2010).

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, NO_x, CO, Volatile Organic Compounds (VOCs - R40 Compounds, TA Luft Class II and TA Luft Class III) and Total Organic Compounds (as C). 21 emission points were monitored in 2009 (Appendix 2). Table 2.5 outlines the reasons why selected emission points were not monitored in 2009.

Table 2.5: Emissions to Air Points Not Monitored in 2009.

Emission Point Reference No.	Reasons Why Emission Points Were Not Monitored
A2-1, A1-2	Decommissioned
A2-1, A2-4, A1-11, A2-10, A2-15,, A2-16 to A2-19, A2-20, A2-23 to A2-28, A2-30, A2-34 to A2-37 , A2-41, A2-44, A2-45	Not operational in 2009
A2-49 to A2-94	Undergoing validation/commissioning

Summary details for air emissions for 2009 are presented in Table 2.6 and Figure 2.2.

Table 2.6: Emissions to Air 2005 – 2009 Summary Data [Note 1]

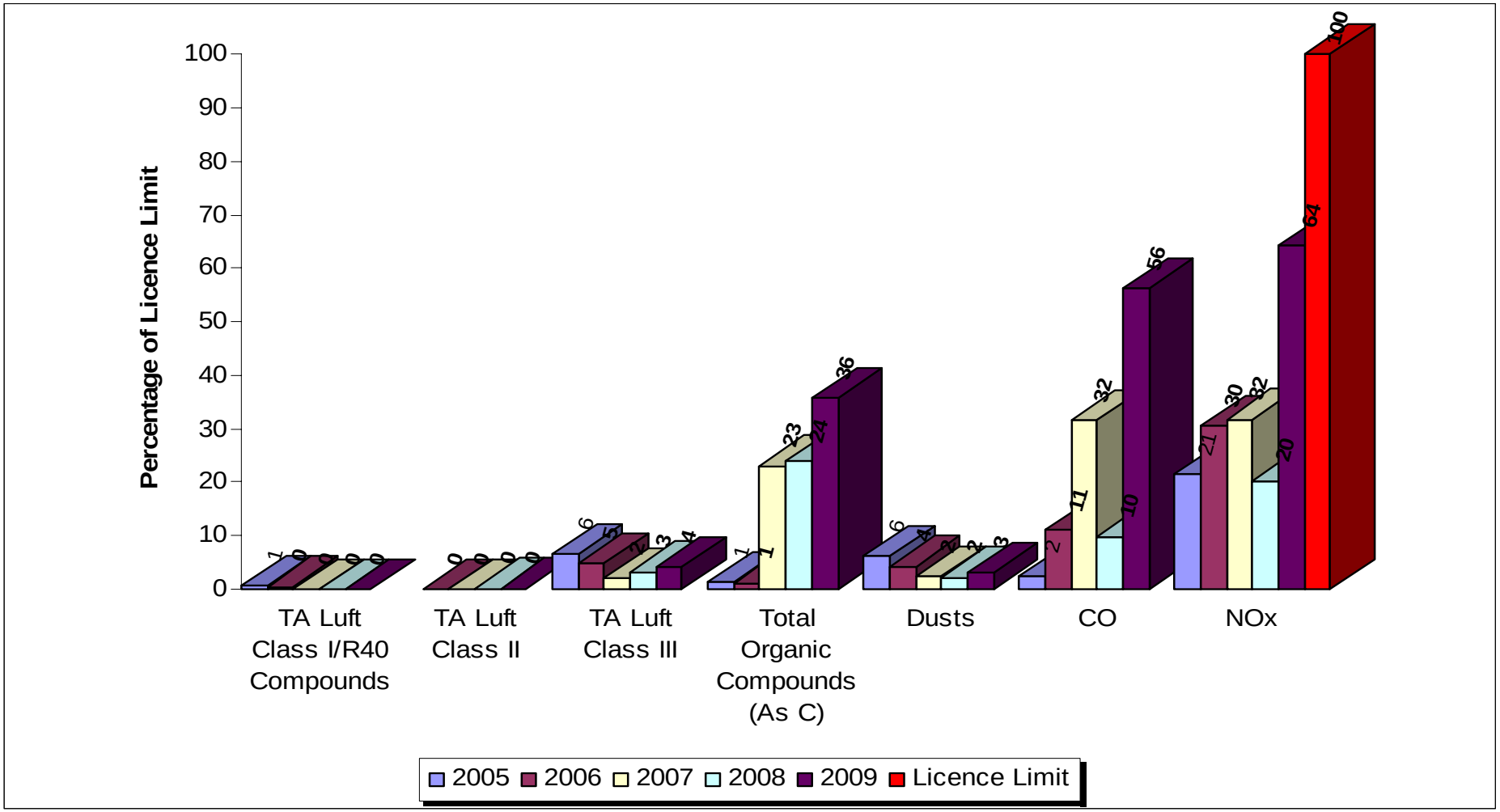
Parameter	Mass Emission (Kg)							
	2005	Licensed 2005	2006	Licensed 2006	2007	2008	2009	Licensed 2007-2009
Total Particulate	104	1680	105	2,427	146	132	182	5987
NO_x	24914	116242	42209	138582	44006	28012	89085 Note 2	138582
CO	5800	236521	36557	329827	104102	32615	185592 Note 2	329827
TA Luft Class I/R40 Compounds	1.7	274.4	0.1	175.2	21	40	60	823200
TA Luft Class II	N/A	N/A	0.4	5840	0.4	34	31	30864
TA Luft Class III	1155	17907	960	19,656	775	1283	1638	39096
Total Organic Compounds (as C) (A2-16 & A2-41)	0.19	14.82	0.21	17.91	6.65	6.92	10.33	28.91

Note 1: Refer to previous AERs for notes on 2005-2008 data.
Note 2: Mass emission increased in 2009 due to increased run-time of the CHP Plant

2.5.2. Summary of Impacts

In 2009 WMI maintained compliance with the annual mass emission limits for the Dust, NO_x, CO, VOCs and Total Organic Compounds (as C) parameters i.e. 0 individual exceedances out of 115 sampling/monitoring determinations.

Figure 2.2 Emission to Air Yearly Mass Emissions (2005-2009) as a Percentage of IPPC Licence Limit.



Note 1: Refer to previous AERs for notes on 2005-2008 data.
Note 2: 2009 TA Luft Class I, II, III and Total Organic Compounds (as C) are compared to the ELVs within Licence Register No. P0153-05.

2.6. NOISE

2.6.1. Overview

Condition 6.13 Noise of Licence Register No. P0153-05 requires WMI to undertake a noise survey at the site on an annual basis. Noise monitoring methodology and results for 2009 are outlined in Appendix 3.

2.6.2. Summary of Impacts

Results for 2009 (refer to appendix 3) 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. No audible tonal or impulsive component from noise emissions emanating from the WMI facility was recorded during the 2009 noise survey.

Over the last 5 years, 2005 – 2009, 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, processed (cardboard is baled, paper is shredded and fibre drums are dechimed) 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 2005 - 2009 are presented in Table 2.8 and Figure 2.3. A detailed waste register is presented in the EPRTR submission (refer to Appendix 12).

Table 2.8: Waste Volumes Sent Off-Site for Treatment 2005 – 2009 **Note 1**

Description of Waste	Quantity (Kg)				
	2005	2006	2007	2008	2009
Hazardous					
Disposed	2,486,000	2,757,000	2,582,000	2,313,582	1,242,382
Recovered	44,000	72,000	248,000	169,860	163,893
Non-Hazardous					
Disposed	1,247,000	1,559,000	840,000	503,000	250,232
Recovered	7,475 ,000	5,182,000	1,891,000	4,242,000	1,511,557
Total Waste Produced	11,252,000	9,570,000	5,561,000	7,228,442	3,168,064

Note 1: Refer to previous AERs for notes on 2005-2008 data

In 2009 there was a significant reduction (decrease of 56%) in waste arisings generated (refer to Table 2.8 and Figure 2.3) i.e. 3,168,064 Kg of waste arisings was generated in 2009 compared to 7,228,442 Kg in 2008. The significant reduction in 2009 waste arisings can be attributed to the following:

- Decrease on the amount of construction waste (Figures 2.3 and 2.4) due to the fact that previous construction activities have been completed and no new construction activities commenced in 2009
- Decrease in site production levels in 2009; and,
- Increased colleague awareness on waste management practices on-site.

The significant reduction in the amount of construction waste generated in 2009 has impacted on the sites recycling rates (Figure 2.5). The total waste recycling rate has reduced from 61% to 53% for 2009 and the corresponding non-hazardous waste recycling rate has reduced from 89% to 86%.

Notwithstanding this, WMI are committed 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 2009 this commitment was demonstrated as follows:

- Increase in the hazardous waste recycling rate for 2009 (increase from 6.8% in 2008 to 11.7% in 2009) due to the recovery of SRS solvent waste as per EPA approval on 20/07/2009 (Ref: P0153-05.ap16djm.doc);
- Diversion of non-hazardous (8.74 tonnes in 2009) waste from the on-site Oils, Fats and Grease WWTP from incineration to composting; and,
- Continued diversion of obsolete non-hazardous raw materials from landfill to composting.

Figure 2.3: Total Waste Arisings 2005 – 2009

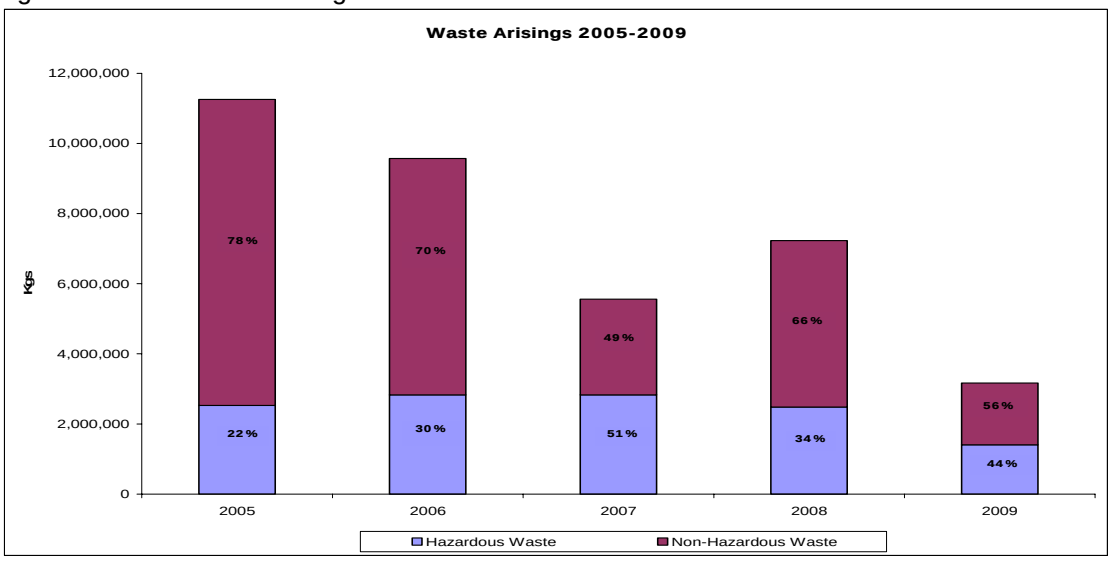


Figure 2.4: Sub-Components of Non-Hazardous Waste Arisings 2008-2009

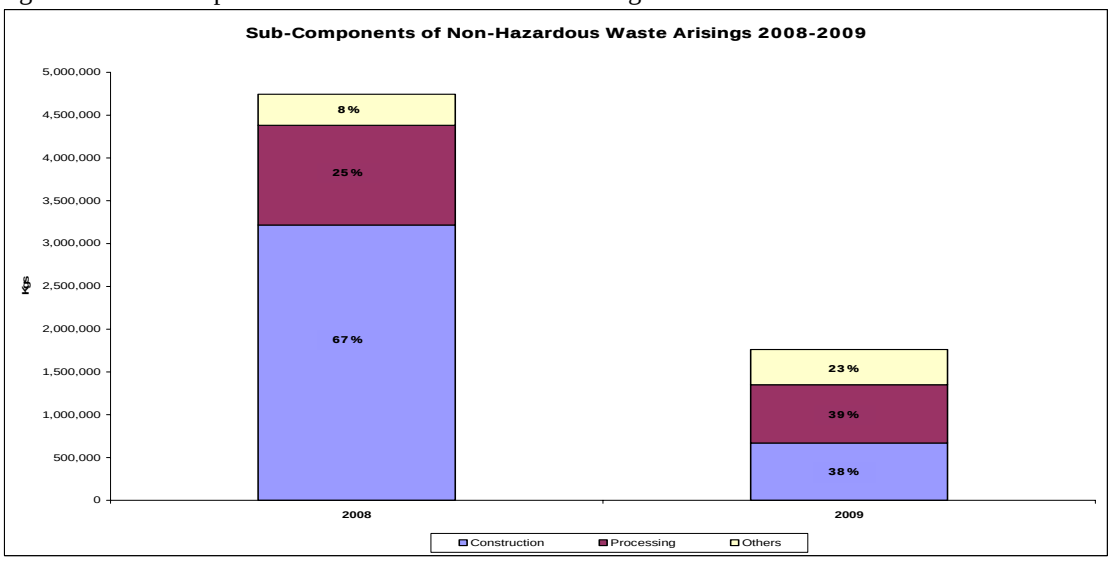
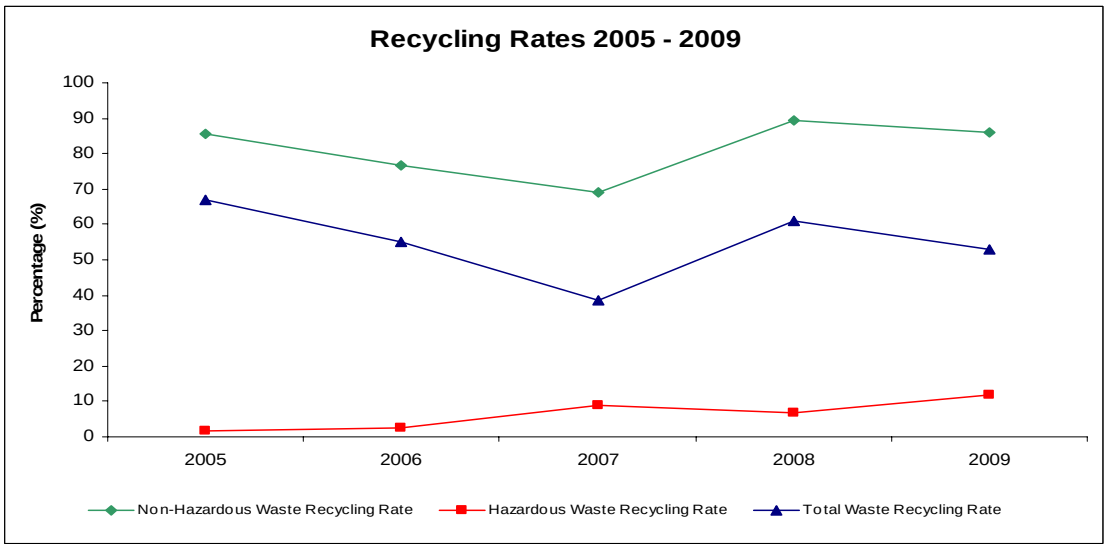


Figure 2.5: Waste Recycling Rates 2005 - 2009



The Pfizer Corporate EHS Department has set a target of a 2% reduction of the 2009 baseline in waste arisings from the Pfizer organisation to be achieved by year end 2010. WMI has committed to achieving:

- a minimum 2% reduction of the 2009 baseline of waste arisings by year end 2010 with a stretch target of 5% reduction (refer to Figure 2.6); and,
- a minimum 6% reduction of the 2009 baseline of waste arisings to be achieved over the 3 year period 2010 – 2012 with a stretch target of a 15% reduction (refer to Figure 2.6)

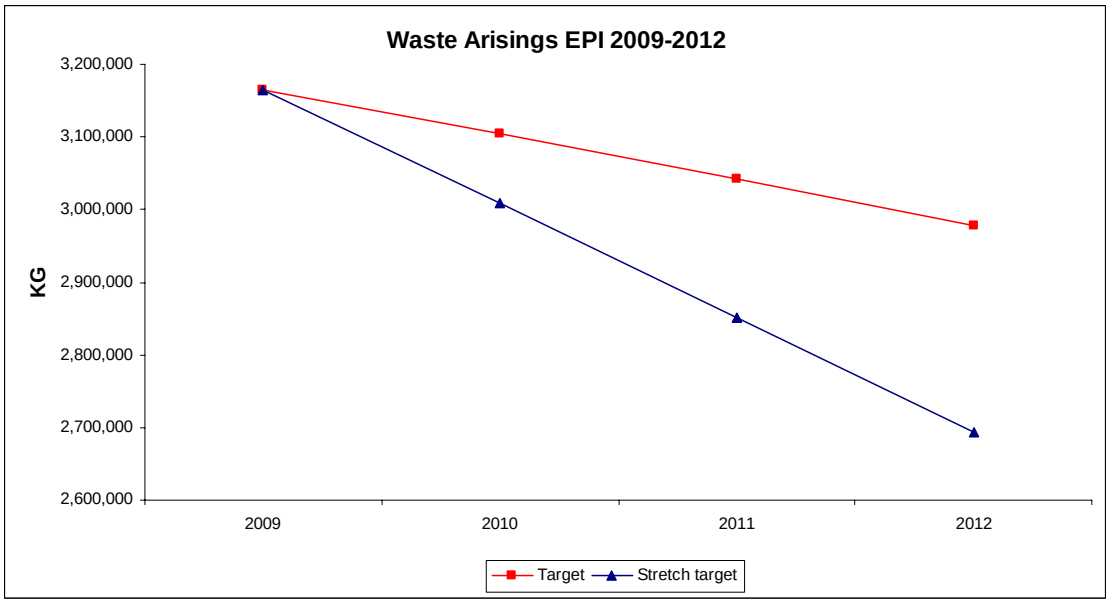
With 3,168,064 Kg of waste arisings in 2009 (Table 2.9), the base year for which the Newbridge reduction targets are set:

- WMI are required to achieve a waste arisings EPI of 3,104,703 Kg by year end 2010 (stretch target 3,009,663 Kg).
- WMI aim to achieve a waste arisings EPI of 2,977,980 Kg by year end 2012 (stretch target 2,692,854 Kg).

The primary waste reduction projects proposed for implementation at the site in 2010 in order to meet the targets presented herein [also refer to Objective 4 *Waste Management* of the Environmental Management Programme 2010 (Appendix 7)] include the following:

- Fibre Drums: Investigate the increased reuse of fibre drums
- SRS Waste: Investigate the possibility of reusing recovered DCM from SRS waste in the Efexor process
- Implement opportunities to reduce waste at source as identified during 2009 area waste reviews

Figure 2.6: Waste Arisings EPI 2009-2012



2.7.2. Waste Analysis

As per *Schedule C.4 Waste Monitoring* of Licence Register No. P0153-05 WMI are required to analyse specific hazardous waste arisings. The WMI approach to comply with this requirement was verbally agreed with the EPA during the Site Inspection of 15/04/2004 and subsequent EPA 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 in previous AERs 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 2.9.

Table 2.9: Contents of Appendix 5

Table No.	Title
A5.1	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 (including Controlled Drugs).
A5.2	Pharmaceutical Liquid – Rinsewater Waste Analysis
A5.3	Pharmaceutical Liquid – Sugar Coating Solutions Waste Analysis
A5.4	Chlorinated Solvent Waste Analysis (Process Waste - SRS)
A5-5	Recovered Solvent from SRS waste Recovery
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

2.8. ENERGY USAGE

2.8.1. Energy Usage – CO_2 Emissions

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 (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 from the site for the period 2005 to 2009 are presented in Table 2.10.

Table 2.10 CO_2 Emissions 2005 – 2009

CO_2 Emissions Source	Tonnes CO_2				
	2005	2006	2007	2008	2009
Electricity Purchased	21260 Note 1	22570 Note 1	19502 Note 1	25106 Note 1	20271 Note 2
Electricity Generated Note 3	16209	17311	22640	22109	24395
Diesel Oil Note 3	7.47	12.67	6.54	10.15	6.16
Propane Note 3	1.55	0.80	0.98	0.30	0.31
Total	**37478**	**39894**	**42150**	**47226**	**44672**

Note 1: Tonnes CO_2 from electrical usage are calculated using the electricity emissions factor provided by the electricity supplier used by WMI, as approved by the Irish Commission of Energy Regulation.

Note 2: In the absence of an electricity emissions factor for 2009 the 2008 factor provided by the electricity supplier used by WMI has been used.

Note 3: Emissions verified as part of EU Emissions Trading Scheme.

The increasing trend observed for 2005 - 2009 ceased in 2009 with a 5% decrease in CO_2 emissions for 2009 in comparison to that generated in 2008. This can be explained by a decreased energy demand associated with the following:

- Completion of energy efficiency projects:
  - Re-use of CHP Low Temperature Hot Water (LTHW) in the new PDC and OC4B buildings i.e. reduced natural gas usage due to the use of previously heated water rather than generating newly heated water – *completed November 2009.*
  - HVAC: More efficient use of HVAC systems in packaging and office areas. A number of Variable Speed Drives (VSDs) were installed across the HVAC

system (supply, extract & recirculation units) to enable timer on/off control and out-of-hours ramp down of HVAC – *Ongoing.*

- Packaging Areas: i.e. Reduced air change rates during production times, Minimisation of HVAC usage during non-production times.
- Office Areas: Air handling units are automatically switched off outside of routine office hours.

- Compressed Air: The linking of the 2 central utilities buildings compressed air systems has resulted in the removal of 3 driers & 2 compressors with 2 compressors currently used rather than 4 – *completed November 2009.*
- Lighting: Installation of Passive Infrared lighting system in Building 4 & Building 9 (lights only only come on when the motion sensor is activated) – *completed October 2009.*

- Decommissioning of areas (GT area in Building 3).
- Temporary shut-down of MHT production area for 2 months to conduct maintenance activities.
- Equipment shut-down at weekends.

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 currently 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) which authorises the facility to undertake energy consumption activities primarily associated with on-site boilers and the CHP plant (combustion installation). CO_2 emissions for 2005 - 2009 from the direct combustion of fossil fuel sources at WMI are presented in Table 2.11.

Table 2.11 CO_2 Emissions from Direct Combustion of Fossil Fuel Sources 2005 – 2009

Parameter	**Tonnes CO_2**				
	2005	**2006**	**2007**	**2008**	**2009**
Allocation	22693	30397	30397	37695	37695
Verified Emissions	16218	17324	22647	22120	24401
Deficit(-)/Surplus(+)	+6475	+13073	+7750	+15575	+13294

The reason for the increased CO_2 emissions from the direct combustion of fossil fuel sources at WMI in 2009 when compared to previous years was due to the increased reliability and operation of the CHP plant i.e. increased usage of natural gas with a corresponding decrease in purchased electricity (refer to Table 2.10).

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.

2.8.3. Energy Usage - Water Consumption

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 the Local Authority 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; and,
- which serve buildings 3A, 3B, 4, 5, 9, 10, 11, the Sub-Contractors Compound and B3C mains water storage tanks which feed building 3C.

The total water usage (m^3) on-site for the period 2005 - 2009 is presented in Table 2.12.

Table 2.12 Water Usage 2005 – 2009

Water Consumption (m^3) Note 1				
2005	**2006**	**2007**	**2008**	**2009**
181,770	342,589	344,267	285,112	283,755

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

Water consumption at the WMI site in 2009 decreased by 0.5% in comparison to 2008 usage. This can be explained by ongoing monitoring of the water mass balance for the site [based on water intake from Local Authority (**Water In**) and effluent discharged via WWTP (**Water Out**)] which allows WMI to promptly respond to any discrepancies in water usage e.g. leaks.

2.9. EPA MONITORING & ENFORCEMENT

2.9.1. EPA Monitoring

(i) Emission to Sewer

The EPA conducted monitoring (grab sampling) of emissions to sewer at the grab sample location for Emission Point Reference No. SE1 on 17/02/2009, 29/04/2009, 29/06/2009 and 16/11/2009. 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). No exceedances for the parameters measured were detected by the EPA or WMI.

(ii) Emissions to Air

On 03/06/2009 the EPA conducted air monitoring (sub contracted to Euro Environmental) on site. No non-compliances were recorded.

