

# Environmental Statement 2004



**EMAS**

VALIDATION INFORMATION  
REG. NO. IRL-S-011

*Company:*

*Address:*

*Date:*

*AHP Manufacturing B.V. T/A Wyeth Medica Ireland*

*Buckley's Cross, Newbridge, Co. Kildare*

*January 2005*

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## **1. INTRODUCTION**

The following is the Interim Environmental Statement No. 1 for the period January - December 2003 for Wyeth Newbridge, Buckley's Cross, Newbridge, Co. Kildare. The Environmental Statement is a consolidated report which includes all aspects of the site's environmental performance for the given period.

Wyeth Newbridge is committed to an ongoing improvements programme at the site and the continuous improvement requirement of the IPPC licencing process is fully embraced by the Environmental Management Team. To this end an Environmental Management System has been installed [ISO14001 certified; this system forms the basis for certification to the European Eco-Management and Audit Scheme (EMAS) which was certified in May 2004], which incorporates a training and awareness programme (thereby involving all personnel at the facility in an improvements programme), review and improvement procedures and measurement and reporting methods.

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## 2. SITE ACTIVITIES

### 2.1. UPDATE

The Wyeth Newbridge facility produces a variety of pharmaceutical products. The main products produced in Wyeth Newbridge are as follows:

- Hormone Replacement (Premarin, Premarin MPA, Prempack C, Premelle and Premique)
- Oral Contraceptives (Harmonet, Trinoridiol, Nordette, Ovranette, Minesse, Minulet, Loette)
- Cardiovascular (Monacor, Isoten)
- Gastrointestinal (Zoton)
- Central Nervous System (Efexor, Efexor XR, Sonata, Tavor)
- Antibiotics (Minocin MR)

The manufacture of Consumer Health Care (GTs) products including Anadin ceased at Wyeth Newbridge in April 2003.

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. There are associated warehouse facilities on-site to provide storage facilities for raw materials and final product.

The production facilities comprise seven main buildings, solvent recovery plant, combined heat & power (CHP) plant and laboratories. Other facilities include warehousing of raw materials, intermediates and finished goods, external materials storage, services including steam, compressed air, nitrogen, cooling water and process water, an engineering office building, an engineering workshop and an administration building and canteen.

Wyeth Newbridge carries out production of medical/pharmaceutical products within the scope of Class 12.2 of the First Schedule to the Environmental Protection Agency Act 1992 i.e. *The manufacture or use of coating materials in processes with a capacity to make or use at least 10 tonnes per year of organic solvents, and powder coating manufacture with a capacity to produce at least 50 tonnes per year.* The company received a revised Integrated Pollution Control (IPC) Licence in April 2004 (IPC Licence Register No. 673) from the Environmental Protection Agency (EPA).

## **2.2. ENVIRONMENTAL ASPECTS & IMPACTS**

The principle environmental aspects that are addressed in the Wyeth Newbridge IPC Licence include:

- Emissions to Atmosphere
- Noise
- Emissions to Sewer
- Emissions to Surface Water
- Groundwater
- Hazardous and Non-Hazardous Waste Management

The following mitigation measures are adopted at the site for individual potential emissions to reduce or remove impact on the receiving environment:

- Emissions to Atmosphere: Solvent and dust outputs to air derive from fugitive and direct emission sources from individual process areas which are extracted by the air extraction system. Solvent and dust emissions are vented to atmosphere via a solvent abatement system and high efficiency particulate air (HEPA) filters, respectively. Combustion emissions are limited through a regular preventative maintenance programme. Engineering works are ongoing in 2004 order to improve the efficiency of the CHP plant.
- Emissions to Sewer: Process wastewater and foul drainage at the Wyeth Newbridge site is conveyed via the on site wastewater collection system to an on site flow equalisation and pH balancing tank. This treated effluent subsequently discharges to Osberstown municipal wastewater treatment plant. Projects proposed for implementation in 2004 in order to ensure compliance with the IPC Licence emission limit values specified for emissions to sewer parameters include installation of:
  - New pH control system (maintain compliance for final effluent pH)
  - Flow buffer tank (maintain compliance for final effluent hourly flow, daily flow, pH and temperature)
  - Heat exchangers at the points of use (maintain compliance for final effluent temperature)

In addition a pilot plant evaluation of a wastewater treatment plant to substantially remove active material from the on-site process wastewater discharge will be conducted in 2004.

- Emissions to Surface Water/ Groundwater: In order to prevent potential contamination of the receiving River Liffey watercourse with water that may be contaminated with oil, appropriately sized oil interceptors are installed through which surface water run-off from the car and HGV parking areas are channelled prior to discharge from the site. In the event of major spillage or discharge of contaminated fire-water to the surface water (storm water) drainage system penstock valves

(which are manually activated for automatic closure) can be closed at the surface water manhole at the point of final discharge of storm water from the site. This ensures that any spillage or potentially contaminated fire-water, which enters the surface water drainage system is retained on site, until the material is assessed and a procedure for safe disposal and/or discharge is decided upon by the Emergency Response Team in conjunction with the Environmental, Health & Safety Department. Projects proposed for implementation in 2004 in order to ensure continued compliance with the IPC Licence requirements specified for surface water discharge (and groundwater) include the following:

- Assessment of firewater retention protection measures
  - Drainage assessment programme (pressure testing, CCTV survey) to assess repair works required.
- Hazardous and Non-Hazardous Waste Management: Waste streams generated at Wyeth Newbridge fall into four main categories namely solid and liquid hazardous waste, and solid and liquid non-hazardous waste. All waste streams are collected, and transported off-site by licenced and EPA approved waste management companies for appropriate disposal and/or treatment.

The Wyeth Newbridge facility has been designed and is operated in such a manner that the potential emissions (wastewater, surface water, air) to the environment are reduced or eliminated. In addition, the BAT principle continues to be implemented during the operation phase of the site with respect to the management of the facility. It is contended that the risk of environmental contamination as a result of both existing activities and potential accidental or emergency situations at the Wyeth Newbridge facility are minimised or eliminated by adherence to the existing protection programmes. The environmental monitoring programme carried out over the 2003 reporting period (refer to Section 4) shows no adverse environmental impact on the environmental media into which discharges from the Wyeth Newbridge facility are made.

### 3. MANAGEMENT OF THE ACTIVITY