2.9.2. EPA Enforcement

EPA inspectors carried out an unannounced audit of the Environmental Laboratory on 15/05/2009 and an unannounced Site Inspection of the site on 11/06/2009. No non-compliances were raised during these audits and any observations noted during the audits have been closed (refer to WMI submissions dated 23/06/2009 and 10/08/2009 respectively).

2.10 REPORTABLE ENVIRONMENTAL INCIDENTS & COMPLAINTS

2.10.1 Reportable Environmental Incidents

Reportable environmental incidents that occurred at the WMI site in 2009 (which were previously notified to the EPA) are summarised in Table 2.13.

Table 2.13: Reportable Environmental Incidents 2009

Date of Incident	Non-Compliance	Cause	Authorities Notified	Corrective Action
Temporary failure in the on-site Wastewater Pre-Treatment Plant (WWTP) alarm system				
24/03/09	Temporary failure in the on-site Wastewater Pre-Treatment Plant (WWTP) alarm system which occurred for a period of 1 hour on 24/03/09. This resulted in a discharge of 36 m^3 of effluent from the site with a residual ozone off-gas level below the set-point of 3ppm (the ozone off-gas is continuously monitored and the effluent discharge from the WWTP should automatically stop if the off-gas ozone levels drop below 3 ppm). The environmental impact of this failure is considered imperceptible as the liquid phase ozone levels in the effluent discharge during this period remained constant, which indicates that there was sufficient ozone present to remove any pharmaceutical actives from the wastewater discharge, and therefore ensure compliance with the ELVs for pharmaceutical actives. The results of analysis of API content for fortnightly composite sample confirmed this assertion i.e. <LOD	A failure in the WWTP alarm system.	Notified EPA and Local Authority on 01/04/09. No issues raised by either EPA or Local Authority.	Investigation to determine the root cause of the alarm failure conducted. Corrective and preventive actions have been completed to prevent recurrence.
Non-Hazardous Waste Spill				
14/07/09	Shredded solid non-hazardous waste (aluminium foil) spilled from a load that had been collected by the WMI approved waste management contractor. This occurred: ▪ internally within the WMI site; and, ▪ externally on the R445 from the WMI site to the 'Bundle of Sticks' roundabout located approximately 5 Km to the North East of the site.	Failure of Waste Contractor to properly cover load with netting.	Notified EPA and Local Authority on 14/07/09. No issues raised by either EPA or Local Authority.	Road sweeper used to clean up all waste spilled. An investigation to determine the root failure conducted. Corrective and preventive actions have been completed to prevent recurrence.
Surface Water Penstock Leak				
30/11/09	Possible breach of containment of the final penstock valve on the surface water system. An investigation to determine whether there is a breach of containment or not, and the extent of same if present is ongoing.	Integrity of seal on penstock breached.	Not a pollution incident. For information purposes EPA and Local Authority notified on 30/11/09. No issues raised by either EPA or Local Authority.	Corrective and preventive actions completed to prevent recurrence.

2.10.2 Environmental Complaints

WMI have received no complaints of any nature in 2009.

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 respectively, 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.

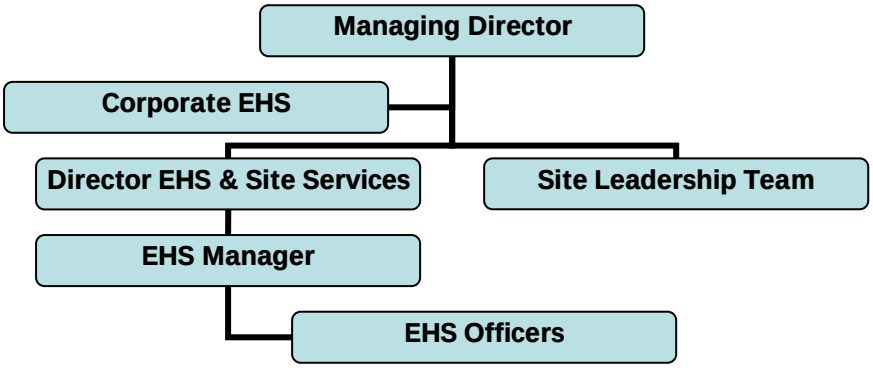
3.1.2. Environmental, Health & Safety Policy

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 colleagues with the company, at every level (including contractors), 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 Site Leadership Team) holds responsibility for their specific area while the EHS & Site Services Director together with the environmental officers within the EHS Department are responsible for the day to day maintenance associated with the environmental management system (refer to Figure 3.1 below).

Figure 3.1 EHS Management Structure at WMI



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 2010

Environmental objectives and targets, which are generated following the identification of environmental aspects, are 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 2010 (Appendix 7). WMI welcome any EPA feedback on the 2010 EMP which is currently undergoing implementation.

3.1.6. Environmental Management Programme – Report 2009

A review of the status of the individual environmental objectives and targets previously detailed in the EMP for 2009, are outlined as in Table 3.1. The majority of the objectives and targets set out in the site EMP for 2009 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 2010 Environmental Management Programme (refer to Appendix 7). Documentation supporting these environmental objectives and targets are available for review by EPA personnel.

Table 3.1: Environmental Management Programme – Report 2009

Objective 1: Compliance - To achieve compliance with all WMI IPPC Licence (Licence Register No. P0153-05), and Wyeth Corporate EHS environmental policy requirements.		
Target	▪ **Monitoring:** Develop and implement an emissions monitoring programme in accordance with Condition 5.1 & 6.1 of IPPC Licence. ▪ **Reporting:** Prepare and submit reports in accordance with IPPC Licence timelines (Condition 5.11, 6.11.1, 6.18, 11.1, 11.2 & 11.8) ▪ **Auditing:** Ensure the site, at all times, can demonstrate compliance for regulator/ Wyeth Corporate EHS audit.	Result	Completed ▪ **Monitoring & Reporting:** No exceedances of Emission Limit Values specified for Emissions to Sewer, Air & Noise. No issues observed for Surface Water or Groundwater monitoring. All required reports submitted to the EPA in accordance with IPPC Licence timelines ▪ **Auditing:** No non-compliances raised at unannounced EPA audits.
Target	**Environmental Performance Indicators:** Measure site environmental performance in accordance with Wyeth Corporate EHS (cEHS) Environmental Performance Indicators (EPIs) & associated 5 year targets.	Result	Completed ▪ 2008 EPI: EPI performance data submitted to EPA as part of the 2009 AER. ▪ 2009 EPI: Quarterly EPI review & report submission to cEHS completed to ascertain performance against EPI targets (Actual performance v. Target). EPI performance data submitted to EPA as part of the 2010 AER.
Target	**Process Effluent:** In accordance with Condition 6.11.3 of IPPC Licence demonstrate the efficiency of destruction of pharmaceutical actives by ozonation in the on-site WWTP: ▪ Complete in-house process validation of WWTP ▪ Implement EPA approved Programme Proposal to demonstrate that the destruction of Pharmaceutical Actives is permanent, and that reversion does not occur.	Result	Ongoing ▪ Completion of the Performance Verification on the WWTP in December 2009 enabled the initiation in January 2010 of a sampling & testing programme to complete the second and final phase of the proposed API reversibility study. Report on the findings of this study due to be submitted to the EPA in Quarter 2 2010.
Target	**Fire Water Retention:** Maintain facilities for the interception of firewater as may arise on the site in accordance with Condition 3.9 of IPPC Licence.	Result	Ongoing ▪ A 'system by system' or 'building by building' based risk assessment is proposed in 2010 to progress the 2005 Fire-Water Retention Study and also take account of on-site developments since 2005. This approach will support an assessment of the sites high risk areas and ultimately determine the level of firewater retention deficiency (if any) currently present on the site.
Target	**Efficiency of Raw Materials Use:** In accordance with Condition 7.4 of IPPC Licence continue to ascertain if more sustainable forms of production can be adopted at the site: ▪ Review progress on implementation of opportunities identified for Efficiency of Raw Materials Use assessments previously conducted for Efexor (completed in 2005) and OC (completed in 2006) processing areas. ▪ Repeat Efficiency of Raw Materials Use assessments for Efexor and OC processing areas. ▪ Prepare schedule for the completion of any improvement actions identified	Result	Completed ▪ Efficiency of Raw Materials Use assessment of the Efexor and OC production areas completed. Report submitted to EPA. ▪ All areas for improvement have been progressed. Additional areas for improvement identified, assessed & implemented on an ongoing basis.
Target	**Environmental Liabilities Risk Assessment:** In accordance with Condition 12.2 of IPPC Licence review the measures taken at the site in relation to the prevention of environmental damage, and the financial provisions in place in relation to the underwriting of costs for remedial actions following anticipated events: ▪ Implement mitigation measures recommended in the ELRA ▪ Revise ELRA 'Risk Score' on completion of individual mitigation measures ▪ Revise Financial Provision cover on completion of individual mitigation measures ▪ Submit update to the EPA on completion of individual mitigation measures (update in AER also required)	Result	Completed ▪ Updated information included in Appendix 9 of the 2010 AER ▪ The EPA has verbally indicated that the Pfizer Ireland Pharmaceuticals (the proposed transferee for Licence Register No. P0153-05) financial provision proposal (parent company guarantee), to underwrite the environmental liabilities identified in the ELRA (unknown liabilities) and RMP (known liabilities) for the WMI Newbridge facility is adequate.
Objective 2: Environmental Training & Awareness - Continue to develop on-site environmental training and awareness programmes.			
Target	**Environmental Training:** Review existing training master kits & update to computer based training.	Result	Completed ▪ Refresher training on the packaging & labelling of waste completed for new MHT processing area.
Target	**Environmental Awareness:** Develop a programme proposal & implement ideas/projects.	Result	Completed ▪ Launch of 'Green Computing' initiative – after a period of inactivity a computer will go into a *sleep or hibernate* mode & will turn-off monitor ▪ Promotion of double sided printing to reduce waste ▪ Highlighting waste arisings at the canteen e.g. quantities of napkins, cups & disposable cutlery used ▪ EHS Quiz organised by the Laboratories ▪ Conducted tours of areas of environmental significance within the plant with employees. Areas visited included WWTP & Waste Management Centre.
Objective 3: Energy Efficiency - Continue to reduce energy and water consumption associated with on-site operations.			
Target	**Energy Management System:** Rationalise & simplify site energy management procedures.	Result	Completed ▪ Procedures simplified where possible. This process will continue as the site continues to implement the system.
Target	**Energy Usage:** Identify, short-list and implement ideas/projects (subject to receiving capital approval) to achieve the following: ▪ **Energy:** Decrease energy usage by 4% of 2007 baseline i.e. 0.056 tonnes CO_2 / Kg product to 0.054 tonnes CO_2 / Kg product ▪ **Water:** Decrease water usage by 2% of 2009 baseline i.e. 0.340 m^3 water / Kg product to 0.333 m^3 water / Kg product Implement corrective action where required for any significant deviation with targets	Result	▪ **Energy:** 0.058 tonnes CO_2 / Kg product **–** *Target Not Achieved.* However, the increasing trend observed for 2005 - 2009 ceased in 2009 with a 5% decrease in absolute CO_2 emissions for 2009 in comparison to that generated in 2008. It is noted that for 2010 onwards Pfizer cEHS targets will be based on absolute data. ▪ **Water:** - 0.361 m^3 water / Kg product **–** *Target Not Achieved.* However, the 5 year Wyeth cEHS target (0.365 m^3 water / Kg product) which was achieved in 2008 was maintained in 2009. Furthermore absolute water consumption at the WMI site in 2009 decreased by 0.5% in comparison to 2008 usage. It is noted that for 2010 onwards Pfizer cEHS targets will be based on absolute data. - Baseline information to assess the viability of the reuse of treated effluent from the cooling towers continues to be collected. It is anticipated that his project will be implemented in 2010 subject to receiving capital approval.
Objective 5: Waste Management: Continue to examine options for reduction & recycling of hazardous and non-hazardous waste.			
Target	**Waste Reduction:** Identify, short-list and implement ideas/projects (subject to receiving capital approval) to achieve a 4% reduction of the 2007 baseline waste arisings (6.55 Kg waste / Kg product to 6.29 Kg waste / Kg product).	Result	▪ Waste: 3.21 tonnes CO_2 / Kg product **–** *Target Achieved.*. It is noted that for 2010 onwards Pfizer cEHS targets will be based on absolute data.
Target	**Waste Recycling:** Identify, short-list and implement ideas/projects (subject to receiving capital approval) to achieve the following: ▪ **Hazardous Waste:** Increase recycling rate by 2% of 2008 baseline i.e. 7% to 9%. ▪ **Non-Hazardous Waste:** Increase recycling rate by 2% of 2008 baseline i.e. 89% to 91%.	Result	Completed ▪ Hazardous Waste: 2009 Recycling rate = 11% **–** *Target Achieved.* ▪ Non-hazardous Waste: 2009 Recycling rate = 87% **–** *Target Not Achieved.* This is due to the significant reduction in the amount of construction waste generated in 2009. However WMI continue to ensure that all possible material that can be recycled is being recycled.
Target	**Waste Logistics:** Evaluate the use of software to replace existing hardcopy logbook system for the tracking of movement of hazardous waste within and from the site	Result	Ongoing ▪ In 2010 SAP will be used to log weight and movement of controlled drug waste. Once complete and successful operation of the system is proven the extension of SAP to all hazardous waste streams will be evaluated.

3.2. POLLUTION EMISSIONS REGISTER- EPRTR

The WMI PRTR submission is presented in Appendix 12. The electronic submission was successfully uploaded to the EPA website on 26/03/2010 and the following receipt number was issued:

- 0f337d3c3b1f719cfcf77a56942b265c

WMI have as yet received no response from the Agency to the query sent on the 12/11/09 regarding the EPA inaccuracy of the 2007 PRTR data presented and published on http://prtr.ec.europa.eu/FacilityLevels.aspx.

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, to prepare a Solvent Management Plan (SMP) to demonstrate compliance with *Condition 5.4* and *Condition 6.15* of the Licence. To-date, in accordance with a request from the EPA [as per EPA Site Inspection Report of 19/04/2004 (Reference: M673/gc001bk.doc)], WMI have submitted SMPs for the site in AERs 2005-2008. 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 2005 – 2009 **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
2005	628,930	19,134	3.04	Total emissions to air of volatile organic compounds shall be reduced to no more than **5%** of the total solvent input.
2006	629,966	23,892	3.79	
2007	699,755	24,966	3.57	
2008	662,491	22,345	3.37	
2009	392,965	17,371	4.4	

Note 1: Refer to previous AERs for notes on 2005-2008 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 EPA 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 will 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.

Note 3: Refer to Table 3.5 for detailed SMP mass balance

3.3.2. Scope

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

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

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

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

- Dichloromethane (DCM)
- Methanol
- Industrial Methylated Spirits (IMS)
- Isopropyl Alcohol (IPA)
- Pharmaglaze
- Acetonitrile.

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 the majority (refer to Table 3.5) of solvent used at the site. For this reason, these solvents were chosen for detailed examination as part of the SMP (and previous SMPs), in order to assess compliance with the ELVs outlined in *Condition 5.4.1(ii)* of Licence Register No. P0153-05.

3.3.3. Methodology

The methodology which was applied to previous SMPs (which is outlined in detail in AERs 2005-2008) was used in the preparation of the 2009 SMP.

3.3.4. Mass Balance

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 2009 was approximately 392,964.9 kg (refer to Table 3.3). DCM, Methanol and IMS account for approximately 96% of total solvent input on-site for 2009 ((375,978.9 kg refer to table 3.3 and 3.5).

Key figures from Table 3.5 are as follows:

- Total solvent emissions to air for DCM (O1+O4) is: 86.88kg.
- Total solvent emissions to air for Methanol (O1+O4) is: 154.26kg.
- Total solvent emissions to air for IMS (O1+O4) is: 143.47kg.
- This results in a Total solvent emission to air for all 3 solvents of: 384.61kg.

This is equivalent to total solvent emissions to air of less than 0.10% of the total solvent input (375,978.9kg) 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 2009 data indicated that there was approximately 16,986 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 17,370.61 kg (16,986 kg + 384.61 kg), representing 4.4 % 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 2009 for the Entire Site

Solvent Containing Materials	Amount Used in 2009 (Kg)	VOC Content (%) Note 1	Amount VOC Used 2009 (Kg)
1,2 Dichloroethane	110 Note 2	100.00%	110
3M Stainless Steel Cleaner	1 Note 4	5.00%	0.05
Acetic Acid	37.5 Note 2	100.00%	37.5
Acetone	167.05 Note 2	100.00%	167.05
Acetonitrile	2025.5 Note 2	100.00%	2025.5
Black Printing Ink	3000 Note 4	98.00%	2940
Chemcraft Label Remover	1 Note 4	60.00%	0.6
Cyclohexane	2 Note 2	100.00%	2
DCM (Laboratory)	145 Note 2	100.00%	145
DCM (Processing)	230332.3 Note 2	100.00%	230332.3
Diethyl Ether	22.5 Note 2	100.00%	22.5
Domino 0121X Makeup	1000 Note 4	98.50%	985
Domino 1000 Wash	1000 Note 4	80.00%	800
Domino WL200 Wash	1000 Note 4	80.00%	800
Ethanol	140 Note 2	100.00%	140
Ethyl Acetate	47.5 Note 2	100.00%	47.5
Formic Acid	5 Note 2	100.00%	5
General Purpose Thinners	1 Note 4	80.00%	0.8
IMS (Laboratory)	57 Note 2	100.00%	57
IMS (Processing)	1107.9 Note 2	100.00%	1107.9
Ink Black Opacode S-8-27741	488.4 Note 2	44.50%	217.34
Ink White Opacode S-8-28905	359.89 Note 2	23.75%	85.47
IPA	4200 Note 3	100.00%	4200
IPA Wipes	10 Note 4	50.00%	5
Methanol (Laboratory)	3637.5 Note 2	100.00%	3637.5
Methanol (Processing)	140699.20 Note 2	100.00%	140699.2
Mineral Spirits Odourless	212.48 Note 2	100.00%	212.48
n-hexane	8 Note 2	100.00%	8
Nitro ethane	2.5 Note 2	100.00%	2.5
Opacode	1100 Note 4	40.00%	440
Opacode A-14004 /A-14030 Pink	150 Note 4	40.00%	60
Opacode S-8-29007	52 Note 4	40.00%	20.8
Pentane	2.5 Note 2	100.00%	2.5
Petroleum Ether	0.5 Note 2	100.00%	0.5
Pharmaglaze	3191.88 Note 2	50.00%	1595.94
Propan-1-ol	10 Note 2	100.00%	10
Propan-2-ol	75 Note 2	100.00%	75
TEK ink SW-9007/9008	5 Note 5	90.00%	4.5
Tetrahydrofuran	30 Note 2	100.00%	30
Toluene	50 Note 2	100.00%	50
Triethylamine	42.5 Note 2	100.00%	42.5
Videojet Ink 16-8420	1000 Note 5	92.00%	920
Videojet Ink 16-8425	1000 Note 5	92.00%	920
Total	**396529.6**		**392964.9**

Note 1: VOC content was determined by reference to the MSDS filed on-site for each material.

Note 2: Amount used in 2009 determined from SAP data recording/processing system.

Note 3: Usage data was taken from *Table G.1(i): Details of Process Related Raw Materials, Intermediates, Products, etc., Used or Generated on the Site* and was a combination of usage figures for IPA and Isopropanol.

Note 4: 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 EPA 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 and Table G.1 (i) of IPPC Licence***
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 wastewater discharge from the site (SE-1).***
O3	***The quantity of organic solvent that remains as contamination or residue in products output from the process.***	***Relevant: In line with manufacturing specification and relevant regulatory body guidelines***
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 (including fugitive emissions), discharged to wastewater or collected as waste.
O6	***Organic Solvents contained in collected waste.***	***Relevant: Solvents recovered from the Efexor SRS/SAS systems, HT printing solvents and laboratory waste are 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 via the Efexor SRS/SAS systems are transported off-site for treatment not on-site re-use.
O9	***Organic solvents released in other ways.***	***Relevant: Bypasses of the Efexor SAS systems. No means of quantifying this in 2009 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 [Note 1]

Mass Balance Component		Solvent (kg)			Total (kg)
		DCM	Methanol	IMS	
I1: Inputs	Processing	230,332.30	140,699.20	1,107.90	372,139.40
	Laboratories	145.00	3637.50	57.00	3,839.50
	Total	**230,477.30**	**144,336.70**	**1,164.90**	**375,978.90**
O1: Organic solvent emissions in waste gases	Processing [Note 2]	44.27	11.02	134.32	189.61
	Processing [Note 3]	-	-	9.74	9.74
	Laboratory	1.45	36.38	0.57	38.40
	Total	**45.72**	**47.40**	**144.63**	**237.75**
O2: Organic solvents lost in water	**Total**	**0.07**	**22.81**	**1.16**	**24.04**
O3: Organic Solvents remaining on Product	**Total**	* [Note 4]	* [Note 4]	* [Note 4]	**0**
O4: Fugitive organic solvent emissions	**Total**	**41.23**	**129.67**	**0**	**170.9**
O6: Collected Waste Solvent	SRS/SAS	230,246.8	140,558.50	-	370,805.30
	Ink & Shellac [Note 3]	-	-	963.84	963.84
	Laboratories	143.55	3601.13	56.43	3,801.11
	Total	**230,390.35**	**144159.63**	**1020.27**	**375,570.25**
Total emissions of solvent to air – (O1+O4) = I1–(O2+O3+O6)	**Total**	**86.88**	**154.26**	**143.47**	**384.61**

Note 1: Refer to previous AERs for notes on 2005-2008 data.

Note 2: As per *Condition 6.21.2* of Technical Amendment D to Licence Register No. P0153-05, the solvent usage (IMS) associated with Emission Point Reference No. A2-6 is logged and in 2009 134.32 Kg was used. This is within the licenced use of 560Kg for 2009.

Note 3: IMS is used in the HT print process to dilute printing inks. This waste [Inks and shellac (containing Printing Ink, Pharmaceutical Glaze, Glycerol Mono Oleate, Polyethylene Glycol and Industrial Methylated Spirits)] is collected in drums and transported off-site for appropriate treatment. It is estimated that 99% of IMS used in the HT print process is collected as waste with 1% being emitted to air via fugitive losses.

Note 4: In line with manufacturing specification and relevant regulatory body guidelines

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

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. 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.

WMI test all bunds on-site over a 3 year cycle. In 2009 25 No. bunds were tested as per an internal schedule. Of the bunds tested 24 passed with 1 failure (refer to Appendix 10). The following actions were taken for the 1 No. bund that failed integrity testing:

- Bund PE 45 (Kunhi Tower bund) is currently not in use. The Kunhi Tower was not operational in 2009 and PE45 will be repaired before any operations recommence.

There is no environmental impact associated with this failure as no spill was collected in the bund since the previous testing and no rainwater collected in the bund as it is enclosed.

4.3. TANK & PIPELINE INSPECTION REPORT

As per *Condition 6.9* of Licence Register No. P0153-05, every 3 years WMI are required to assess the integrity and water tightness of all underground pipes and tanks and their resistance to penetration by water or other materials carried or stored therein. A survey of the underground tanks and pipelines, which was conducted during 2008, highlighted defects and blockages in some underground pipes. The defects noted were not significant and did not impact on the integrity of the pipework. A work programme developed to mitigate all the defects identified has now been completed and a copy of the report is available for inspection by EPA personnel.

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 11.

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. In accordance with *Condition 6.17.3* of Licence Register No. P0153-05, 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 atmospheric emissions installed in 2009 (refer to Table 1.1 & Table 4.1).

Table 4.1: Atmospheric Emission Points Installed/Decommissioned in 2009

Emission Point Reference	Installed/Decommissioned	Net Increase/Decrease
Main Atmospheric Emissions		
A2-49a to A2-49k	Installed	+10
A2-73	Decommissioned	-1
		Net Change: +9
Minor Atmospheric Emissions		
A3-87	Decommissioned	-1
A3-120, A3-121	Decommissioned	-2
A3-138, A3-139	Decommissioned	-2
A3-187, A3-188	Decommissioned	-2
A3-189	Decommissioned	-1
A3-448	Installed	+1
A3-449	Installed	+1
A3-450	Installed	+1
A3-451 to A3-467	Installed	+17
A3-469 to A3-475	Installed	+7
		Net Change: +19
Potential Atmospheric Emissions		
A4-227 to A4-231	Installed	+5
		Net Change: +5

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 EPA on 18/10/2007. This document was subsequently updated at the request of the EPA on 26/06/2009 (Ref: P0153-05/gc20djm.doc) to include information previously submitted by WMI to the EPA on 08/08/2008. The updated ELRA, which was submitted to the EPA on 10/08/2009, was approved on 21/08/2009 (Ref: P0153-05/gc22djm.doc). Currently there are no changes on the information presented in the ELRA approved by the EPA, apart from the timelines for completion of selected risk mitigation measures i.e. Risk ID 8 and 9. A revised "Table 5.2" as extracted from the ELRA, including changes for Risk ID 8 and 9 is presented in Appendix 9. This has no impact on the 'current risk scoring' until as such time as these mitigation measures are implemented. Once the mitigation measures are completed, as indicated where required in "Table 5.2" of the ELRA, the EPA will be updated on same by WMI.

The financial provision proposal has been assessed by the EPA as part of the Transfer of Licence Application process following the acquisition of Wyeth by Pfizer Inc., (refer to Section 1.2.1).

4.7. ENERGY EFFICIENCY & WATER USAGE SUMMARY

4.7.1. Overview

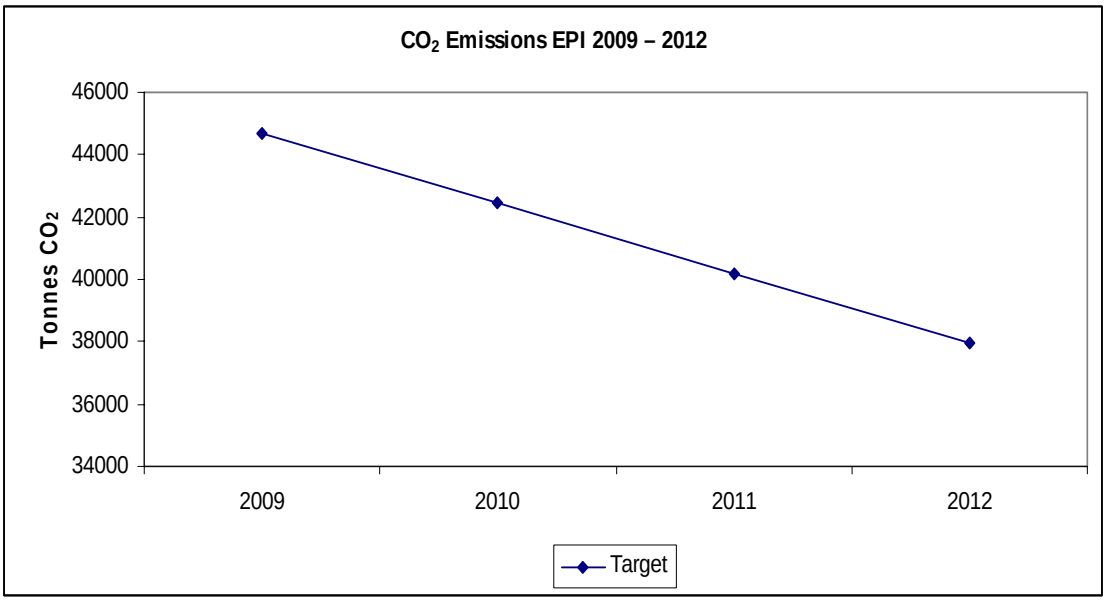
The area of energy reduction is a key environmental objective for the site. An energy management system (eNMS), which applies to all energy sources including electricity, natural gas and water, was installed at WMI in 2008. The eNMS is designed to optimise the use of energy and identify areas for energy use reduction at the WMI site. The eNMS includes a list of Key Performance Indicators (relative to energy performance of systems and equipment) and associated targets.

Energy related objectives and targets are formulated via an energy management programme (eNMP). Scheduling and responsibilities for individual targets/projects are included in the eNMP to allow for the successful achievement of the energy objectives. Projects identified to meet the targets presented in *Objective 3: Energy Management* of Environmental Management Programme – Proposal 2010 (Appendix 7) are undergoing evaluation by the WMI Senior Management Group. This evaluation is based on capital investment requirements and time-frame for implementation (short-term, long-term). An overview of these projects is presented in Section 4.7.2 (Energy Usage) and 4.7.3 (Water Usage). In addition a suitable staff awareness programme continues to be developed and implemented to increase awareness of energy efficiency at the WMI site.

4.7.2. Energy Usage

WMI has a target of a 15% reduction of the 2009 baseline of absolute CO_2 emissions to be achieved over the 3 year period 2010 – 2012 (refer to Figure 4.1).

Figure 4.1 CO_2 Emissions EPI 2009 – 2012



With 44672 tonnes of CO_2 emissions generated in 2009 (Table 2.12), the base year for which the Newbridge reduction target is set, WMI are required to achieve an absolute CO_2 emissions EPI of 37971 tonnes by 2012. In order to achieve this long-term target WMI has identified an interim annual reduction target of 5% which equates to an absolute CO_2 emissions EPI of 42439 tonnes for 2010.

Energy usage efficiency projects proposed for implementation at the site in 2010 in order to meet the targets presented in *Objective 3: Energy Management* of Environmental Management Programme – Proposal 2010 (Appendix 7) include the following:

- HVAC: More efficient use of HVAC systems in processing areas and laboratories.
- Compressed Air Remediation (repair of leaks in distribution pipework).
- Optimisation of Efficiency & Control of Medium Temperature Hot Water and Chilled Water Systems: Installation of new intelligent control systems to operate based on demand.
- Steam: Evaluate the linking of the 2 central utilities buildings steam generation systems.
- Equipment Decommissioning.

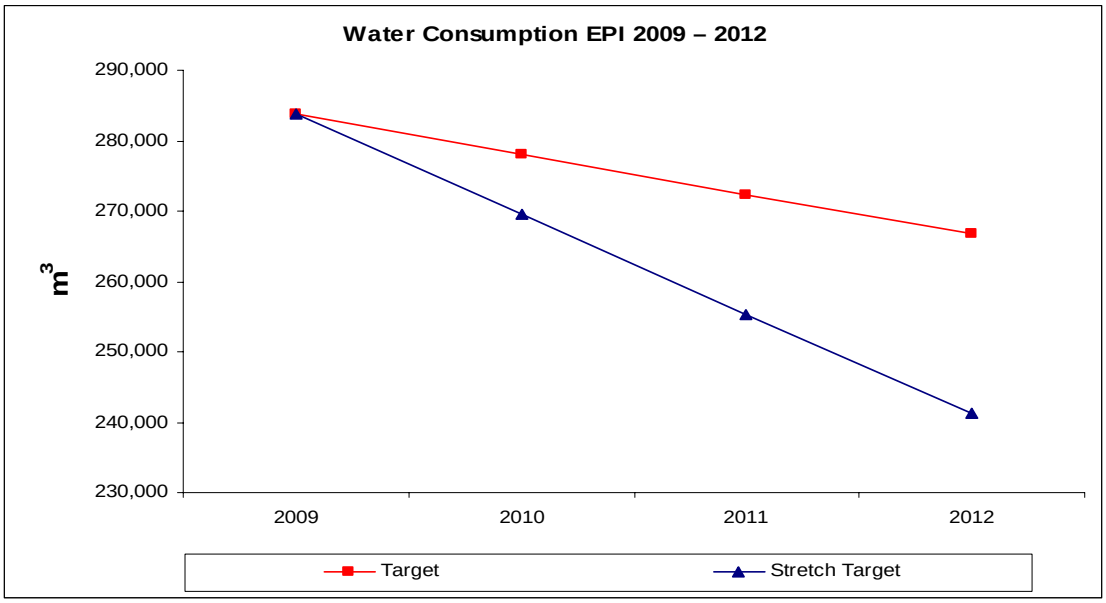
In line with Pfizer Corporate EHS Department sustainable development initiatives, and as outlined in *Objective 3: Energy Management* of Environmental Management Programme – Proposal 2010 (Appendix 7) WMI will complete a study into the available options for the generation of 'green' energy on-site (from renewable sources) e.g. CHP options (including new biomass fuelled CHP and alternative fuels for existing CHP), wind, solar systems, geothermal systems to exploit local geological features, etc.

4.7.3. Water Usage

The Pfizer Corporate EHS Department has set a target of a 2% reduction of the 2009 baseline of absolute water usage from the Pfizer organisation to be achieved by year end 2010. WMI has committed to achieving:

- a minimum 2% reduction of the 2009 baseline of absolute water usage by year end 2010 with a stretch target of 5% reduction (refer to Figure 4.2); and,
- a minimum 6% reduction of the 2009 baseline of absolute water usage to be achieved over the 3 year period 2010 – 2012 with a stretch target of a 15% reduction (refer to Figure 4.2)

Figure 4.2 Water Consumption EPI 2009 – 2012



With 283,755 m^3 of water used in 2009 (Table 2.14), the base year for which the Newbridge reduction targets are set:

- WMI are required to achieve a water usage EPI of 278,080 m^3 by year end 2010 (stretch target 269,567 m^3).
- WMI aim to achieve a water usage EPI of 266,730 m^3 by year end 2012 (stretch target 241,192 m^3).

Water usage efficiency projects proposed for implementation at the site in 2010 in order to meet the target presented in *Objective 3: Energy Management* of Environmental Management Programme – Proposal 2010 (Appendix 7) include the following:

- Projects
  - Assess feasibility of re-use of reject water from the water purification process for production of purified water for use in the domestic and process water systems.
  - Continue to assess the feasibility for re-use of WWTP effluent as cooling tower make up.
- Operations
  - Evaluate if the frequency of cleans between production batches and the quantity of water used in production cleaning processes can be reduced.

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

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). WMI continues to implement the Raw Material Efficiency Assessment Protocol as previously approved by the EPA (EPA reference M673/ap12mmcg.doc dated 01/02/2005). The proposal for 2010 [*Objective 1: Environmental Compliance - Efficiency of Raw Materials Use* of Environmental Management Programme – Proposal 2010 (Appendix 7)] is to revisit areas where a Raw Material Efficiency Assessment was previously carried out in order to determine:

- Process yield improvements achieved; and,
- Projects implemented in these areas in order to improve process yield,

since the previous Raw Material Efficiency Assessment studies were conducted in these areas.

5. CONCLUDING REMARKS

5.1. EMISSIONS FROM THE INSTALLATION

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. 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 (which are based on BAT).

The environmental monitoring carried out over the 2009 reporting period shows no adverse environmental impact on the environmental media into which discharges from the WMI facility are made:

- No exceedance of any emission limit value specified for emissions to sewer (wastewater), , emissions to air (including solvent management plan) or noise emissions;
- Storm water emission (surface water) of good chemical quality with no exceedance of either the TOC warning or action limits;
- Groundwater was of good chemical quality with no indication that the diesel spill that occurred on-site in 2007 has had a significant impact on the receiving groundwater;
- Environmental incidents are detected and responded to appropriately with no significant on the environment; and,
- No complaints of an environmental nature were received.

5.2. MANAGEMENT OF THE INSTALLATION

The majority of the objectives and targets set out in the site Environmental Management Programme for 2009 were achieved – those that could not be fully implemented or are ongoing as part of the long-term environmental objectives and targets have been incorporated into the 2010 Environmental Management Programme.

5.3. SUMMARY

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 environmental improvements programme at the site and the continuous improvement requirement of the IPPC licencing process is fully embraced by the WMI Site Leadership Team. 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 for 2009 is reflected by the:

- EPA audit and site inspection conducted at the site which were fully compliant;
- Ongoing independent certification with ISO14001 and IS393:2005 management system standards, and verification to the EMAS Regulation.

Appendix 1

Groundwater Monitoring Report –2009

Groundwater Monitoring at Wyeth Medica Ireland

2009

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	First & Second Biannual Groundwater Analysis 2009					
Document No.	MDE0643Rp0012F01					
This Document Comprises	DCS	TOC	Text	List of Tables	List of Figures	No. of Appendices
	1	1	19	1	-	1

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F01	Final	C. Reilly	N. Mitchell	S. Herlihy	West Pier	15/10/09

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1 INTRODUCTION

This report outlines the results of the first and second biannual groundwater monitoring for 2009, as conducted by RPS specialist groundwater monitoring personnel, on behalf of Wyeth Medica Ireland (WMI) at their facility in Newbridge, Co. Kildare.

The biannual monitoring events were carried out on the 19th of February and on the 16th of July. 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 2 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 Severn Trent Laboratories. 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
- Hydrocarbons

Groundwater samples were analysed by Severn Trent Laboratories, 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 – Severn Trent Laboratories

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)[1]	4.68	4.60	6.24	6.36	6.95	6.95	8.24	8.22	-
Static water Level	(mbgl)	2.647	2.78	2.94	3.27	3.82	3.82	3.46	4.03	-
Volume Extracted	(Litres)	40	20	40	30	40	30	50	45	-
pH	(pH Units)	7.3	7.17	7.8	7.49	7.5	7.17	7.3	6.68	>6.5 & <9.5
Temp	(^{o}C)	9.97	14.5	13.78	17.3	10.67	13.2	9.91	10.8	<25^{O}C
Conductivity	(µS/cm)	877	999	456	579	736	821	720	968	1000
Dissolved O_2	(ppm)	7.9	6.77	5.3	5.71	1.3	3.17	4.6	4.68	No Abnormal Change
Visual Observations		Grey, murky water, clearing slightly with purging. Odourless	Grey, murky water, clearing slightly with purging. Odourless	Silt rich water, clearing slightly to a cloudy brown colour with purging. Odourless.	Silt rich water, clearing slightly to a cloudy brown colour with purging. Odourless.	Black silt rich water, which changed to a pale brown with purging. Odourless.	Dirty brown colour, which changed to a paler brown with purging. Odourless.	Grey, murky water, clearing slightly with purging. Odourless	Clear water on purging, samples cloudy, sediment which settled to bottom, Odourless	-

Note 1 mbgl = metres below ground level

3.2 GROUNDWATER CHEMICAL ANALYSIS

Table 3: Results of Laboratory 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	
Total Alkalinity (as $CaCO_3$)	mg/l	388	389	349	258	363	318	437	384	No abnormal change
pH	pH units	7.3	7.4	7.8	7.7	7.5	7.4	7.3	7.3	6.5 – 9.5
Aluminum	mg/l	**0.258**	0.093	**3.91**	**1.96**	0.096	0.157	**2.260**	**2.03**	0.2
Total Ammonia (NH_4)	mg/l	0.06	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	<0.05	0.15
Ammoniacal Nitrogen	mg/l	<0.3	<0.3	<0.3	<0.3	<0.3	<0.3	<0.3	<0.3	-
Boron	mg/l	0.367	<0.3	<0.3	<0.3	0.3	<0.3	<0.3	<0.3	1.0
Calcium	mg/l	167	149	173	141	137	120	**242**	**202**	200
Chloride	mg/l	26	22	22	16	22	17	16	18	30
COD	mg/l	<8	39	12	40	20	32	<8	35	No abnormal change
Colour	Hazen units	<1	<1	<1	<1	<1	<1	<1	<1	No abnormal change
Fluoride	mg/l	**1.1**	0.2	0.3	0.2	0.2	0.2	0.1	0.2	1.0
Iron	mg/l	0.19	0.05	**6.03**	**3.37**	0.12	**0.28**	**3.54**	**4.67**	0.2
Magnesium	mg/l	23	18	10	8.22	18	16	15	14	50
Manganese	mg/l	**3.650**	**2.39**	**0.646**	**0.344**	**0.305**	**0.772**	**0.805**	**0.738**	0.05
Nitrate (as NO3)	mg/l	3.8	2.5	0.7	<0.3	3.9	2.9	3.4	3.0	25

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	
Nitrite (as NO2)	mg/l	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.1
Orthophosphate (as PO4)	mg/l	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	<0.1	0.03
Potassium	mg/l	1.06	0.85	4.35	3.80	0.99	1.15	**6.57**	4.35	5
Sodium	mg/l	22	14	24	15	14	10	17	17	150
Sulphate	mg/l	34	31	39	43	39	27	21	47	200
Potassium:Sodium Ratio		0.05	0.06	0.2	0.3	0.7	0.12	0.4	0.3	

Note 1 Figures in bold exceed guideline values

3.3 HEAVY METALS

Table 4: Results of Heavy Metal Groundwater Analysis

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	µg/l	1	1	<1	1	<1	1	<1	1	-
Arsenic	mg/l	<0.001	<0.001	0.001	<0.001	<0.001	<0.001	<0.001	<0.002	0.01
Beryllium	µg/l	<5	<5	<5	<5	<5	<5	<5	<5	-
Cadmium	mg/l	<0.0003	0.0022	0.002	0.0023	0.004	0.0013	<0.004	0.0025	0.005
Chromium	mg/l	<0.001	<0.001	0.008	0.005	<0.001	<0.001	0.003	0.006	0.03
Cobalt	µg/l	<5.3	5.1	4.2	2.9	<0.5	<0.5	<1	4.4	-
Copper	mg/l	0.013	0.004	0.025	0.013	<0.001	<0.001	<0.001	0.018	0.03
Lead	mg/l	0.004	0.008	**0.020**	**0.028**	0.004	**0.018**	**0.015**	**0.034**	0.01
Mercury	mg/l	<0.0001	<0.0001	0.0001	<0.0001	<0.0001	<0.001	<0.00005	<0.0001	0.001
Nickel	mg/l	0.007	<0.0009	0.0198	0.0077	<0.0009	0.0009	0.003	0.0117	0.02
Zinc	mg/l	0.020	0.009	0.007	0.043	0.007	0.011	0.005	0.049	0.1

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	<1	<1	<1	<1	<1	<1	<1	<1	<1	500
1,1,2,2-Tetrachloroethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,1,2-Trichloroethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,2-Dichloroethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,1-Dichloroethene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,1-Dichloropropene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,2,3-Trichlorobenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,2,3-Trichloropropane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,2,4-Trichlorobenzene [Note 1]	<1	<1	<1	<1	<1	<1	<1	<1	<1	0.4
1,2,4-Trimethylbenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,2-Dibromo-3-chloropropane	<2	<1	<2	<1	<2	<1	<2	<1	<2	-
1,2-Dibromoethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,2-Dichlorobenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	10
1,2-Dichloroethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	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	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,3,5-Trimethylbenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,3-Dichlorobenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,3-Dichloropropane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
1,4-Dichlorobenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
2,2-Dichloropropane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
2-Chlorotoluene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
4-Chlorotoluene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
p-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	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Bromodichloromethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Bromoform	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Bromomethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Carbontetrachloride	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Chlorobenzene	<1	<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	
Chloroethane	<2	<2	<1	<2	<1	<2	<1	<2	<1	-
Chloroform	<1	<1.0	<1	<1.0	<1	2	3.7	<1.0	<1	12
Chloromethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
cis-1,2-Dichloroethene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
cis-1,3-Dichloropropene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Dibromochloromethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Dibromomethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Dichlorodifluoromethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Dichloromethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	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	<1	<1	<1	<1	<1	<1	<1	<1	<1	1
n-Butylbenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
o-Xylene	<1	<1	<1	<1	<1	<1	<1	<1	<1	10
p/m-Xylene	<1	<1	<1	<1	<1	<1	<1	<1	<1	10
Propylbenzene	<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	
sec-Butylbenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Styrene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
tert-Butylbenzene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Tetrachloroethene	<1	<1	<1	<1	<1	<1	<1	<1	<1	40
Toluene	<1	<1	<1	<1	<1	<1	<1	<1	<1	10
Trans-1,2-Dichloroethene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
trans-1,3-Dichloropropene	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Trichloroethene	<1	<1	<1	<1	<1	<1	<1	<1	<1	70
Trichlorofluoromethane	<1	<1	<1	<1	<1	<1	<1	<1	<1	-
Vinyl Chloride	<1	<1	<1	<1	<1	<1	<1	<1	<1	-

Note 1 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	<2.0	<2.0	<1.0	<2.0	<1.0	<2.0	<1.0	<2.0	<1.0	0.5
2-Chlorophenol	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	200
2-Methylphenol	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
4-Methylphenol	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
2-Nitrophenol	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
4-Nitrophenol	<5.0	<5.0	<5.0	<5.0	<5.0	<5.0	<5.0	<5.0	<5.0	-
2,4-Dichlorophenol	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
2,4-Dimethylphenol	<2.0	<2.0	<1.0	<2.0	<1.0	<2.0	<1.0	<2.0	<1.0	-
4-Chloro-3-methylphenol	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
2,4,6-Trichlorophenol	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	200
2,4,5-Trichlorophenol	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Pentachlorophenol	<5.0	<5.0	<1.0	<5.0	<1.0	<5.0	<1.0	<5.0	<1.0	2
1,3-Dichlorobenzene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
1,4-Dichlorobenzene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
1,2-Dichlorobenzene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	10
1,2,4-Trichlorobenzene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	0.4
Nitrobenzene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	10
Azobenzene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Hexachlorobenzene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	0.03
Naphthalene	<1.0	<1.0	<2.0	<1.0	<2.0	<1.0	<2.0	<1.0	<2.0	1
Acenaphthylene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Acenaphthene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Fluorene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Phenanthrene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Anthracene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	10000
Fluoranthene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	1
Pyrene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-

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	
Benzo(a)anthracene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Chrysene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Benzo(b)flouranthrene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	0.5
Benzo(k)flouranthrene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	0.05
Benzo(a)pyrene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	0.01
Indeno(1,2,3-cd)pyrene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	0.05
Dibenzo(a,h)anthracene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Benzo(ghi)perylene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	0.05
2-Chloronaphthalene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
2-Methylnaphthalene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Carbazole	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Isophorone	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Dibenzofuran	<3.0	<3.0	<1.0	<3.0	<1.0	<3.0	<1.0	<3.0	<1.0	-
Dimethyl phthalate	<10.0	<10.0	<1.0	<10.0	<1.0	<10.0	<1.0	<10.0	<1.0	-
Diethyl phthalate	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Di-n-butylphthalate	<10	<10	<1.0	<10	<1.0	<10	<1.0	<10	<1.0	2
Di-n-octylphthalate	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Bis(2-ethylhexyl)phthalate	<1.0	<1.0	<10.0	<1.0	<10.0	<1.0	<10.0	<1.0	<10.0	-
Butylbenzylphthalate	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
4-Chloroaniline	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
2-Nitroanaline	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
3-Nitroaniline	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
4-Nitroaniline	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
2,4-Dinitrotoluene	<2.0	<2.0	<1.0	<2.0	<1.0	<2.0	<1.0	<2.0	<1.0	-
2,6-Dinitrotoluene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Bis(2-chloroethyl)ether	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Hexachloroethane	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Hexachlorobutadiene	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	<1.0	-
Bis(2-chloroethoxy)methane	<5.0	<5.0	<2.0	<5.0	<2.0	<5.0	<2.0	<5.0	<2.0	-
Bis(2-chloroisopropyl)ether	<1	<1	<1.0	<1	<1.0	<1	<1.0	<1	<1.0	0.1

4 DISCUSSION

The results of groundwater monitoring at the WMI facility for 2009 are presented in Tables 2 - 6 of this report. The results demonstrate that samples collected from the four wells (AGW1, AGW2, AGW3, AGW4) on the Wyeth Medica site during the year 2009 were generally of good quality, with the majority of parameters remaining within the Environmental Protection Agency (EPA) Interim Guideline Values (IGV) as set out in the agency report *'Towards Setting Guideline Values for the Protection of Groundwater in Ireland'* 2004. There were however, some exceedances of inorganic compounds. Discussion of the results and their significance are outlined below.

4.1 BIANNUAL 1 & BIANNUAL 2

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

Temperature, Dissolved Oxygen, pH and Electrical Conductivity were all within the ranges prescribed by the EPA IGVs during the both bi-annual monitoring events. pH was unable to be collected on-site as a result of a faulty probe during the first bi-annual event. pH readings from the laboratory were deemed sufficient to determine pH levels from the monitoring wells on this occasion.

Total Alkalinity concentrations ranging between 349 and 437 mg/l were observed across the site during the first bi-annual event, while concentrations ranging between 258mg/l and 389mg/l were observed during the second bi-annual event. The IGV guideline for alkalinity is *"no abnormal change"* which refers to no significant changes with respect to background values. No significant variations were recorded for Total Alkalinity during the 2006 to 2009 monitoring periods.

Aluminium, Iron and Lead, recorded increases in concentrations with respect to previous monitoring events in 2008 in at least one borehole during the February 2009 monitoring round and two boreholes (AGW2 and AGW4) during the July 2009 monitoring round, and are discussed in the following paragraphs.

Iron was recorded above the IGV (0.01 mg/l) in borehole AGW2 (1st and 2nd biannual monitoring event of 2009), AGW3 (2nd biannual 2009) and AGW4 (1st and 2nd biannual event 2009) ranging in concentrations between 0.015 and 0.034 mg/l. These concentrations represented slightly increased levels when compared with the 2008 biannual monitoring event for AGW1 and AGW4 and similar levels for AGW3. Concentrations in AGW2, although increased from the 2008 biannual monitoring levels, recorded a decrease from 6.05 to 3.37 during the 2009 biannual monitoring events.

Aluminium was recorded above the IGV (0.2 mg/l) ranging between 0.258 and 3.91 during the 2009 monitoring events in AGW1 (1st biannual) and AGW2 (1st and 2nd biannual). In general, these levels represented a reduction in concentrations from the 2008 monitoring periods.

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.

Potential sources of iron at the WMI site include the use of ferric sulphate in the Wastewater Treatment Plant (WWTP) and in weedkiller on site. The quantities used and stored on site are extremely small and if a spill occurred, attenuation within the soil matrix is likely to be sufficient to prevent vertical ingress to groundwater. A potential source of aluminium at the WMI site is the use of carluite catalyst in the WWTP. Approximately 300kg is stored on site at any one time (45kg has been used this year to date and is stored in a contained area indoors. Given the quantities of iron and aluminium stored and used at the WMI site and the groundwater protection measures in place, these materials are not deemed to pose a risk to groundwater.

The observed fluctuations of iron and aluminium 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.

Lead recorded elevated concentrations in AGW2 and AGW4 during the both biannual events in 2009. In addition, elevated concentrations were detected in AGW3 during the second biannual event. No previous elevations of lead have been detected across the site. There are no potential sources of lead at the WMI site.

Ammonia concentrations reduced in February 2009 from the slightly elevated values recorded in the 2nd biannual event 2008. There were no exceedences of guideline values during the 2009 monitoring events.

Calcium and manganese recorded concentrations slightly in excess of their respective IGVs during both biannual monitoring events in 2009. However these concentrations and the pattern of distribution is broadly similar to that seen in the biannual monitoring in 2008 and other previous monitoring events and do not represent a significant change.

Potassium and *fluoride* also recorded concentrations slightly in excess of their respective IGVs during February 2009. Fluoride concentrations in February 2009 (1.1 mg/l) recorded slightly elevated levels above the guideline values for the first time in AGW1, but remain significantly below the IGV in AGW2,

AGW3 and AGW4. Potassium concentrations were slightly elevated in AGW4 (6.35 mg/l) above the IGV of 5 mg/l in the 1st biannual monitoring event of 2009. No further elevated concentrations were observed in the remainder of the wells. Fluoride and potassium concentrations were below their respective IGVs during the second biannual event, and the fluoride level at AGW1 decreased since the February 2009 monitoring period.

Slightly elevated levels of calcium were detected in AGW4 in excess of the IGV during the second biannual monitoring period of 2009, which is consistent with the first biannual event and monitoring events in 2008. The level of calcium detected in AGW4 although in excess of the IGV, has decreased since the first monitoring event of 2009. No elevated levels were detected in the remaining monitoring wells.

Both calcium and fluoride are naturally occurring compounds and are unlikely to be sourced from the WMI facility. Potassium and manganese can also 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 0.4 and 0.3 in the upgradient borehole AGW4 for the first and second biannual monitoring event. During the second biannual event, this reduced to 0.3 and it continues to indicate inputs from upgradient offsite sources.

Organo-halogens, VOC's and SVOC's were found to be below the relevant limit of detection of laboratory for each compound and all concentrations were found to be below the IGVs, with the exception of 1,2,4-Trichlorobenzene in the first biannual event and chloroform in both the first and second biannual event.

The lowest level of detection of 1,2,4–Trichlorobenzene for the laboratory is 1 µg/l and the corresponding IGV value is 0.4 µg/l. RPS were unable to source a laboratory to undertake testing for 1,2,4-Trichlorobenzene at a detection level equivalent to the IGV. The laboratory method by STL is UKAS accredited to ISO 17025 and given the general absence of VOCs and SVOCs in water samples across the WMI site, RPS are confident that this contaminant is not present in the groundwater.

Chloroform was recorded in monitoring well AGW3 at a concentration of 2µg/l during the first round of 2009 biannual monitoring of IPPC boundary wells. A concentration of 3.7µg/l was detected in the second biannual event for July. Both concentrations are significantly below the EPA IGV for chloroform (12 µg/l) in groundwater.

Historical detections of chloroform were not detected at the IPPC wells during previous IPPC monitoring events although concentrations of 9 µg/l and 5µg/l were recorded in AGW3 during two diesel spill monitoring periods at this location in 2007 and 2008 respectively.

Following an investigation to determine the potential source of chloroform in AGW3, it was identified that a pipeline containing mains supplied water to the canteen, within the WMI plant, is located in close proximity to monitoring well AGW3. A number of significant pipe leaks (due to frosty conditions) occurred over this period of time, which has subsequently been repaired. RPS considers that the likely source of the chloroform detections in AGW3 is resultant from these leakages – the most recent leak occurring in April 2009. No further leakages have been recorded to date. In addition to the detected levels being below the EPA IGV, chloroform levels have significantly decreased to date in this location and it is anticipated that they will continue to reduce further.

5 CONCLUSIONS

- The observed elevated concentrations of iron and manganese 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. The calculated potassium:sodium ratios provide additional supporting evidence to this scenario. No elevated detections of ammonia were observed during 2009.

- Slightly elevated levels of inorganic compounds with respect to the EPA IGVs were encountered within the monitoring wells during this monitoring period. As discussed in detail within the second 2009 biannual IPPC groundwater monitoring report (ref: MDE0643Rp0010, Sept 2009), the slightly elevated levels of calcium, iron, lead, aluminium, chloride and manganese across the site are attributed to a combination of natural variations in groundwater geochemistry and a potential up gradient off-site source of contamination.

- No notable detections of lead were recorded previously. Future monitoring of this parameter in the next round of biannual groundwater monitoring is recommended to confirm the persistency of this detected compound.

- The detections of chloroform in monitoring well AGW3 are attributed to a number of water main leaks in the immediate area of the well since 2007. In addition to the detected levels being below the EPA IGV, chloroform levels have significantly decreased to date at this location and it is anticipated that they will continue to reduce further. RPS does not deem the levels constitute a risk to the underlying aquifer.

- Based on the above information, 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 operations conducted at the site and the groundwater protection measures in place.

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: 19th February 2009

Biannual 2: 16th July 2009

A.1.3 Personnel Present During Sampling

Biannual 1 - Yvonne McGillycuddy, Graduate Scientist, RPS Group, Dublin

Biannual 2 – Caitriona Reilly, Project Scientist, 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 - 2009

SiteRIGHT Environmental
Environmental Monitoring and Consultancy

Ballybrew,
Enniskerry,
Co. Wicklow
Ireland

Air Emission Monitoring Report

Report No:	**WYN A1c 09**
Report revision No:	**2**
Client:	**Wyeth Medica Ireland,** **Newbridge,** **Co.Kildare**
Report Title:	**IPPC Licence Register No. P0153-05 Air Emission Compliance Monitoring 2009**
Report issue date:	**23/03/10**

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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 EPA 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 2009. 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 was conducted by WMI.

This report details the results of air emission monitoring that was completed in 2009. Copies of analytical reports have also been supplied separately.

Operating information:

The timing of the sample collection was coordinated with WMI staff, Mr. Martin Gallagher 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 6 and Table 7 contain field data relating to Total Particulate sampling and API analysis data respectively.

Table 1 Summary Results and Compliance Status (TP, API and Volume Flow)

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
A2-2	14-Apr-09	12:22:00	30	0.615	Compliant	7173	14256	Compliant	*0.00280*	Compliant
A2-3	16-Apr-09	16:02:00	30	0.264	Compliant	6887	10674	Compliant	*0.01530*	Compliant
A2-5	14-Apr-09	13:10:00	30	0.253	Compliant	3036	6013	Compliant	*0.00005*	Compliant
A2-7	16-Apr-09	15:14:00	30	0.867	Compliant	4496	6007	Compliant	*0.00004*	Compliant
A2-8	27-Feb-09	12:40:00	30	0.238	Compliant	11763	14904	Compliant	*0.00006*	Compliant
A2-9	14-Apr-09	15:30:00	30	0.694	Compliant	9273	11744	Compliant	*0.00003*	Compliant
A2-12	14-Apr-09	16:25:00	30	0.250	Compliant	516	2670	Compliant	*0.00003*	Compliant
A2-13	16-Apr-09	14:33:00	30	0.442	Compliant	5444	6007	Compliant	*0.00008*	Compliant
A2-14	16-Apr-09	16:50:00	30	0.110	Compliant	2917	3067	Compliant	*0.00003*	Compliant
A2-21	27-Feb-09	10:10:00	30	0.622	Compliant	589	5860	Compliant	*0.00024*	Compliant
A2-22	27-Feb-09	11:56:00	30	0.117	Compliant	1184	3564	Compliant	*0.00017*	Compliant
A2-29	27-Feb-09	13:30:00	30	0.215	Compliant	2347	9504	Compliant	*0.00005*	Compliant
A2-31	22-Apr-09	16:15:00	30	0.686	Compliant	1482	1850	Compliant	*0.00003*	Compliant
A2-32	22-Apr-09	16:50:00	30	0.118	Compliant	1607	1850	Compliant	*0.00003*	Compliant
A2-33	14-Apr-09	14:00:00	30	0.315	Compliant	640	1728	Compliant	*0.00206*	Compliant
A2-38	14-Jul-09	12:20:00	30	0.445	Compliant	2662	4500	Compliant	*0.00017*	Compliant
A2-39	17-Jul-09	10:30:00	30	0.081	Compliant	894	2670	Compliant	*0.00012*	Compliant
A2-40	26-Feb-09	15:23:00	30	0.520	Compliant	1979	6613	Compliant	*0.00024*	Compliant
A2-42	09-Sep-09	11:04:00	30	0.233	Compliant	8755	15200	Compliant	*0.00002*	Compliant
A2-43	28-Oct-09	12:59:00	30	0.168	Compliant	502	578	Compliant	*0.00005*	Compliant
A2-46	15-Dec-09	14:00:00	30	0.199	Compliant	1984	4500	Compliant	*0.00007*	Compliant

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	04-Mar	04-Mar	14-Jul	04-Mar	04-Mar	05-Jun	05-Jun	05-Jun
Start time	11:10	15:05	15:38	13:05	13:50	12:55	14:25	14:59
Duration (min)	30	30	30	30	30	30	30	30
Oxygen	4.2	4.9	5.7	4.1	6.7	9.8	18.9	15.7
NOx (mg/Nm3 @ 5%O_2, dry)	145	165	112	140	98	470	91	81
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	1269	27	<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)	83.36	81.35	84.1	82.78	82.86	efficiency calc. Not applicable to CHP plant	81.04	81.14

Table 3 Summary results and compliance of quarterly monitoring at A2-16 and A2-41

Air Emision Point (Ref P0153-05)	A2-41	A2-41	A2-41	A2-41
Quarter	Q1	Q2	Q3	Q4
Sample #	wyn9q141	wyn9q2a41	wyn9q3a41	wyn9q4a41
Date	26-Feb	22-Apr	13-Jul	15-Dec
Start time	11:56:00	12:00:00	14:45:00	19:00:00
Duration (min)	30	30	30	30
Duct Volume Flow Nm3/hr	165	165	165	165
TUBE 226-09 Test Cert	WK09-1571	WK09-2926	WK09-4893	WK09-8191
Impinger DI water Test Cert	WK09-1571 liq	WK09-2937	WK09-4894v2	WK09-8192
DCM mg/Nm3	112	27	5	33
DCM g/hr	18.545	4.458	0.851	5.452
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)
Compliance	Compliant	Compliant	Compliant	Compliant
TA Luft class II mg/Nm3	2	2	3	4
TA Luft class II kg/hr	0.0003	0.0003	0.0004	0.0006
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)
Compliance	Compliant	Compliant	Compliant	Compliant
TA Luft class III mg/Nm3	2.2	5.4	3.3	5.3
TA Luft class III kg/hr	0.0004	0.001	0.00	0.00
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)
Compliance	Compliant	Compliant	Compliant	Compliant
TOC (as C) mg/Nm3	19.6	2.2	1.4	5.4
Licence limit TOC (as C)	20 mg/m3	20 mg/m3	20 mg/m3	20 mg/m3
Compliance	Compliant	Compliant	Compliant	Compliant

Note 1: As the sampling port was unsuitable for velocity measurements, the mass flow results for A2-41 were calculated on the assumption that the volume flow was equal the licence limit of 165 Nm3/hr (Note: Schedule B.1 Emissions to Air: Dust Emissions to Air sets a total combined flow rate of 165m3/hr for A2-16 and for A2-41

Note 2: No monitoring took place at A2—16 in 2009 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 #	wyn9q2a6	wyn9q4a6
Date	22-Apr	09-Sep
Start time	13:40:00	14:04:00
Duration (min)	30	30
Duct Volume Flow Nm3/hr	2268	2076
TUBE 226-09 Test Cert	2937	6022
Impinger DI water Test Cert	2937	6021
TA Luft Class II mg/Nm3	2	4
TA Luft Class II kg/hr	0.005	0.01
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	912	833
TA Luft Class III kg/hr	2.069	1.730
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.

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

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
A2-2	6, 4331	14-Apr-09	12:22:00	30	wyn9a2	1	1	0.196	7173	0.65		ok	ok	ok	ok	0.4	2842	0.615
A2-3	4,2 333	16-Apr-09	16:02:00	30	wyn9a33	0	1	0.126		0.379	6887	ok	ok	ok	ok	0.1	2842	0.264
A2-5	6, 4330	14-Apr-09	13:10:00	30	wyn9a5	0	1	0.095		0.513	3036	ok	ok	ok	ok	0.13	2842	0.253
A2-7	5,2 325	16-Apr-09	15:14:00	30	wyn9a7	0	1	0.08		0.588	4496	ok	ok	ok	ok	0.51	2842	0.867
A2-8	4, 2331	27-Feb-09	12:40:00	30	wyn9a8	0	4	0.196		0.42	11763	ok	ok	ok	ok	0.1	1750	0.238
A2-9	5,2 333	14-Apr-09	15:30:00	30	wyn9a9	1	1	0.126	9397	0.778	9273	ok	ok	ok	ok	0.54	2842	0.694
A2-12	8,0 330	14-Apr-09	16:25:00	30	wyn9a12	0	1	0.017		0.759	516	ok	ok	ok	ok	0.19	2842	0.250
A2-13	5,2 332	16-Apr-09	14:33:00	30	wyn9a13	4	1	0.196	5368	0.294	5444	ok	ok	ok	ok	0.13	2842	0.442
A2-14	10, 324	16-Apr-09	16:50:00	30	wyn9a14	0	1	0.126		0.908	2917	ok	ok	ok	ok	0.1	2842	0.110
A2-21	11,5 331	27-Feb-09	10:10:00	30	wyn9a21	4	4	0.049	654	0.627	589	ok	ok	ok	ok	0.39	1750	0.622
A2-22	11, 5333	27-Feb-09	11:56:00	30	wyn9a22	0	1	0.071		0.858	1184	ok	ok	ok	ok	0.1	1750	0.117
A2-29	8,0 332	27-Feb-09	13:30:00	30	wyn9a29	1	4	0.126		0.465	2347	ok	ok	ok	ok	0.1	1750	0.215
A2-31	8,0 331	22-Apr-09	16:15:00	30	wyn9a31	1	1	0.049		0.758	1482	ok	ok	ok	ok	0.520	2927	0.686
A2-32	8,0 334	22-Apr-09	16:50:00	30	wyn9a32	1	1	0.049		0.847	1607	ok	ok	ok	ok	0.100	2927	0.118
A2-33	6,4 334	14-Apr-09	14:00:00	30	wyn9a33	0	1	0.015		0.572	640	ok	ok	ok	ok	0.18	2842	0.315
A2-38	11,5 332	14-Jul-09	12:20:00	30	wyn9A38	0	1	0.166		0.876	2662	ok	ok	ok	ok	0.39	4895	0.445
A2-39	10,0 330	17-Jul-09	10:30:00	30	wyn9a39	1	1	0.051	894	1.228	818	ok	ok	ok	ok	0.1	5055	0.081
A2-40	6.4 332	26-Feb-09	15:23:00	30	wyn9a40	0	1	0.05		0.635	1979	ok	ok	ok	ok	0.33	1750	0.520
A2-42	10.0 331	09-Sep-09	11:04:00	30	wyn9A42	0	4	0.16		1.246	8755	ok	ok	ok	ok	0.29	6103	0.233
A2-43	10.0 328	28-Oct-09	12:59:00	30	wyn9A43r	0	1	0.05		0.597	502	ok	ok	ok	ok	0.1	8189	0.168
A2-46	8,0 325	15-Dec-09	14:00:00	30	wyn9a46r	1	1	0.08	1981	0.502	1984	ok	no	ok	ok	0.1	8189	0.199

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 Bazedoxifene BZA (ug/filter)	API Tigecycline	API Norgestrel (ug/filter)	Total API (ug/filter)	Total API Emission result mg/Nm3
A2-2	04/06/2009	*0.2*	1.22	*0.4*								1.820	*0.00280*
A2-3	04/06/2009	*0.2*	5.2	*0.4*								5.800	*0.01530*
A2-5	04/06/2009				*0.024*							*0.024*	*0.00005*
A2-7	04/06/2009				*0.024*							*0.024*	*0.00004*
A2-8	08/05/2009				*0.024*							*0.024*	*0.00006*
A2-9	07/07/2009						*0.004*	*0.010*			*0.012*	*0.026*	*0.00003*
A2-12	07/07/2009						*0.004*	*0.010*			*0.012*	*0.026*	*0.00003*
A2-13	04/06/2009				*0.024*							*0.024*	*0.00008*
A2-14	04/06/2009				*0.024*							*0.024*	*0.00003*
A2-21	30/04/2009					*0.15*						*0.150*	*0.00024*
A2-22	30/04/2009					*0.15*						*0.150*	*0.00017*
A2-29	08/05/2009				*0.024*							*0.024*	*0.00005*
A2-31	04/06/2009				*0.024*							*0.024*	*0.00003*
A2-32	04/06/2009				*0.024*							*0.024*	*0.00003*
A2-33	04/06/2009	*0.2*	0.58	*0.4*								1.180	*0.00206*
A2-38	24/09/2009					*0.15*						*0.150*	*0.00017*
A2-39	24/09/2009					*0.15*						*0.150*	*0.00012*
A2-40	30/04/2009					*0.15*						*0.150*	*0.00024*
A2-42	17/12/2009a						*0.004*	*0.010*			*0.012*	*0.026*	*0.00002*
A2-43	MG 20/01/10				*0.0328*							*0.033*	*0.00005*
A2-46	MG 20/01/10				*0.0328*							*0.033*	*0.00007*

Appendix 3

Noise Monitoring Report - 2009

anv | technology

ENVIRONMENTAL NOISE SURVEY

WYETH MEDICA IRELAND

March 2009

REPORT 29133

♦ANV Technology, Clonroad, Ennis, Co. Clare ♦
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ANV Technology **Report 29133**

Environmental Noise Survey - Wyeth Medica Ireland
March 2009

SUMMARY

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

Schedule B.4 Noise Emissions of 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. 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, and N4, the daytime specific WMI plant noise level was <46, <42, <44 dB(A) and <51 dB(A) respectively and in compliance with the daytime noise limit of 55 dB(A).

Nighttime
At houses N1, N2, N3, N4, and N5, the nighttime specific WMI plant noise level was 40, <39, 37, 42 and 34 dB(A) respectively, and in compliance with the nightime noise limit of 45 dB(A).

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

Boundaries
Noise limits do not apply at the plant boundaries. Measurements are made at the plant boundaries for the purpose determining trends in overall noise emissions from the site. Specific noise levels at boundary positions B2 to B4 were similar to levels measured in 2008. There was an increase of 5 dB at boundary B1. However this is still within the historical range detected at this position. There was a decrease in the industrial noise component at B5. This was due to lower noise emission from the neighbouring commercial site.

Report Originator: Colin Doyle M.Sc. MIOA
Reviewer: Bridget Ginnity Dip. Acoustics M.Sc. MIOA MFOH MICI

Report issued: 16/04/2009

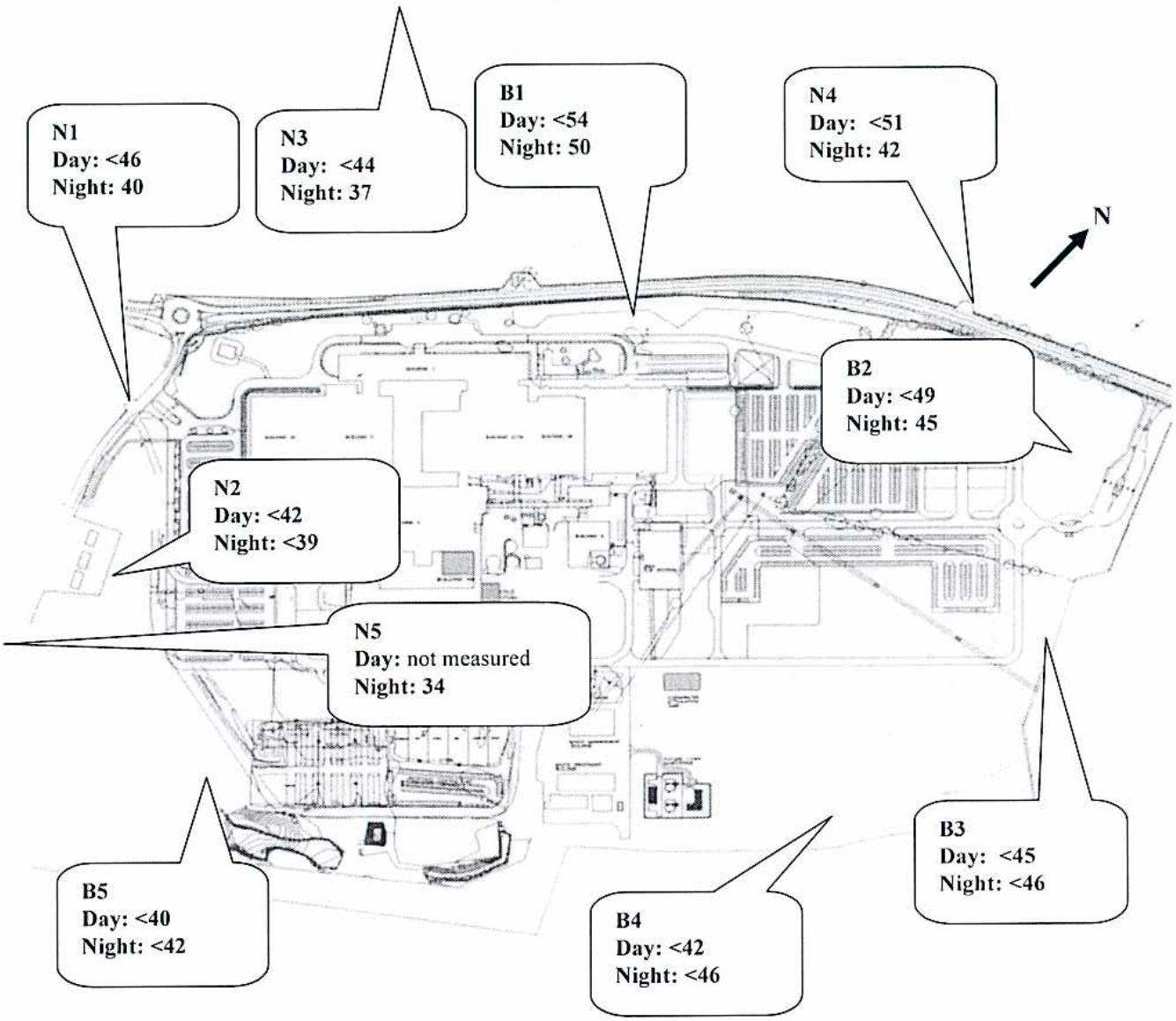


Figure 1. Summary of measured specific noise levels in dB(A), March 2009 . N5: Connell Drive is off the map, at a distance of 30m from the site boundary

Environmental Noise Survey - Wyeth Medica Ireland March 2009

CONTENTS

TABLES & FIGURES

Environmental Noise Survey, March 2009
Wyeth Medica Ireland

1 INTRODUCTION

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

Schedule B.4 Noise Emissions of Licence Register No. P0153-05 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. Measurements were also made at the plant boundaries for the purpose determining trends in overall noise emissions from the site. There are no noise limits applicable at the boundaries. The daytime survey was carried out on the 31/03/09. The night-time survey was carried out on the night of 31/03/09 – 01/04/09.

2 MEASUREMENT DETAILS

2.1 METHODOLOGY

The survey methodology followed the Environmental Protection Agency (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 monitoring. A summary of noise terminology is given in Appendix A.

Noise measurements and reporting were both 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

The annual noise surveys at Wyeth Medica include four house locations and five boundary measurement locations. In the present survey, an additional house location was measured at nighttime at Connell Drive located to the southwest of the site. The measurement locations are indicated in Figure B.1, and described in Table 1.

Location	Description
Houses	
N1	House opposite main entrance
N2	Adjoining house, near main entrance, measured inside WMI site at rear boundary wall
N3	Old Connell House, measured at entrance gate; noise propagation to house calculated
N4	Houses at Old Connell Stud, at entrance gate
N5	Connell Drive, at entrance to estate
Boundaries	
B1	North west, opposite Old Connell House entrance
B2	Northern boundary, on embankment adjacent rear site entrance
B3	North east, at embankment in line with farmhouse
B4	Eastern boundary
B5	Southern boundary, rear of plant, at edge of contractors compound

Table 1. Noise measurement locations

2.3 MEASUREMENT AND ASSESSMENT PARAMETERS

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

The limits in the 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} (specific) + L_{Aeq} (residual)

During the survey the specific noise levels due to noise emissions from Wyeth were determined, 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. Generally, the specific noise level was best represented by the L_{A90} parameter.

Description of Noise	**Parameter best representing specific noise from plant**
Plant noise dominant, no other significant noise sources	L_{Aeq}
Interfering noise (e.g. birds, traffic, wind), with underlying plant noise audible	L_{A90}, if plant noise is steady, with significant interference from other noise, but clearly audible in lulls L_{A50} if plant noise is slowly varying and clearly audible, with occasional interference from other noise sources
Plant barely audible in interfering noise (i.e. not immediately noticeable, unless actively listening)	< L_{A90} (up to 5 dB lower)
Plant not audible in interfering noise	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 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	31/03/09			
	Nighttime	31/03/09 – 01/04/09			
Weather conditions	Daytime	10:50 - 16.30 Dry, light south-westerly breeze (Beaufort 1- 2), Temperature 20 C, humidity 37%			
	Nighttime	22:30 – 02:20 Dry, light southerly breeze (Beaufort 1 -2), Temperature 8 C, humidity 90%			
Measurement period	30 minutes at each location				
Plant Operating Conditions	Wyeth Medica 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	0806337	9/6/2008
Svantek	SLM 949 (Type 1) serial no. 8183		AV Calibration	No. 0808491	15/8/2008
Svantek	SLM 955 (Type 1) serial no. 11127		AV Calibration	0806336	9/6/2008
Brüel & Kjær	Calibrator 4231 serial no. 1859044		AV Calibration	03905	20/5/2008

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	<46	40
N2	Adjoining house, near main entrance	<42	<39
N3	Old Connell House	<44	37
N4	Houses at Old Connell Stud	<51	42
N5	Connell Drive, at entrance to estate	Not measured	34
Boundaries			
B1	North west, opposite Old Connell House entrance	<54	50
B2	Northern boundary, on embankment adjacent rear site entrance	<49	45
B3	North east, at embankment in line with farmhouse	<45	<46
B4	Eastern boundary	<42	<46
B5	Southern boundary, rear of plant. Taken at edge of contractors compound	<40	<42

Table 4. Specific Noise Levels, Wyeth Medica Ireland, March 31st /April 1st 2009

[1] The Specific Noise Level is the noise level attributable to WMI

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	31/3/09	11:55	59	46	53	61	**<46**	Traffic, grass-cutting, WMI not audible
N2	31/3/09	10:50	49	42	46	53	**<42**	Distant traffic, grass-cutting, birds, WMI not audible
N3	31/3/09	15:05	70	55	68	75	**<44** [2]	Continuous traffic noise, WMI barely audible
N4	31/3/09	13:45	67	51	62	68	**<51**	Continuous traffic noise, WMI barely audible
Boundaries								
B1	31/3/09	12:10	62	54	61	65	**<54**	Continuous traffic noise, WMI barely audible
B2	31/3/09	13:00	53	49	52	55	**<49**	Traffic, birds, low level WMI noise
B3	31/3/09	13:05	50	45	47	51	**<45**	Occasional WMI car, birds, distant traffic, WMI barely audible
B4	31/3/09	13:45	46	42	45	47	**<42**	Low level WMI noise + neighbouring commercial site + birds
B5	31/3/09	11:00	44	40	42	46	**<40**	Distant traffic, WMI barely audible
NIGHT-TIME								
Houses								
N1	01/04/09	01:10	50	40	42	50	**40**	Occasional traffic, low level WMI noise
N2	31/03/09	22:40	45	39	42	48	**<39**	Distant traffic noise, WMI barely audible
N3	01/04/09	00:20	63	48	49	63	**37** [2]	Occasional traffic, low level WMI noise
N4	01/04/09	01:00	55	42	45	57	**42**	Occasional traffic, low level WMI noise
N5	01/04/09	01:50	52	34	37	42	**34**	Occasional fast car, distant traffic, WMI barely audible
Boundaries								
B1	31/03/09	23:30	58	50	53	63	**50**	Traffic, steady WMI noise
B2	01/04/09	00:25	48	45	47	50	**45**	Occasional traffic, low level WMI noise
B3	31/03/09	23:50	48	46	47	50	**<46**	Neighbouring commercial site + WMI noise, distant traffic
B4	31/03/09	23:40	48	46	47	49	**<46**	WMI + neighbouring commercial site noise (occasional horns)
B5	31/03/09	22:50	44	42	44	46	**<42**	Distant traffic, low level noise from neighbouring commercial site (occasional horns), WMI barely audible

Table 5. Measured noise levels, Wyeth Medica Ireland, 2009

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

[2] Calculated noise level at N3 (Old Connell House) in accordance with ISO 9613. The steady WMI noise level at the entrance gate was <55 dB(A) during daytime, and 48 dB(A) at nighttime. This extrapolates to <44 dB(A) at the house during daytime, and 37 dB(A) at nighttime.

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.

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 pure tonal peaks.

4 COMPLIANCE WITH IPPC LICENCE NOISE LIMITS

Schedule B.4 Noise Emissions of 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. Noise limits do not apply at the site boundaries.

Daytime
At houses N1, N2, N3, and N4, the daytime specific WMI plant noise level was <46, <42, <44 dB(A) and <51 dB(A) respectively and in compliance with the daytime noise limit of 55 dB(A).

Nighttime
At houses N1, N2, N3, N4, and N5, the nighttime specific WMI plant noise level was 40, <39, 37, 42 and 34 dB(A) respectively and in compliance with the nightime 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 2009 are presented in Table 6, and in Figure 2. The historical comparison is confined to nighttime 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 2009 were on average lower than in 2008, and were consistent with the historical data measured since 2000. House location N3 showed a slight increase of 2 dB, which is within the measurement repeatability range.

Specific noise levels at boundary positions B2 to B4 were similar to levels measured in 2008. There was an increase of 5 dB at boundary B1. However this is still within the historical range detected at this position. There was a decrease in the industrial noise component at B5. This was due to lower noise emission from the neighbouring commercial site.

Location	WMI Specific Noise Level at Nighttime dB(A)									
	Nov 2000	March 2001	Jul 2002	Nov 2003	Apr 2004	Feb 2005	Aug 2006	March-2007	March 2008	March 2009
Houses										
N1	44	44	41	40	44	40	40	38	<46	**40**
N2	42	42	40	<38	41	37	<41	44	<47	**<39**
N3	43	40	34	35	37	36	35	37	35	**37**
N4	-	-	-	-	-	-	45	45	45	**42**
Boundaries										
B1	-	-	-	46	50	50	45	47	45	**50**
B2	55	51	44	52	50	50	45	46	45	**45**
B3	-	-	-	51	50	50	<46	46	44	**<46**
B4	53	52	50	49	46	46	47	45	<44	**<46**
B5	< 49	< 43	41	<47	<44	<44	48	44	ND <<50	**<42**

Table 6. Comparison of night-time specific noise levels, 2000 to 2009

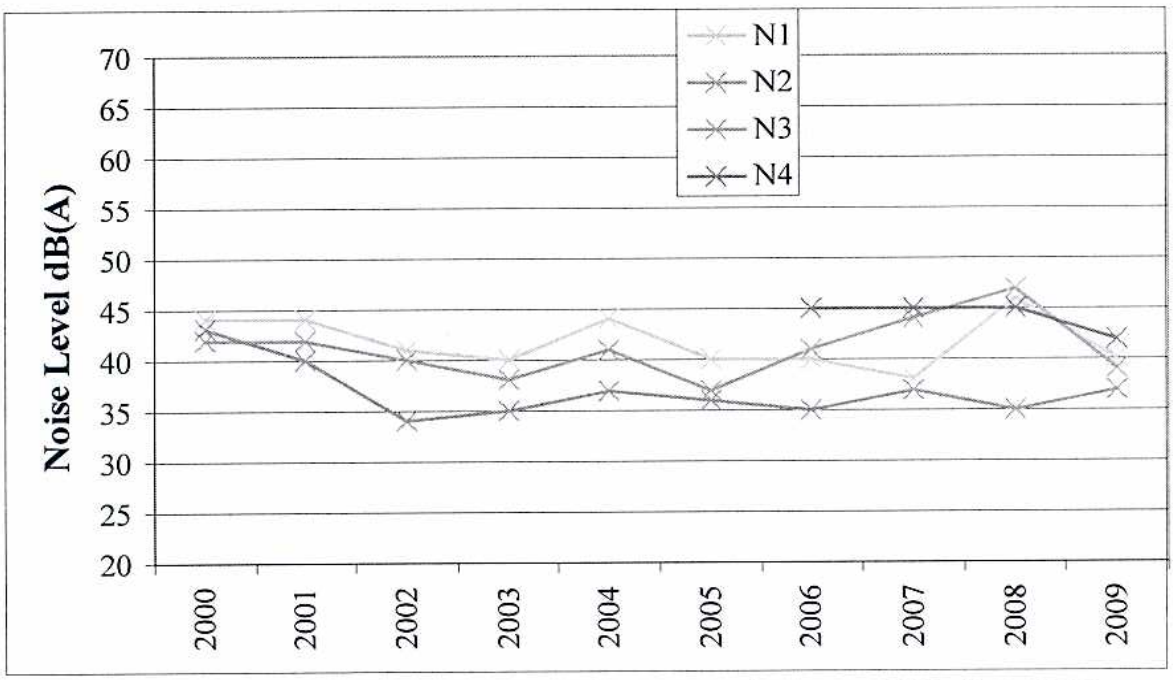


Figure 2. Variation of specific noise levels at nearest houses to WMI, from 2000 to 2009

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.

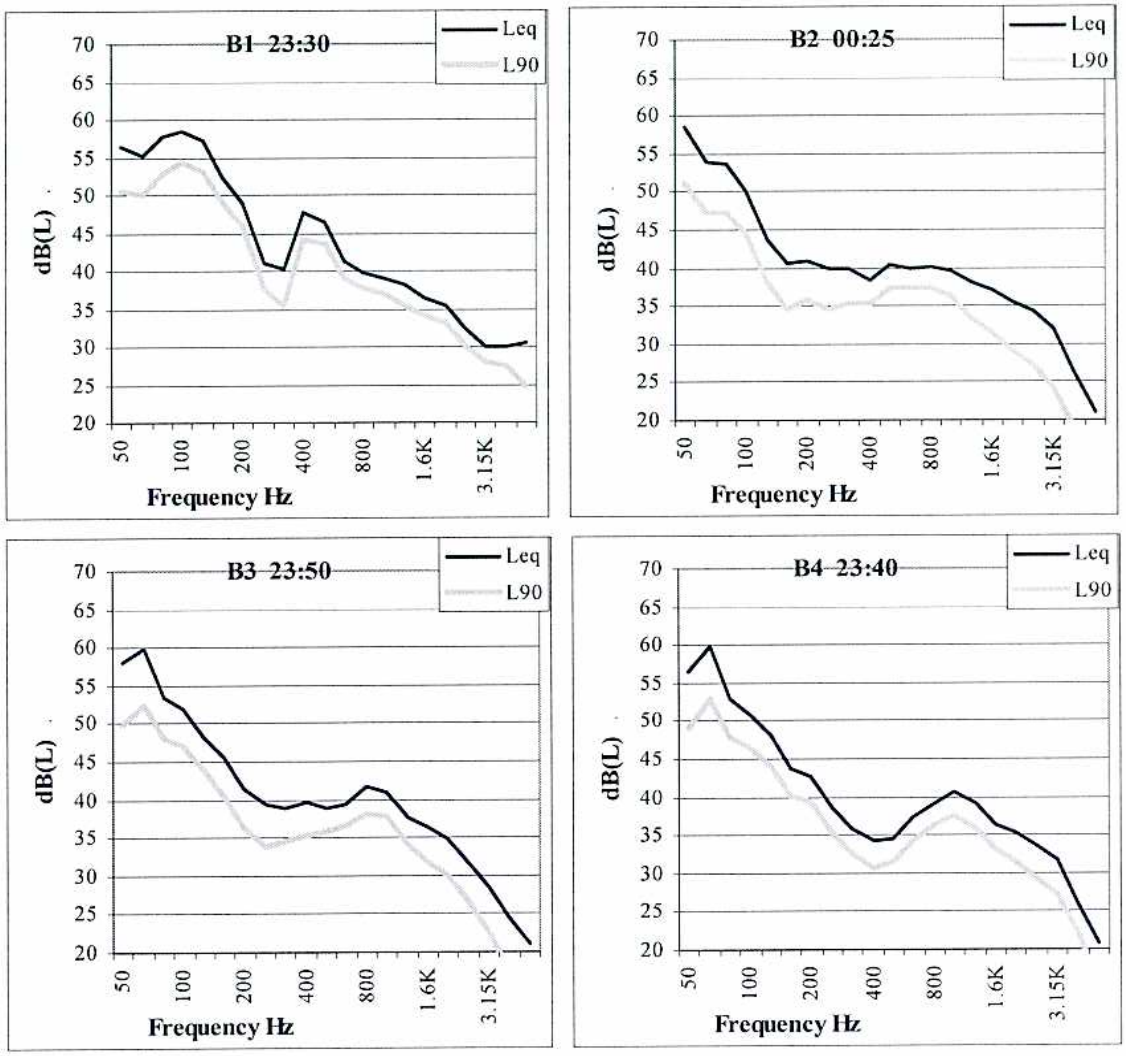
Residual Noise the noise level that would exist in the absence of the specific noise source

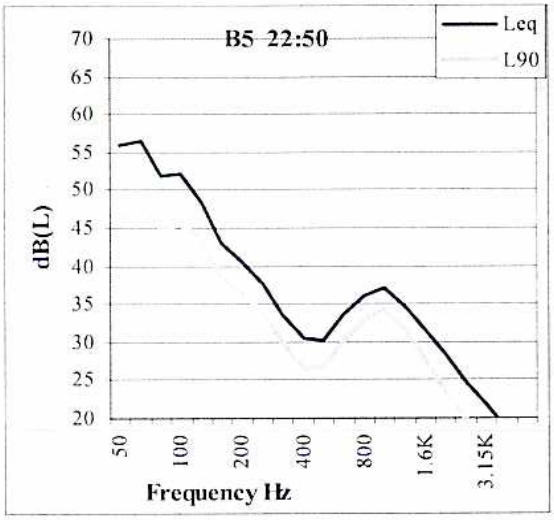
Noise Profile noise level logged at short intervals (10 second intervals in this survey).

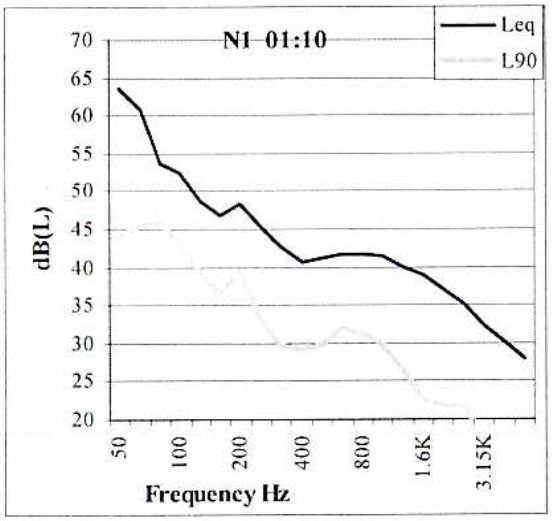
APPENDIX B - ADDITIONAL DATA

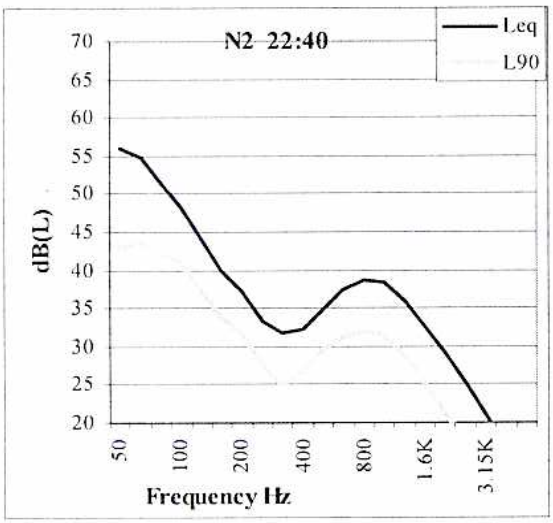
B.1 NIGHT-TIME NOISE SPECTRA

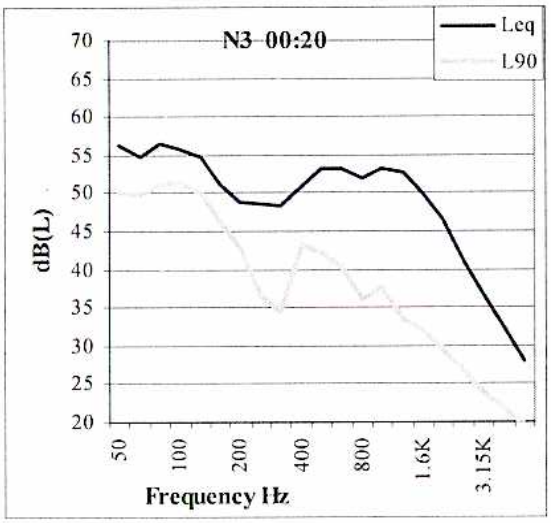
L_{eq} spectra are subject to interference from traffic noise. Steady tonal components are best detected by the L_{90} spectra

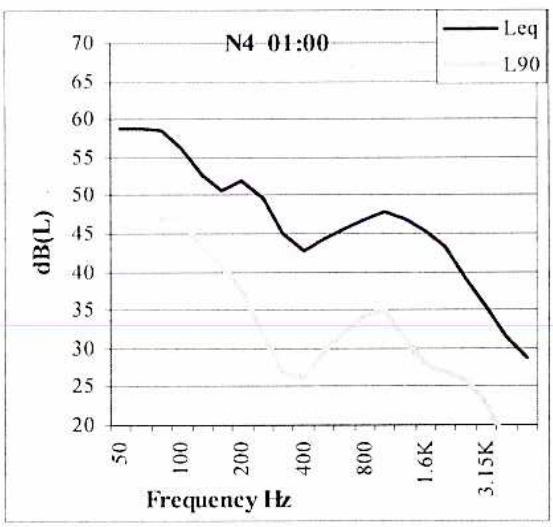


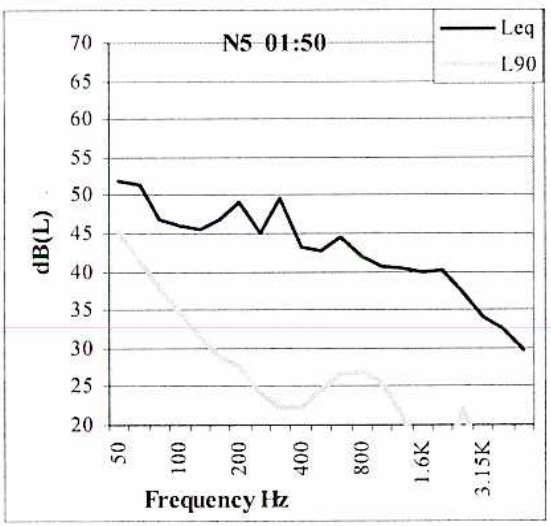

B5 22:50
Leq
L90
dB(L)
70
65
60
55
50
45
40
35
30
25
20
50
100
200
400
800
1.6K
3.15K
Frequency Hz


N1 01:10
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


N2 22:40
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


N3 00:20
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


N4 01:00
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


N5 01:50
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

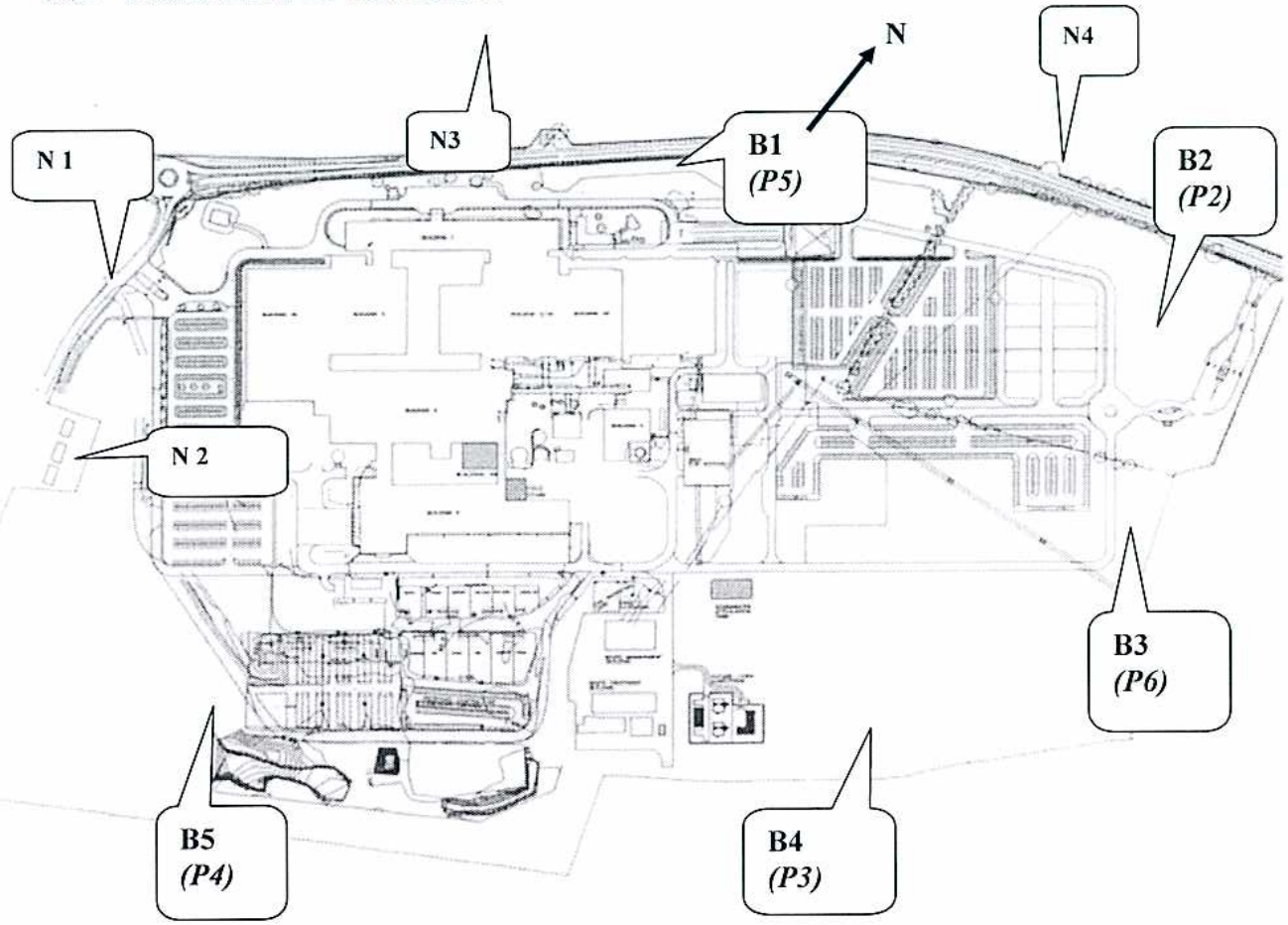


Figure B.1 Noise measurement locations. Houses: N1 to N4. Boundaries: B1 to B5 (labelled P2 to P6 in reports up to 2006)

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 - 2009

A4.1 Analysis Overview and Strategy

The WMI approach to comply with the requirement of *Schedule C.4 Waste Monitoring* of Licence Register P0153-05 was verbally agreed with the EPA during the Site Inspection of 15/04/2004 and subsequently confirmed in EPA 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 was done for AERs 2006-2008, as outlined herein to reflect the updated practices adopted in 2009 (text outlined in ***bold italics*** throughout the strategy has been modified from the 2008 waste analysis strategy previously submitted to the EPA in the 2008 AER). Hazardous waste streams for analysis are summarised in Table A4.1.

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
Recovered Solvent Product from SRS Waste Recycling	***Annual***	▪ ***API Content*** Note 3	▪ ***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 [as previously agreed with the EPA on the 31/01/07 (EPA reference: P0153-05/ap02bc.doc)]. The thresholds which allows he waste stream to sent for recovery is pharmaceutical active content present at levels less than 5 mg/l as agreed with the EPA on the 20/07/2009 (EPA reference: P0153-05.ap16djm.doc). This threshold was not exceeded in 2009 (refer to Table A5.5).

Note 3: Recovered solvent from SRS waste recycling is tested for API annually as agreed with the EPA on the 20/07/2009 (EPA reference: P0153-05.ap16djm.doc)

The sampling methodologies adopted to complete the analysis as per Table A4.1 are described herein.

Various analytical laboratories were employed in 2009 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.

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 as 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 arisings) and 'Full Characterisation' parameter (as Materials Records indicate the active material type for all of the Pharmaceutical Solid Waste arisings) 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. ***In 2009 all rinsewaters except first rinse wastewater generated in the Efexor process, were treated in the on-site Wastewater Pre-Treatment Plant.***
- Sugar Coating Solution (Hazardous) - sugar and water solution containing actives.
- Sugar Coating Solution (Non-Hazardous) - sugar and water solution Environmentally hazardous for transport

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

- Given the consistency in the nature of the waste generated in the processing areas, single once-off sampling during the defined period (every 6 months) is considered appropriate i.e. the production process is consistent and relates 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 at EPA 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).

Table A4.2: Pharmaceutical Liquid Waste Analysis

Waste Type	Analysis	Classification	Laboratory
Rinsewater			
Rinsewater containing Venlafaxine pharmaceutical active (Efexor PPU)	Venlafaxine Pharmaceutical Active	Hazardous	WMI
Sugar Coating Solution			
Sugar Coating Solution containing HT pharmaceutical active (HT PPU)	HT Pharmaceutical Actives (MPA, Estradiol, Trimegestone)	Hazardous	WMI
	Water Content, Sucrose, Povidone, Titanium	Hazardous	RSSL
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)	Hazardous	WMI
	Water Content, Sucrose, Glucose	Hazardous	RSSL
Sugar Coating Solution Environmentally hazardous for transport (MHT PPU)	Water Content, Sucrose, Glucose	Non-Hazardous	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
  - ***Recovered Solvent from SRS Waste Recovery***
  - 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.

On an annual basis recovered solvent product from the off-site SRS Waste stream is obtained from the licenced waste recovery facility and sent to the 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***
Recovered Solvent Product from SRS Waste Recovery	***API content***	***WMI***

A4.2.3 Wastewater Pre-Treatment Plant Sludge

Given the consistency in the nature of the sludges generated at the WWTP a single once-off sampling event during the defined annual period is considered appropriate. A grab sampling methodology is employed to sample the sludge from the containers. The sludge is sampled after the initial primary coarse screening and after processing through the wastewater pre-treatment plant, where the sludge has gone through sludge thickening, conditioning and dewatering. The APIs, analysed for in the WMI Laboratory, are reflective of the compounds used in the production processes at WMI.

Table A4.4 Sludge Analysis

Waste Type	Analysis	Laboratory
Wastewater Pre-Treatment Plant Sludge		
Primary Screenings	Full Characterisation – API content	WMI
Secondary Sludge	Full Characterisation – API content	WMI

A4.2.4 CERES Composting Unit

The CERES composting was decommissioned in 2009 and therefore no compost was produced by the unit, therefore no samples were taken for testing.

Appendix 5

Waste Analysis - 2009

Table A5.1 Pharmaceutical Solid Waste Analysis (Obsolete Pharmaceuticals)

Pick Up Date	C1/TFS Reference	Load Plan [Note 1]	Quantity	Full Characterisation
13/01/09	311664/13	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
16/01/09	311664/14	Yes	4 FIBCS 26 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
27/01/09	B453866	Yes	50 Fibre Kegs 36 Compactor Boxes	Solid Hazardous waste containing: Tranquilliser (CNS) Pharmaceutical Actives -Controlled Drugs
29/01/09	311664/15	Yes	7 FIBCS 32 Compactor Boxes, 42 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
09/02/09	311664/16	Yes	11 FIBCS 31 Compactor Boxes, 24 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
19/02/09	311664/18	Yes	43 FIBCS 2 Compactor Boxes, 48 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
26/02/09	311664/19	Yes	32 FIBCS 12 Compactor Boxes, 24 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
09/03/09	311664/20	Yes	9 FIBCS 30 Compactor Boxes, 33 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
24/03/09	311664/22	Yes	14 FIBCS 29 Compactor Boxes, 28 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
01/04/09	311664/24	Yes	46 FIBCS 1 Compactor Boxes, 3 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
16/04/09	B535454	Yes	39 FIBCS, 35 Fibre Kegs, 5 200L OT plastic, 1 Compactor Boxes	Solid Hazardous waste containing: Tranquilliser (CNS) Pharmaceutical Actives -Controlled Drugs
23/04/09	311664/25	Yes	11 FIBCS 31 Compactor Boxes, 38 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
19/05/09	311664/26	Yes	10 FIBCS 33 Compactor Boxes, 20 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
29/05/09	311875/2	Yes	10 FIBCS 31 Compactor Boxes, 25 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
11/06/09	311664/27	Yes	14 FIBCS 22 Compactor Boxes, 46 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Lederle/Efexor Pharmaceutical Actives
03/07/09	311664/28	Yes	11 FIBCS 28 Compactor Boxes, 67 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Lederle/Efexor Pharmaceutical Actives
23/07/09	312146/8	Yes	12 FIBCS 20 Compactor Boxes, 192 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Lederle/Efexor Pharmaceutical Actives
06/08/09	312146/11	Yes	10 FIBCS 16 Compactor Boxes, 116 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Lederle/Efexor Pharmaceutical Actives
21/08/09	312146/12	Yes	11 FIBCS 22 Compactor Boxes, 87 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Lederle/Efexor Pharmaceutical Actives
14/09/09	312146/15	Yes	18 FIBCS 17 Compactor Boxes, 67 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
30/09/09	312146/16	Yes	14 FIBCS, 30 Compactor Boxes, 21 Fibre Kegs, 1IBC	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives

Pick Up Date	C1 / TFS Reference	Load Plan Note 1	Quantity	Full Characterisation
05/10/09	3122171/1	Yes	47 Fibre Kegs 37 Compactor Boxes	Solid Hazardous waste containing: Tranquilliser (CNS) Pharmaceutical Actives -Controlled Drugs
05/10/09	3122171/2	Yes	50 Fibre Kegs 38 Compactor Boxes	Solid Hazardous waste containing: Tranquilliser (CNS) Pharmaceutical Actives -Controlled Drugs
06/10/09	3122171/3	Yes	29 Fibre Kegs 43 Compactor Boxes	Solid Hazardous waste containing: Tranquilliser (CNS) Pharmaceutical Actives -Controlled Drugs
22/10/09	312146/19	Yes	10 FIBCS 25 Compactor Boxes, 45 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
12/11/09	312146/21	Yes	26 FIBCS 17 Compactor Boxes, 17 Fibre Kegs 12 200L steel combi	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
26/11/09	312146/23	Yes	16 FIBCS 23 Compactor Boxes, 47 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives
16/12/09	312146/26	Yes	17 FIBCS 16 Compactor Boxes, 186 Fibre Kegs	Solid hazardous waste containing: Oral contraceptives Pharmaceutical Actives; Hormone Replacement Therapy Pharmaceutical Actives, Tranquiliser (CNS) Pharmaceutical Actives; Efexor Pharmaceutical Actives

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 A5.2: Pharmaceutical Liquid - Rinsewater Waste Analysis [Note 1]

Active	Units	Efexor Rinsewater	
		Biannual 1 23/06/08	Biannual 2 24/11/09
Venlafaxine HCL	mg/l	1318.3	3178.5

Note 1: In 2009 all rinsewaters except first rinse wastewater generated in the Efexor process, were treated in the on-site Wastewater Pre-Treatment Plant. As a consequence only Efexor rinsewaters were sent off site for disposal.

Table A5.3: Pharmaceutical Liquid - Sugar Coating Solutions Waste Analysis [Note 1]

Analyte	Sugar Coating Solution Environmentally hazardous for transport (MHT PPU)		Sugar Coating Solution containing MHT pharmaceutical active (MHT PPU)		Sugar Coating Solution Environmentally hazardous for transport (HT PPU)		Sugar Coating Solution containing HT pharmaceutical active (HT PPU)		Sugar Coating Solution Environmentally hazardous for transport (OC PPU)	
	Biannual 1 28/04/09	Biannual 2 22/07/09	Biannual 1 28/04/09	Biannual 2 22/07/09	Biannual 1 28/04/09	Biannual 2 22/07/09	Biannual 1 28/04/09	Biannual 2 22/07/09	Biannual 1 28/04/09	Biannual 2 22/07/09
Pharmaceutical Active - MPA			<LOD	<LOD			731.40	<LOD		
Pharmaceutical Active - Trimegestone							<LOD	<0.14		
Pharmaceutical Active - Bazedoxifene			1909.00	<LOD						
Pharmaceutical Active - Conjugated Estrogens			<LOD	<LOD			<LOD	<LOD		
Water Content	86.5 % (w/w)	88.9 % (w/w)	94.5 % (w/w)	88.0 % (w/w)	78.4 % (w/w)	53.8 % (w/w)	65.6 % (w/w)	78.6 % (w/w)	67.4 % (w/w)	33.6 % (w/w)
Sucrose	<0.4 g/kg	12.5 g/kg	2.5 g/kg	9.8 g/kg	225 g/kg	<0.2 g/kg	283 g/kg	<0.2 g/kg	205 g/kg	<0.2 g/kg
Glucose	25.4 g/kg	15.1 g/kg	11.0 g/kg	11.2 g/kg	0.5 g/kg	0.3 g/kg	18.9 g/kg	0.4 g/kg	13.9 g/kg	<0.2 g/kg
Titanium Dioxide	72 ppm	0.12 ppm	70 ppm	0.08 ppm	79 ppm	5.1 ppm	71 ppm	6.8 ppm	164 ppm	0.26 ppm
Fructose	28.2 g/kg	29.2 g/kg	11.3 g/kg	31.3 g/kg	0.7 g/kg	440.8 g/kg	18.1 g/kg	173.3 g/kg	1.2 g/kg	589.9 g/kg
Maltose	<0.4 g/kg	<0.005g/kg	<0.1 g/kg	<0.005g/kg	<0.4 g/kg	<0.005g/kg	0.9 g/kg	<0.005g/kg	<0.6 g/kg	<0.005g/kg
Lactose	<0.4 g/kg	<0.002 g/kg	<0.1 g/kg	<0.002 g/kg	<0.4 g/kg	<0.002 g/kg	<0.8 g/kg	<0.002 g/kg	<0.6 g/kg	<0.002 g/kg
Galactose	<0.4 g/kg	<0.02 g/kg	<0.1 g/kg	<0.02 g/kg	<0.4 g/kg	<0.02 g/kg	<0.8 g/kg	<0.02 g/kg	<0.6 g/kg	<0.02 g/kg
Providone	0.03 %	0.02 %	0.08 %	0.01 %	0.01 %	0.02 %	0.19 %	0.01 %	0.12 %	0.29 %
Talc	0.03 %	<0.01%	<0.01%	<0.01%	<0.01%	<0.01%	<0.01%	<0.01%	<0.01%	<0.01%
Calcium Carbonate	9.9 ppm	90 ppm	9.6 ppm	24 ppm	22 ppm	115 ppm	26 ppm	110 ppm	149 ppm	145 ppm
Vitamin C	< 1 mg/100g	< 1 mg/100g	7.2 mg/100g	< 1 mg/100g	< 1 mg/100g	< 1 mg/100g	<1 mg/100g	<1 mg/100g	<1 mg/100g	<1 mg/100g

LOD: Limit of Detection.

Note 1: Refer to previous AERs for limits of detection for Pharmaceutical Actives.

Chlorinated & Non-Chlorinated Solvent Waste

Table A5.4: Chlorinated Solvent Waste Analysis (Process Waste - SRS) Note 1

Sample Date	DCM (%)	Methanol (%)	Water (%)	Pharmaceutical Active Venlafaxine content (mg/l) Note 2	Residue content Note3 (%)
13/01/2009	66.46	32.85	0.69	0.23	0.66
26/01/2009	65.24	33.85	0.91	0.18	0.33
09/02/2009	66.76	32.14	1.10	0.07	0.36
23/02/2009	56.28	42.81	0.91	0.08	0.60
09/03/2009	61.32	37.84	0.84	0.12	0.84
27/03/2009	59.20	39.85	0.95	0.10	0.20
14/04/2009	37.66	61.47	0.87	0.09	0.72
01/05/2009	65.55	33.22	1.23	0.15	0.69
02/06/2009	61.30	37.85	0.85	0.10	0.51
02/07/2009	61.26	37.78	0.96	0.14	0.20
30/07/2009	73.57	25.49	0.94	0.20	0.58
25/08/2009	76.70	22.3	1.00	0.23	0.53
24/09/2009	60.74	38.27	0.99	0.09	0.44
23/10/2009	75.23	23.81	0.96	0.15	0.92
17/11/2009	74.55	24.72	0.73	0.21	1.25
14/12/2009	78.31	20.63	1.06	0.13	0.62

Note 1: The results given are a percentage of the total organic solvents in the sample
Note 2: As per EPA approval of 20/07/2009 (reference P0153-05.ap16djm.doc), solvent waste with pharmaceutical active levels < 5mg/l was diverted from incineration to recovery
Note 3: Residue content consists of microcrystalline cellulose and glycol.

Table A5-5: Recovered Solvent from SRS Waste Recovery

	Sample Date	Pharmaceutical Active – Venlafaxine content (mg/l) Note 1
Recovered Solvent	**22/10/2009**	**<0.09**
Methanol Back Cut	**22/10/2009**	**<0.09**

Note 1: As per EPA approval of 20/07/2009 (reference P0153-05.ap16djm.doc), recovered solvent from the SRS waste is tested for venlafaxine content on an annual basis.

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

Sample Date	Analysis/Component		
	DCM (%)	Methanol (%)	Water (%)
02/02/2009	3.77	0.65	95.58
20/04/2009	9.70	1.63	88.67
24/06/2009	6.22	2.86	90.92
04/09/2009	15.91	2.91	81.17
13/11/2009	9.65	1.67	88.68

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 (% Total)
20/03/2009	Water Scan	Water Content	30.44
	Solvent Scan (VOCs)	Acetic Acid	0.57
		Isopropanol	0.27
		Methanol	30.70
		Ethanol	14.90
		Acetone	0.81
		Dichloromethane	2.06
		Chloroform	1.86
		Acetonitrile	16.93
		1,2-Dichloroethane	1.45

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 (% Total)
20/03/2009	Water Scan	Water Content	28.52
	Solvent Scan (VOCs)	Tetrahydrofuran	0.63
		Methanol	24.70
		Acetic Acid	0.23
		Ethanol	1.51
		Acetone	0.88
		Acetonitrile	40.54
		Isopropanol	1.27
		1-Propanol	0.19
		1, 4-Dioxane	1.54

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	
	Primary Screenings (mg/kg) [Note 2]	Secondary Sludge (mg/kg) [Note 3]
Oxazepam	<0.7	<0.4
Lorazepam	<0.7	<0.4
Lormetazepam	<1.4	<0.7
Conjugated Estrogens	3.67	0.99
Medroxyprogesterone Acetate	<0.26	<0.22
Trimegestone	0.194	0.017
Bazedoxifene Acetate	7.74	6.11
Venlafaxine HCL	0.26	1.127
Lansoprazole	<0.66	<0.54
Ethinylestradiol	<0.015	<0.009
Gestodene	0.244	0.044
Norgestrel/Levonorgestrel	0.060	1.185

Note 1: Sampled on 25/08/2009.
Note 2: Screenings after the initial primary coarse screening.
Note 3: Sludge after processing through the wastewater pre-treatment plant, where the sludge has gone through sludge thickening, conditioning and dewatering.

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 the prevention of injury and ill health in the work place and 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
Director EHS/Site Services
Wyeth Newbridge

Date	Version	Summary of Changes
01/03/07	**B**	Revised Policy
24/08/09	**C**	Revised in line with OHSAS 18001 :2007

Appendix 7

Environmental Management Programme - 2010

Environmental Management Programme 2010

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 2010***

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OBJECTIVE 1: ENVIRONMENTAL COMPLIANCE

Assure regulatory compliance.

Target

- Achieve compliance with the requirements of current site IPPC Licence, and where possible improve compliance on previous years. Ensure the site, at all times, can demonstrate compliance for regulator.
- Measure site environmental performance in accordance with Corporate EHS environmental indicators & associated targets.

Why

To comply with all conditions of the current site IPPC Licence (Licence Register No. P0153-05), in particular Emission Limit Values, and *Conditions 2.2.2.2, 3.9, 5.1, 6.1, 6.11.3*, and to implement year on year continuous improvement where possible. It is expected that this will assist in preventing major environmental incidents and reduce significant environmental risks.

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)												
Data									***Project Manager: R Cully***			
Process 2010 data for Wyeth cEHS EPIs (waste, CO_2, water)												
Submit report to EPA for review (AER)												
Monitoring									***Project Manager: R Cully***			
Monitor site performance against 2010 Pfizer cEHS EPI targets												
Implement corrective action where required for any significant deviation to Pfizer cEHS EPI targets												
Process Effluent (IPPC Condition 6.11.3)									***Project Manager: R Cully***			
Complete reversion study												
Produce report on findings												
Submit to EPA												
Fire Water Retention (IPPC Condition 3.9)									***Project Manager: R Cully***			
Phase II of study to be completed and report prepared.												
Submit report to the EPA for approval												
Invite tenders for any remedial action identified and award contract.												
Complete any remedial action identified												
Efficiency of Raw Materials Use (IPPC Condition 7.4)									***Project Manager: E Molyneaux***			
Gather raw data for RMUE for OC/HT/Efexor/CNS												
Provide interim update to EPA (AER)												
Produce report on findings												
Submit report to EPA for assessment												

Who

EHS, Processing, Packaging, Engineering, External Consultants.

OBJECTIVE 2: ENVIRONMENTAL MANAGEMENT SYSTEMS

Drive continuous improvement of environmental management systems.

Target

- Maintain ongoing environmental training on site with particular focus on delivery through different media.
- Implement an ongoing environmental awareness campaign in order to further heighten environmental awareness on site (in particular energy management).
- Assure Corporate EHS guideline compliance
- Rationalise & simplify EHS related documentation
- Evaluate feasibility with EPA of reducing monitoring requirement for standard parameters (e.g. BOD/COD, etc) for SE1 discharge.

Why

To achieve compliance with the requirements of the current site IPPC Licence (Licence Register No. P0153-05), in particular *Condition 2.2.2.6* To comply with all conditions of the current site IPPC Licence (Licence Register No. P0153-05), in particular *Condition 2.2.2.6*, and Corporate EHS environmental policies. The environmental awareness programme will enhance the sites reputation through colleague, community and targeted stakeholder engagement.

How & When

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
Environmental Training (IPPC Condition 2.2.2.6)									***Project Manager: R Cully***			
Develop area specific CBTs for processing/ packaging/laboratories to support rationalisation & simplification of waste procedures												
Environmental Awareness (IPPC Condition 2.2.2.6)									***Project Manager: E Molyneaux***			
Develop Programme Proposal (with particular focus on energy management)												
Draw up short-list of proposed ideas/projects												
Implement ideas/projects												
Corporate EHS Environmental Policies									***Project Manager: E Molyneaux***			
Promote new Pfizer Corporate EHS policies within relevant work areas												
Identify system owners for individual policies i.e. engineering SMEs												
Conduct gap analysis of site systems / procedures against revised policies (via environmental protocols)												
Implement work programme (as co-ordinated by system owners) to address gaps identified												
Audit on site systems / procedures for compliance against revised policies (confirm that gaps identified have been closed)												
Documentation									***Project Manager: E Molyneaux***			
SOPs: Where feasible rationalise the number of procedures currently in place												
Other: Review all EHS related documentation currently in use and identify opportunities for rationalising & simplifying documentation.												
Auditing: Develop checklists for new system to audit significant environmental aspects												
Monitoring Programme (IPPC Condition 5.1, 6.1)									***Project Manager: M Gallagher***			
Based on high quality effluent generated since installation of WWTP evaluate feasibility with EPA of reducing monitoring requirement for standard parameters (e.g. BOD/COD, etc) for SE1 discharge.												

Who

EHS, Training, External Consultants.

OBJECTIVE 3: ENERGY MANAGEMENT

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

Target

Reduce absolute energy (CO_2) and water consumption (m^3) associated with on-site operations:

- Energy Usage – Decrease energy usage by a minimum of 5% of 2009 baseline (i.e. 44672 to 42439 tonnes CO_2).
- Water Usage – Decrease water usage by a minimum of 5% of 2009 baseline (i.e. 283,755 to 269,567 m^3 water).

Why

This project is being undertaken to introduce a programme of minimising energy and water usage at the site thereby achieving compliance with the requirements of site IPPC Licence (Licence Register No. P0153-05), in particular *Conditions 2.2.2.2, 7.1, 7.2, 7.3*. It is expected that assessment of the feasibility of projects for improvements in energy and water usage will result in environmental benefits (i.e. minimize the sites environmental footprint) and create business opportunities (i.e. financial benefit associated with reduced energy costs).

How & When

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
Energy Usage – General (IPPC Condition 2.2.2.2, 7.1, 7.2)												***Project Manager: P Kane***
Identify ideas/projects												
Draw up short-list of proposed ideas/projects												
Implement programme ideas/projects (subject to receiving capital approval)												
Review progress quarterly												
Energy Usage – Renewable Energy (IPPC Condition 7.1, 7.2)												***Project Manager: P Kane***
Evaluate the use of renewable energy sources												
Draw up short-list of proposed ideas/projects												
Water Usage (IPPC Condition 7.3)												***Project Manager: C Devine/P Kane***
Identify ideas/projects												
Draw up short-list of proposed ideas/projects												
Implement programme ideas/projects (subject to receiving capital approval) including evaluation of reuse of WWTP effluent in Cooling Towers												
Review progress quarterly												
Energy Management System (IPPC Condition 2.2.2.2, 7.1, 7.2)												***Project Manager: E Molyneaux***
Simplification & rationalisation of site energy management procedures												
Obtain certification to EN16001:2009												

Who

Engineering, EHS, External Consultants.

OBJECTIVE 4: WASTE MANAGEMENT

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

Target

- Waste Reduction/Recycling
  - Decrease total waste arisings by a minimum of 5% of 2009 baseline (i.e. 3,164,862 to 3,006,619 Kg).
  - Increase hazardous waste recycling rate by 2% of 2009 baseline (i.e. 11 to 13%)
  - Maintain 2009 non-hazardous waste recycling rate (i.e. ≥87%) – Increase canteen non-hazardous waste recycling rate by 50% of 2009 baseline (i.e. 20 to 70%)
- Waste Logistics – To develop and implement a system for the tracking of controlled drug waste from point of generation to movement off-site for disposal

Why

The sites long-term objective is, where possible, to reduce the quantities of waste requiring disposal thereby achieving compliance with the requirements of site IPPC Licence (Licence Register No. P0153-05), in particular *Condition 2.2.2.2.* It is expected that assessment of innovative strategies to reduce waste arisings and increase waste recycling will minimize the sites environmental footprint and create business opportunities (i.e. financial benefit associated with reduced waste management costs).

How & When

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
Waste Reduction – Hazardous Waste (IPPC Condition 2.2.2.2)												***Project Managers: R Cully / E Molyneaux***
▪ General: Implement opportunities to reduce waste at source as identified during 2009 area waste reviews												
▪ Controlled Drugs Waste: Packaging de-blistering												
▪ Solvent Waste: Investigate the possibility of reusing recovered DCM from SRS waste in the Efexor process												
Waste Recycling – Hazardous Waste (IPPC Condition 2.2.2.2)												
▪ Investigate the possibility of declassification of WWTP sludge for subsequent use as an alternative fuel at cement kilns												
▪ Investigate the possibility of re-classification of disused metal equipment that has historically been in contact with API i.e. if it can be appropriately decontaminated may be recycled as non-hazardous metal.												
Waste Reduction -Non-Hazardous Waste (IPPC Condition 2.2.2.2)												***Project Managers: E Molyneaux/ R Cully***
▪ Fibre Drums: Investigate the increased reuse of fibre drums												
Waste Recycling -Non-Hazardous Waste (IPPC Condition 2.2.2.2)												***Project Managers: E Molyneaux/ R Cully***
▪ General: Conduct waste characterisation study on compactor to identify any opportunities to divert waste from landfill												
▪ Canteen: Segregate compostables from all canteen waste streams												
▪ Non-hazardous Sugar Coating Solution: Investigate the possibility of diverting non-hazardous sugar coating solution from incineration (D10) to alternative treatment (R3).												
Waste Logistics – Hazardous Waste Documentation/Tracking												***Project Managers: R Cully / E Molyneaux***
Complete process mapping of Controlled Drugs waste streams												
Phase 1: Develop and implement new process flows for Warehouse/Packaging/Processing)												
Phase 2: Review success of phase 1 and assess if phase 2 implementation for Laboratories & Utilities is feasible												

Who

Engineering, Processing, Packaging, Warehouse, SAP, Quality, 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.	MDE0856Rp0004					
This Document Comprises	DCS	TOC	Text	List of Tables	List of Figures	No. of Appendices
	1	1	19	1	1	-

Rev.	Status	Author(s)	Reviewed By	Approved By	Office of Origin	Issue Date
A01	Draft for comment	M. Doherty	P. Chadwick	S. Herlihy	West Pier	8/02/10
F01	Final					10/03/10

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1 INTRODUCTION

1.1 FACILITY AND LICENCE DETAILS

AHP Manufacturing B.V. trading as 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 2009. All RMP reports have been submitted to the EPA 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, which was submitted to the EPA 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.

This report represents the most recent annual update to the RMP. The full RMP (reference MDE0856Rp0001F02) was submitted to and approved by the EPA in 2009. This updated RMP contains amendments to the original financial provisions specified in the RMP. Section 7 of this report contains the amended financial provision figures and will require approval from the EPA.

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**

Based on an Overall Risk Score of 36 the WMI site is classified in Risk 3. The requirements for assessing Category 3 facilities detailed in the EPA 2006 must therefore be followed.

The RMP is 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 decommissioning procedures. 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**(1)***.*

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.

Note (1): WMI is in the process of completing a submission to the EPA justifying the reclassification of this waste stream from hazardous to non-hazardous waste.

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 approximately 1200 people employed at the 1,000,000 sq ft (92,900sqm) facility. WMI operates on a 24 hour, 5 days per week shift basis, with some production at weekends.

The manufacture of solid dose pharmaceutical products at WMI is 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 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, CHP, wastewater treatment plant, waste management centre, an engineering workshop, and an administration building with canteen.

On 15th October 2009, Pfizer Inc., completed its acquisition of Wyeth in the United States, with Wyeth becoming a subsidiary of Pfizer. Because of the merger, Pfizer owns Wyeth and became the ultimate corporate parent of the WMI Newbridge facility. Further to this acquisition, and due to certain planned corporate restructurings (which were subject to change) , WMI submitted a Transfer of a Licence Application to the EPA on 15/12/2009 to account for the planned technical change in the ownership of the Newbridge facility..

On 17/02/2010 WMI advised the EPA that Pfizer Corporate had indicated that the organisational details of the proposed transferee had not yet been finalised. Until and unless the Licence transfer is finalised the Newbridge site will continue to trade as AHP Manufacturing B.V. trading as Wyeth Medica Ireland.

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. The function of each building and plant item is included as well as any changes in 2009.

Table 2.1 List of WMI Site Buildings and Plant

Building/Plant Area	Function	Changes in 2009(1)
Building 1	Administration services (accounting, purchasing, HR etc), Canteen	
Building 2	Packaging	
Building 3	Production	Removed 1 No. main atmospheric emission [Emission Point Reference No. A2-73 [Oral Contraceptive (OC) emission] from the scope of licensed vents as listed in *Schedule B.1 Emissions to Air; Dust Emissions to Air* of Licence Register No. P0153-05 as part of the application for Technical Amendment D. *Technical Amendment D to Licence Register No. P0153-05* issued on 16/12/2009 to extend the timeline specified in Condition 6.21 of Technical Amendment A to Licence Register No. P0153-05 for the cessation of solvent emissions from Emission Point Reference No. A2-6 from 31/12/2009 to 31/12/2012.
Building 3A	Production	
Building 3B	Production	
Building 3C & associated Central Utilities Building	Production	Validation ongoing
Building 4	Warehouse/ Production (OC4B) PDC (Pharmaceutical Development Centre) Solvent Storage Area Waste Staging Areas	Validation ongoing *Technical Amendment C to Licence Register No. P0153-05* issued on 30/06/09 to run 11 No. main emission points (Emission Point Reference No. A2-49a to A2-49k) for the Pharmaceutical Development Centre (PDC) *Technical Amendment D to Licence Register No. P0153-05* issued on 16/12/2009 to increase run-time from 16 hrs a day to 24 hrs a day for Emission Point Reference No. A2-49a to A2-49k
Building 5	Central Utilities Building (boilers, CHP, cooling towers etc.)	On 01/05/2009 2 boilers were decommissioned (Emission Point References No's A1-1 and A1-2)
Building 9	AS/RS automated warehouse	
Solvent Tank Farm	Raw Material / Waste Solvent storage in 7 No. 30m^3 bunded tanks.	

Building/Plant Area	Function	Changes in 2009[(1)]
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	On the 24/03/09 a temporary failure in the on-site Wastewater Pre-Treatment Plant (WWTP) alarm system (which occurred for a period of 1 hour) resulted in a discharge of 36 m^3 of effluent from the site with a residual ozone off-gas level below the set-point of 3ppm (the ozone off-gas is continuously monitored and the effluent discharge from the WWTP should automatically stop if the off-gas ozone levels drop below 3 ppm). There was no environmental impact as a result of this failure as the liquid phase ozone levels in the effluent discharge during this period remained constant, which indicated that there was sufficient ozone present to remove any pharmaceutical actives from the wastewater discharge, and therefore ensure compliance with the ELVs for pharmaceutical actives. The results of analysis for the fortnightly composite sample confirmed this as no pharmaceutical active was detected (results less than the analytical limit of detection for each active).
Oils, Fats & Greases (OFG) Waste Water Treatment Plant	Treatment unit for canteen waste water	OFG waste in now being composted as detailed in the revised Table H(ii) *Waste –Other Waste Recovery/Disposal* submitted to the agency on 03/06/2009.
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	A 'system by system' or 'building by building' based risk assessment is proposed to progress the 2005 Fire-Water Retention Study and also take account of on-site developments 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.
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	

Note [(1)]: Only where changes occur is information included. If no information is provided for an area then No change occurred in 2009

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 EPA on 02/03/2007). A Detailed Quantitative Risk Assessment (DQRA) was subsequently completed by RPS Group (submitted to the EPA 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. *The original RMP contains a detailed description of each stage of the Closure Plan. There have been no significant alterations on site that affect the content of the detailed description so to avoid unnecessary repetition the text is omitted from this updated RMP.*

Figure 2.1 Programme of Closure for WMI facility.

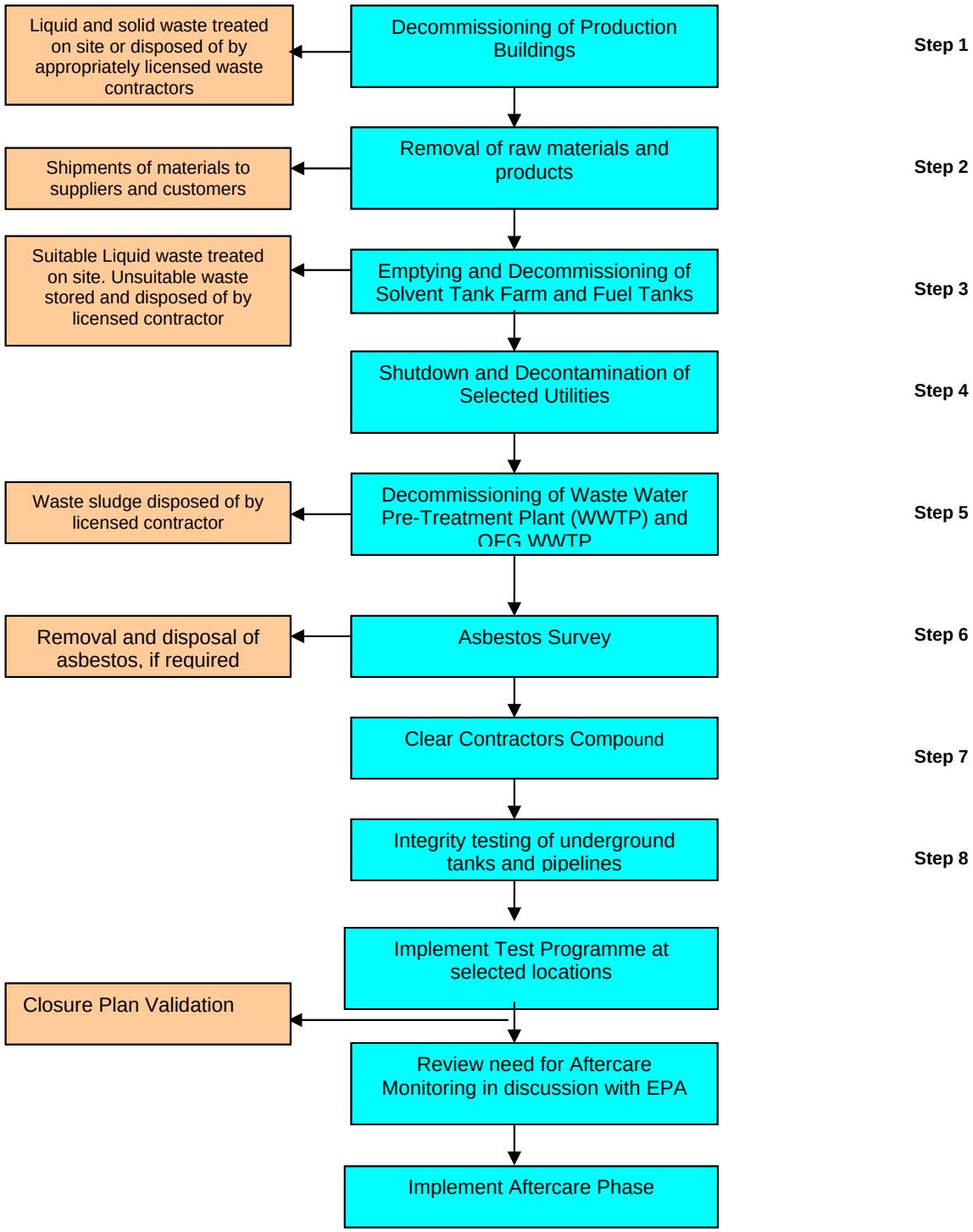
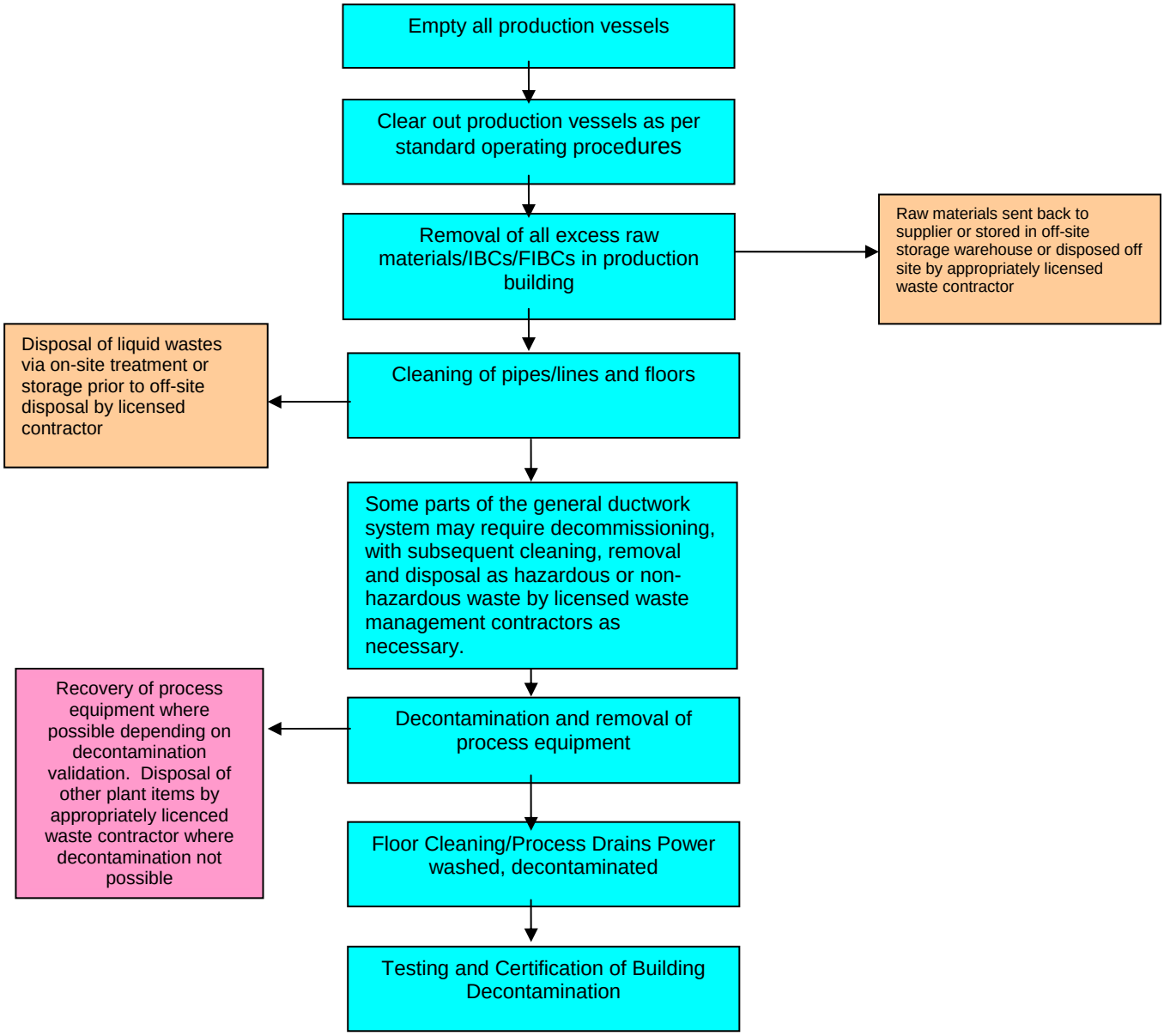


Figure 2.2 Flow Diagram of Likely Order of Decommissioning of a WMI Production Building



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 2009. 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: 2009 Off Site Waste Disposal.

Type	Amount[(1)] (tonne)	Methods of Disposal
Hazardous	1406	Licensed waste management contractor
Non-hazardous	1762	Licensed waste management contractor

(1) Figure based on 2009 waste figures

Table 3.2 RMP Off Site Waste Disposal Costs.

Type	Amount[(1)] (tonne)	Approximate Cost per tonne (€)	Cost (€)
Hazardous	469	750	351,750
Non-hazardous	587	150	88,050
Total			**439,800**

(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 entire 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:	30 wells x €2,000 per well = **€60,000**
(b) 2 x rounds of monitoring:	30 wells x €300 per well x 2 rounds **= €18,000**
(c) Soil sampling programme:	**€20,000**
(d) Reporting	€**20,000**
Total	**€118,000**

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. This cost is subject to change based on the proposal submitted to the EPA by RPS to decrease the scope and frequency of the monitoring programme in the area of the diesel spill. At the time of some future closure it may not be necessary to continue monitoring at this location. However, as a precaution it is proposed to include the costs of the three-year post-closure monitoring programme in the area of the diesel spill in the RMP.

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	**€439,800**
Process Equipment Hazardous Waste Disposal	**€30,000,000**[(1), (2)]
Sewer network investigation and repair (if required)	**€70,000**
Ground Investigation	**€118,000**
Monitoring in area of diesel spill	**€50,000**
Independent Verification Audit	**€10,000**
Total	**€31,272,800**

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.

Note [(2)]: WMI is in the process of completing a submission to the EPA justifying the reclassification of this waste stream from hazardous to non-hazardous waste. If the EPA approves the proposal this cost will reduce significantly.

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 and the original that it is based on (refer to RPS Report MDE0856Rp0001F02) 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. Consequent upon a decision to decommission all or part of the Newbridge 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 central Pfizer Inc and central funding would be released by central Pfizer Inc to cover both short-term and longer-term costs as required. Such central funding may be structured by central Pfizer Inc to stretch over several years as required to cover longer-term activities.

Pfizer Inc would take a decision to decommission all or part of the Newbridge site centrally under a coordinated review. Any such decision would be announced by central Pfizer Inc 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 Newbridge 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 Newbridge site will have the resources in terms of financial inputs to implement the RMP through to completion, with no requirement for external financing.

Appendix 9

Updated “Table 5.2” of Environmental Liability Risk Assessment

Table 5.2: Impact of Risk Mitigation. Ranked in order of Revised Risk Score.

Risk ID	Process	Potential Hazards	Current Controls	Current Occurrence Rating	Current Severity rating	Current Risk Score	Recommended Mitigation Measures	Responsibility	Current Status/Completion date	Revised Risk Score
8	Liquid Hazardous Waste Storage Area	Major Spillage in Hazardous Waste Storage Compound	All hazardous waste is bunded. Regular WMI inspections of loading/unloading	2	3	6	WMI will decommission this area as part of planned works. This will remove the risk of spillage in this area.	Facilities	The liquid hazardous waste storage area may only be decommissioned or downsized when all rinsewater is discharged to on-site WWTP. This is dependent on completion of the ongoing Performance Verification process. This is likely to be completed by April 2010. Notwithstanding this there is currently no funding available to fully decommission this area and relocate the remaining waste management activities to an alternative area. Funding may become available at a later date at which time this project will be re-evaluated.	Risk is removed when all waste has been discharged. WMI may decide to store some waste here in future. If so, the risk will be re-evaluated.
9	Liquid Hazardous Waste Storage Area	Fire in Hazardous Waste Storage Compound	7 Fire extinguishers located on perimeter of compound. Fire hydrant located beside compound. Visual detection both locally and through security cameras in area. Daily inspections of compound.	1	4	4	WMI will decommission this area as part of planned works. This will remove the risk of spillage in this area.	Facilities	Same as Risk ID 8	Same as Risk ID 8

Appendix 10

Bund Integrity Testing 2009

ID	Test Date	Test Result	ID	Test Date	Test Result	ID	Test Date	Test Result
PE 09	02/04/2009	Pass Note 1	*PE 33*	02/12/2009	Pass Note 1	*TP169*	02/06/2009	Pass Note 1
PE 10	02/04/2009	Pass Note 1	*PE 34*	13/02/2009	Pass Note 1	*TP170*	02/06/2009	Pass Note 1
PE 27	26/02/2009	Pass Note 1	*PE 42*	02/03/2009	Pass Note 1	*TP171*	02/06/2009	Pass Note 1
PE 28	03/06/2009	Pass Note 1	*PE 44*	15/01/2009	Pass Note 1	*TP172*	01/06/2009	Pass Note 1
PE 29	22/01/2009	Pass Note 1	*PE 41*	06/03/2009	Pass Note 1	*TP173*	01/06/2009	Pass Note 1
PE 30	22/01/2009	Pass Note 1	*PE 45*	02/04/2009	Pass Note 1	*TP186*	02/06/2009	Pass Note 1
PE 31	13/02/2009	Pass Note 1	*TP114*	15/10/2009	Pass Note 1	*TP186*	02/06/2009	Pass Note 1
PE 32	13/02/2009	Pass Note 1	*TP115*	15/10/2009	Pass Note 1	*TP187*	02/06/2009	Pass Note 1

Note 1: The Integrity testing methodology employed is based on BS8007;1987, Section 9.2

ID	Test Date	*Test Result*
PE46	06/03/2009	***Fail*** Note 2

Note 2: This bund is currently not in use. The Kunhi Tower was not operational in 2009 and PE45 will be repaired before any operations recommence.

Appendix 11

Boiler Maintenance Programme 2009

Pfizer **Pfizer Ireland**

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

To: **Martin Gallagher**

From: **Frank Mahon, Utilities Planning Engineer**

Date: **09/02/10**

Subject: **Boilers – Service & 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: Frank Mahon Date: 09/02/10

Frank Mahon
Utilities Planning Engineer

Signed: Date: 09/02/10

Ger Dolan
Utilities Supervisor

Appendix 12

European Pollutant Release and Transfer Register 2009

Environmental Protection Agency

AER Returns Worksheet

Version 1.1.10

REFERENCE YEAR	2009

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	##

Address 1	Buckley's Cross Roads
Address 2	Old Connell
Address 3	Newbridge
Address 4	County Kildare
Country	Ireland
Coordinates of Location	-6.77887 53.1863
River Basin District	IEEA
NACE Code	2110
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	EHS & Site Services Director
AER Returns Contact Telephone Number	045 447000
AER Returns Contact Mobile Phone Number	0879192924
AER Returns Contact Fax Number	045 434113
Production Volume	743049.0
Production Volume Units	Kg
Number of Installations	1
Number of Operating Hours in Year	0
Number of Employees	1100
User Feedback/Comments	
Web Address	www.wyeth.ie

2. PRTR CLASS ACTIVITIES

Activity Number	Activity Name
9(c)	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 ?	

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 and 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	-	183361.36	527.85	444.27	1258.58	0.0	0.0	185592.06	0.0	0.0
06	Nitrogen oxides (NOx/NO2)	M	Siteright Environmental I.S. EN 14792; Analysis - Flue gas Analyser	-	67911.62	1779.05	3598.57	15796.11	0.0	0.0	89085.35	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	24401000.0	0.0	24401000.0	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	44.27	131.15	0.0	86.88

* 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
					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							QUANTITY		
			Method Used		A2-1-A2-94	A2-16,A2-41	A2-6, A2-16 and A2-41				
Pollutant No.	Name	M/C/E	Method Code	Designation or Description	Emission Point 1	Emission Point 2	Emission Point 3	Emission Point 4	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	-	181.69	0.0	0.0	0.0	181.69	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	60.1	0.0	0.0	60.1	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	31.38	0.0	31.38	0.0	0.0
232	TA Luft organic substances class 3	C	Siteright Environmental method based on IS EN 13649; Analysis by GCFID	-	0.0	0.0	1638.11	0.0	1638.11	0.0	0.0
351	Total Organic Carbon (as C)	C	Siteright Environmental method based on IS EN 13649; Analysis by GCFID	-	0.0	10.33	0.0	0.0	10.33	0.0	0.0

4.2 RELEASES TO WATERS

SECTION A : SECTOR SPECIFIC 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 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

4.3 RELEASES TO WASTEWATER OR SEWER

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	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 Absorpti		0.27	0.27	0.0	0.0
27	Atrazine	M	Part of a group testing for triazine/Herbicides by GCI		0.0	0.0	0.0	0.0
79	Chlorides (as Cl)	M	SLS TM 097 based on USEPA Method 525.1/2		28471.0	28471.0	0.0	0.0
19	Chromium and compounds (as Cr)	M	SLS TM 152 by ICPMS		0.28	0.28	0.0	0.0
20	Copper and compounds (as Cu)	M	SLS TM 152 by ICPMS		3.78	3.78	0.0	0.0
22	Nickel and compounds (as Ni)	M	SLS TM 152 by ICPMS		0.34	0.34	0.0	0.0
51	Simazine	M	Part of a group testing for triazine/Herbicides by GCI		0.0	0.0	0.0	0.0
12	Total nitrogen	M	SLS TM 102 D based on AWWA/APHA 20th Edition		1441.0	1441.0	0.0	0.0
13	Total phosphorus	M	SLS TM 100 based on BS 2690:Part 105:1983		390.0	390.0	0.0	0.0
82	Cyanides (as total CN)	M	GLS TM 134 by Steam Distillation		0.0	0.0	0.0	0.0
83	Fluorides (as total F)	M	SLS TM 104		176.0	176.0	0.0	0.0
35	Dichloromethane (DCM)	M	SLS TM 116 by Headspace A Autosampler and Gas		0.07	0.07	0.0	0.0
23	Lead and compounds (as Pb)	M	SLS TM 152 by ICPMS		0.23	0.23	0.0	0.0
21	Mercury and compounds (as Hg)	M	SLS TM 127 by Cold Vapour Atomic Absorption Spe		0.0002	0.0002	0.0	0.0
73	Toluene	M	SLS TM 116 by Headspace A Autosampler and Gas		0.0	0.0	0.0	0.0
78	Xylenes	M	SLS TM 116 by Headspace A Autosampler and Gas		0.0	0.0	0.0	0.0
24	Zinc and compounds (as Zn)	M	SLS TM 152 by ICPMS		9.87	9.87	0.0	0.0
06	Ammonia (NH3)	M	SLS TM 099 based on BS2690 Part 7:1968/ BS 606		135.0	135.0	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)

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	24933.0	24933.0	0.0	0.0
303	BOD	M	SLS TM 045 based on MEWAM BOD5 2nd Edition 1988/AWWA/ APHA 20th Edition - Method 5210B		749.0	749.0	0.0	0.0
306	COD	M	SLS TM 107 D using Dr Lange Kit		2907.0	2907.0	0.0	0.0
343	Sulphate	M	SLS TM 098		10976.0	10976.0	0.0	0.0
314	Fats, Oils and Greases	M	SLS TM 235 Using Infra-red Spectroscopy		268.0	268.0	0.0	0.0
240	Suspended Solids	M	SLS TM 021 by Gravimetric Determination Based on BS2690 Part 121:1981		901.0	901.0	0.0	0.0
330	Organic solvents	M	SLS TM 232 Using Mass Spectromy		25.44	25.44	0.0	0.0

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

4.4 RELEASES TO LAND

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

5. ONSITE TREATMENT & OFFSITE TRANSFERS OF WASTE

Transfer Destination	European Waste Code	Hazardous	Quantity (Tonnes per Year)	Description of Waste	Waste Treatment Operation	Method Used		Location of Treatment	Haz Waste : Name and Licence/Permit No of Next Destination Facility Non Haz Waste: Name and Licence/Permit No of Recover/Disposer	Haz Waste : Address of Next Destination Facility Non Haz Waste: Address of Recover/Disposer	Name and License / Permit No. and Address of Final Recoverer / Disposer (HAZARDOUS WASTE ONLY)	Actual Address of Final Destination i.e. Final Recovery / Disposal Site (HAZARDOUS WASTE ONLY)
						M/C/E	Method Used					
To Other Countries	07 05 01	Yes	273.411	aqueous washing liquids and mother liquors	D10	M	Weighed	Abroad	Indaver NV ,MLAVI/9800000485/MV/bd	Industriele Afvalverwerking ,Poldervlietweg ,B-2030, Antwerpen 3 ,Belgium	Indaver NV,MLAVI/9800000485/MV/bd,Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium	Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium
To Other Countries	07 05 01	Yes	17.468	aqueous washing liquids and mother liquors	D10	M	Weighed	Abroad	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB	Borsigstrasse 2 , D-22112 , Hamburg,.,Germany	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB,Borsigstrasse 2,D-22112 ,Hamburg,.,Germany	Borsigstrasse 2,D-22112 ,Hamburg,.,Germany
To Other Countries	07 05 03	Yes	229.18	Organic halogenated solvents, washing liquids and mother liquors	D10	M	Weighed	Abroad	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB	Borsigstrasse 2 , D-22112 , Hamburg,.,Germany	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB,Borsigstrasse 2,D-22112 ,Hamburg,.,Germany	Borsigstrasse 2,D-22112 ,Hamburg,.,Germany
To Other Countries	07 05 03	Yes	134.601	Organic halogenated solvents, washing liquids and mother liquors	D10	M	Weighed	Abroad	Indaver NV ,MLAVI/9800000485/MV/bd	Industriele Afvalverwerking ,Poldervlietweg ,B-2030, Antwerpen 3 ,Belgium	Indaver NV,MLAVI/9800000485/MV/bd,Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium	Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium
To Other Countries	07 05 03	Yes	135.78	Organic halogenated solvents, washing liquids and mother liquors	R2	M	Weighed	Abroad	Solvent Resource Management Ltd,BL7302ID	Middleton Road,Lancashire,.,LA3 3JW,United Kingdom	Solvent Resource Management Ltd.,BL7302ID, Middleton Road,.,Lancashire,LA3 3JW,United Kingdom	Middleton Road,.,Lancashire,LA3 3JW,United Kingdom
To Other Countries	07 05 04	Yes	0.008	Other organic solvents, washing liquids and mother liquors	D10	M	Weighed	Abroad	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB	Borsigstrasse 2 , D-22112 , Hamburg,.,Germany	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB,Borsigstrasse 2,D-22112 ,Hamburg,.,Germany	Borsigstrasse 2,D-22112 ,Hamburg,.,Germany
To Other Countries	07 05 04	Yes	25.409	Other organic solvents, washing liquids and mother liquors	D10	M	Weighed	Abroad	Indaver NV ,MLAVI/9800000485/MV/bd	Industriele Afvalverwerking ,Poldervlietweg ,B-2030, Antwerpen 3 ,Belgium	Indaver NV,MLAVI/9800000485/MV/bd,Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium	Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium
To Other Countries	07 05 04	Yes	2.617	Other organic solvents, washing liquids and mother liquors	R2	M	Weighed	Abroad	Solvent Resource Management Ltd,BL7302ID	Middleton Road,Lancashire,.,LA3 3JW,United Kingdom	Solvent Resource Management Ltd.,BL7302ID, Middleton Road,.,Lancashire,LA3 3JW,United Kingdom	Middleton Road,.,Lancashire,LA3 3JW,United Kingdom
To Other Countries	07 05 08	Yes	3.297	Other still bottoms and reaction residues	D10	M	Weighed	Abroad	Indaver NV ,MLAVI/9800000485/MV/bd	Industriele Afvalverwerking ,Poldervlietweg ,B-2030, Antwerpen 3 ,Belgium	Indaver NV,MLAVI/9800000485/MV/bd,Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium	Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium
To Other Countries	07 05 11	Yes	147.673	Sludges from on-site effluent treatment containing dangerous substances	D10	M	Weighed	Abroad	Indaver NV ,MLAVI/9800000485/MV/bd	Industriele Afvalverwerking ,Poldervlietweg ,B-2030, Antwerpen 3 ,Belgium	Indaver NV,MLAVI/9800000485/MV/bd,Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium	Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium

Transfer Destination	European Waste Code	Hazardous	Quantity (Tonnes per Year)	Description of Waste	Waste Treatment Operation	Method Used		Location of Treatment	Haz Waste : Name and Licence/Permit No of Next Destination Facility Non Haz Waste: Name and Licence/Permit No of Recover/Disposer	Haz Waste : Address of Next Destination Facility Non Haz Waste: Address of Recover/Disposer	Name and License / Permit No. and Address of Final Recoverer / Disposer (HAZARDOUS WASTE ONLY)	Actual Address of Final Destination i.e. Final Recovery / Disposal Site (HAZARDOUS WASTE ONLY)
						M/C/E	Method Used					
To Other Countries	07 05 13	Yes	249.403	Solid Hazardous Waste (Containing or Contaminated with Pharmaceutical Actives)	D10	M	Weighed	Abroad	Indaver NV ,MLAVI/9800000485/MV/bd	Industriele Afvalverwerking ,Poldervlietweg ,B-2030, Antwerpen 3 ,Belgium	Indaver NV,MLAVI/9800000485/MV/bd,Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium	Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium
To Other Countries	07 05 13	Yes	12.74	Solid Hazardous Waste (Containing or Contaminated with Pharmaceutical Actives)	D5	M	Weighed	Abroad	IAG Ihlenberger Abfallentsorgungsgesellschaft mbH,M58SAD001	Ihlenberg 1 ,.,Selmsdorf,23923,Germany	IAG Ihlenberger Abfallentsorgungsgesellschaft mbH, M58SAD001,Ihlenberg 1,.,Selmsdorf,23923,Germany	Ihlenberg 1,.,Selmsdorf,23923,Germany
To Other Countries	07 05 13	Yes	0.155	Solid Hazardous Waste (Containing or Contaminated with Pharmaceutical Actives)	D10	M	Weighed	Abroad	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB	Borsigstrasse 2 , D-22112 , Hamburg,.,Germany	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB,Borsigstrasse 2,D-22112 ,Hamburg,.,Germany	Borsigstrasse 2,D-22112 ,Hamburg,.,Germany
To Other Countries	07 05 13	Yes	55.838	Solid Hazardous Waste (Containing or Contaminated with Pharmaceutical Actives)	D10	M	Weighed	Abroad	TRV Thermische Ruckstandsverwertung Gmbh & Co. KG,55.8851.8.1-73/94-koln	Rodenkirchener Str ,., Wesseling,50389,Germany	TRV Thermische Ruckstandsverwertung Gmbh & Co. KG,55.8851.8.1-73/94-koln,Rodenkirchener Str,.,Wesseling,50389,Germany	Rodenkirchener Str,.,Wesseling,50389,Germany
Within the Country	07 05 99	No	46.22	Wastes not otherwise specified	R3	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	08 03 18	No	1.361	waste printing toner other than those mentioned in 08 03 17	R5	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
To Other Countries	13 01 13	Yes	0.339	Other Hydraulic Oils	D10	M	Weighed	Abroad	Indaver NV ,MLAVI/9800000485/MV/bd	Industriele Afvalverwerking ,Poldervlietweg ,B-2030, Antwerpen 3 ,Belgium	Indaver NV,MLAVI/9800000485/MV/bd,Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium	Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium
Within the Country	15 01 01	No	140.813	Paper and cardboard packaging	R12	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	15 01 02	No	38.718	Plastic Packaging	R5	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	15 01 03	No	139.848	Wooden Packaging	R3	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	15 01 04	No	10.207	Metallic Packaging	R4	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	15 01 05	No	47.544	Composite packaging	R4	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	15 01 06	No	25.53	Mixed packaging	R12	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	15 01 07	No	3.541	Glass Packaging	R5	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		

Transfer Destination	European Waste Code	Hazardous	Quantity (Tonnes per Year)	Description of Waste	Waste Treatment Operation	Method Used		Location of Treatment	Haz Waste : Name and Licence/Permit No of Next Destination Facility Non Haz Waste: Name and Licence/Permit No of Recover/Disposer	Haz Waste : Address of Next Destination Facility Non Haz Waste: Address of Recover/Disposer	Name and License / Permit No. and Address of Final Recoverer / Disposer (HAZARDOUS WASTE ONLY)	Actual Address of Final Destination i.e. Final Recovery / Disposal Site (HAZARDOUS WASTE ONLY)
						M/C/E	Method Used					
To Other Countries	15 01 10	Yes	0.053	packaging containing or contaminated by dangerous substances	D10	M	Weighed	Abroad	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB	Borsigstrasse 2 , D-22112 , Hamburg,.,Germany	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB,Borsigstrasse 2,D-22112 ,Hamburg,.,Germany	Borsigstrasse 2,D-22112 ,Hamburg,.,Germany
To Other Countries	15 01 10	Yes	32.336	packaging containing or contaminated by dangerous substances	D10	M	Weighed	Abroad	Indaver NV ,MLAVI/9800000485/MV/bd	Industriele Afvalverwerking ,Poldervlietweg ,B-2030, Antwerpen 3 ,Belgium	Indaver NV,MLAVI/9800000485/MV/bd,Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium	Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium
Within the Country	15 01 10	Yes	11.476	packaging containing or contaminated by dangerous substances	R4	M	Weighed	Offsite in Ireland	Indaver Ireland Ltd,W0036-02	Tolka Quay Rd,Dublin Port ,Dublin 1. ,.,Ireland	Rilta Ltd.,W00192-02,Block 402 Greenogue Business Park Rathcoole,.,Dublin,.,Ireland	Block 402 Greenogue Business Park Rathcoole,.,Dublin,.,Ireland
To Other Countries	15 02 02	Yes	0.437	absorbents, filter material, contaminated by dangerous substances	D10	M	Weighed	Abroad	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB	Borsigstrasse 2 , D-22112 , Hamburg,.,Germany	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB,Borsigstrasse 2,D-22112 ,Hamburg,.,Germany	Borsigstrasse 2,D-22112 ,Hamburg,.,Germany
To Other Countries	15 02 02	Yes	0.329	absorbents, filter material, contaminated by dangerous substances	D10	M	Weighed	Abroad	Indaver NV ,MLAVI/9800000485/MV/bd	Industriele Afvalverwerking ,Poldervlietweg ,B-2030, Antwerpen 3 ,Belgium	Indaver NV,MLAVI/9800000485/MV/bd,Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium	Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium
To Other Countries	07 05 99	No	54.087	Wastes not otherwise specified	D10	M	Weighed	Abroad	Indaver NV ,MLAVI/9800000485/MV/bd	Industriele Afvalverwerking ,Poldervlietweg ,B-2030, Antwerpen 3 ,Belgium		
To Other Countries	16 02 13	Yes	12.62	discarded equipment containing hazardous component	R12	M	Weighed	Abroad	Apparec NV ,2/MV/MLOV/9900000092/GVDA	Baeckelmansstraat 125 ,.,Willebroek 2830,.,Belgium	Apparec NV,2/MV/MLOV/9900000092/GVDA,Baeckelmansstraat 125,.,Willebroek 2830,.,Belgium	Baeckelmansstraat 125,.,Willebroek 2830,.,Belgium
To Other Countries	16 05 04	Yes	0.123	gases in pressurised containers containing dangerous substances	D10	M	Weighed	Abroad	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB	Borsigstrasse 2 , D-22112 , Hamburg,.,Germany	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB,Borsigstrasse 2,D-22112 ,Hamburg,.,Germany	Borsigstrasse 2,D-22112 ,Hamburg,.,Germany
To Other Countries	16 05 04	Yes	0.312	gases in pressurised containers containing dangerous substances	D10	M	Weighed	Abroad	Chemogas NV. ,D/DMVC/05F09103933	Westvaartdijk 85,B1850 ,Grimbergen,.,Belgium	Chemogas NV. ,D/DMVC/05F09103933,Westvaartdijk 85,B1850 ,Grimbergen,.,Belgium	Westvaartdijk 85,B1850 ,Grimbergen,.,Belgium
To Other Countries	16 05 06	Yes	0.844	laboratory chemicals, consisting of or containing dangerous substances, including mixtures of dangerous substances	D10	M	Weighed	Abroad	Indaver Ireland Ltd,W0036-02	Tolka Quay Rd,Dublin Port ,Dublin 1. ,.,Ireland	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB,Borsigstrasse 2,D-22112 ,Hamburg,.,Germany	Borsigstrasse 2,D-22112 ,Hamburg,.,Germany
Within the Country	16 05 06	Yes	0.573	laboratory chemicals, consisting of or containing dangerous substances, including mixtures of dangerous substances	D10	M	Weighed	Offsite in Ireland	Indaver Ireland Ltd,W0036-02	Tolka Quay Rd,Dublin Port ,Dublin 1. ,.,Ireland	Indaver NV,MLAVI/9800000485/MV/bd,Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium	Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium

Transfer Destination	European Waste Code	Hazardous	Quantity (Tonnes per Year)	Description of Waste	Waste Treatment Operation	Method Used		Location of Treatment	Haz Waste : Name and Licence/Permit No of Next Destination Facility Non Haz Waste: Name and Licence/Permit No of Recover/Disposer	Haz Waste : Address of Next Destination Facility Non Haz Waste: Address of Recover/Disposer	Name and License / Permit No. and Address of Final Recoverer / Disposer (HAZARDOUS WASTE ONLY)	Actual Address of Final Destination i.e. Final Recovery / Disposal Site (HAZARDOUS WASTE ONLY)
						M/C/E	Method Used					
Within the Country	16 05 07	Yes	3.516	discarded inorganic chemicals consisting of or containing dangerous substances	D10	M	Weighed	Offsite in Ireland	Indaver Ireland Ltd,W0036-02	Tolka Quay Rd,Dublin Port ,Dublin 1. ,.,Ireland	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB,Borsigstrasse 2,D-22112 ,Hamburg,.,Germany	Borsigstrasse 2,D-22112 ,Hamburg,.,Germany
Within the Country	16 05 07	Yes	15.191	discarded inorganic chemicals consisting of or containing dangerous substances	D10	M	Weighed	Offsite in Ireland	Indaver Ireland Ltd,W0036-02	Tolka Quay Rd,Dublin Port ,Dublin 1. ,.,Ireland	Indaver NV,MLAVI/9800000485/MV/bd,Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium	Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium
Within the Country	16 05 08	Yes	9.149	discarded organic chemicals consisting of or containing dangerous substances	D10	M	Weighed	Offsite in Ireland	Indaver Ireland Ltd,W0036-02	Tolka Quay Rd,Dublin Port ,Dublin 1. ,.,Ireland	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB,Borsigstrasse 2,D-22112 ,Hamburg,.,Germany	Borsigstrasse 2,D-22112 ,Hamburg,.,Germany
Within the Country	16 05 08	Yes	7.606	discarded organic chemicals consisting of or containing dangerous substances	D10	M	Weighed	Offsite in Ireland	Indaver Ireland Ltd,W0036-02	Tolka Quay Rd,Dublin Port ,Dublin 1. ,.,Ireland	Indaver NV,MLAVI/9800000485/MV/bd,Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium	Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium
Within the Country	17 01 07	No	240.68	Mixtures of concrete,bricks, tiles and ceramics other than those mentioned in 17 01 06	R12	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	17 05 04	No	97.5	soil and stones other than those mentioned in 17 05 03	R12	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
To Other Countries	18 01 03	Yes	12.567	wastes whose collection and disposal is subject to special requirements in order to prevent infection	D10	M	Weighed	Abroad	Indaver NV ,MLAVI/9800000485/MV/bd	Industriele Afvalverwerking ,Poldervlietweg ,B-2030, Antwerpen 3 ,Belgium	Indaver NV,MLAVI/9800000485/MV/bd,Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium	Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium
To Other Countries	19 09 05	No	0.809	saturated or spent ion exchange resins	D10	M	Weighed	Abroad	Indaver NV ,MLAVI/9800000485/MV/bd	Industriele Afvalverwerking ,Poldervlietweg ,B-2030, Antwerpen 3 ,Belgium		
Within the Country	20 01 01	No	197.699	paper and cardboard	R3	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	20 01 08	No	53.068	biodegradable kitchen and canteen waste	R3	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	20 01 21	Yes	0.36	fluorescent tubes and other mercury-containing waste	R13	M	Weighed	Offsite in Ireland	Indaver Ireland Ltd,W0036-02	Tolka Quay Rd,Dublin Port ,Dublin 1. ,.,Ireland	Irish Lamp Recycling Co. Ltd.,COR-KE-08-0004-01,Woodstock Industrial Estate,Kilkenny Road,Athy Co.Kildare.,.,Ireland	Woodstock Industrial Estate,Kilkenny Road,Athy Co.Kildare.,.,Ireland
To Other Countries	20 01 21	Yes	0.01	fluorescent tubes and other mercury-containing waste	D10	M	Weighed	Abroad	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB	Borsigstrasse 2 , D-22112 , Hamburg,.,Germany	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB,Borsigstrasse 2,D-22112 ,Hamburg,.,Germany	Borsigstrasse 2,D-22112 ,Hamburg,.,Germany
Within the Country	20 01 25	No	13.264	Edible oil and fat	D10	M	Weighed	Offsite in Ireland	Indaver NV ,MLAVI/9800000485/MV/bd	Industriele Afvalverwerking ,Poldervlietweg ,B-2030, Antwerpen 3 ,Belgium		

Transfer Destination	European Waste Code	Hazardous	Quantity (Tonnes per Year)	Description of Waste	Waste Treatment Operation	Method Used		Location of Treatment	Haz Waste : Name and Licence/Permit No of Next Destination Facility Non Haz Waste: Name and Licence/Permit No of Recover/Disposer	Haz Waste : Address of Next Destination Facility Non Haz Waste: Address of Recover/Disposer	Name and License / Permit No. and Address of Final Recoverer / Disposer (HAZARDOUS WASTE ONLY)	Actual Address of Final Destination i.e. Final Recovery / Disposal Site (HAZARDOUS WASTE ONLY)
						M/C/E	Method Used					
Within the Country	20 01 25	No	1.6	Edible oil and fat	R9	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
To Other Countries	20 01 27	Yes	0.077	paint, inks, adhesives and resins containing dangerous substances	D10	M	Weighed	Abroad	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB	Borsigstrasse 2 , D-22112 , Hamburg,.,Germany	AVG Abfalls-Verwertungs-Geselleschaft GMBH,E2310/AVG-GENB,Borsigstrasse 2,D-22112 ,Hamburg,.,Germany	Borsigstrasse 2,D-22112 ,Hamburg,.,Germany
To Other Countries	20 01 27	Yes	9.737	paint, inks, adhesives and resins containing dangerous substances	D10	M	Weighed	Abroad	Indaver NV ,MLAVI/9800000485/MV/bd	Industriele Afvalverwerking ,Poldervlietweg ,B-2030, Antwerpen 3 ,Belgium	Indaver NV,MLAVI/9800000485/MV/bd,Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium	Industriele Afvalverwerking Poldervlietweg ,B-2030 ,Antwerpen,3,Belgium
Within the Country	20 01 38	No	60.92	wood other than that mentioned in 20 01 37	R3	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	20 01 40	No	151.16	Metals	R4	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	20 03 01	No	120.231	Mixed municipal waste	D5	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	20 03 07	No	58.637	Bulky waste	D5	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	20 03 07	No	234.548	Bulky waste	R12	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	16 06 01	Yes	0.77	Lead batteries	R13	M	Weighed	Offsite in Ireland	Indaver Ireland Ltd,W0036-02	Tolka Quay Rd,Dublin Port ,Dublin 1. ,.,Ireland	The Recycling Village Ltd.,WP2007/20,Units 4 & 4a Tinure Park ,.,Tinure Dunleer Co. Louth,.,Ireland	Units 4 & 4a Tinure Park ,.,Tinure Dunleer Co. Louth,.,Ireland
Within the Country	16 06 02	Yes	0.27	Ni-Cd batteries	R13	M	Weighed	Offsite in Ireland	Indaver Ireland Ltd,W0036-02	Tolka Quay Rd,Dublin Port ,Dublin 1. ,.,Ireland	The Recycling Village Ltd.,WP2007/20,Units 4 & 4a Tinure Park ,.,Tinure Dunleer Co. Louth,.,Ireland	Units 4 & 4a Tinure Park ,.,Tinure Dunleer Co. Louth,.,Ireland
Within the Country	19 08 09	No	8.76	grease and oil mixture from oil/water separation containing only edible oil and fats	R3	M	Weighed	Offsite in Ireland	Greenstar Ltd,W0188-1	Greenogue Industrial Estate ,Rathcoole,Dublin,.,Ireland		
Within the Country	20 01 40	No	11.84	Metals	R4	M	Weighed	Offsite in Ireland	Hammond Lane,WFP-DC-0013-01	Pigeon House Road,Ringsend ,Dublin 4.,.,Ireland		
Within the Country	18 01 04	No	3.204	wastes whose collection and disposal is not subject to special requirements in order to prevent infection (for example dressings, plaster casts, linen, disposable clothing, diapers)	D5	E	Volume Calculation	Offsite in Ireland	OCS Cannon Ltd.,WFP-DC-09-0006-01	Century House Richmond Industrial Estate,8 North Circular Road,Dublin,.,Ireland		

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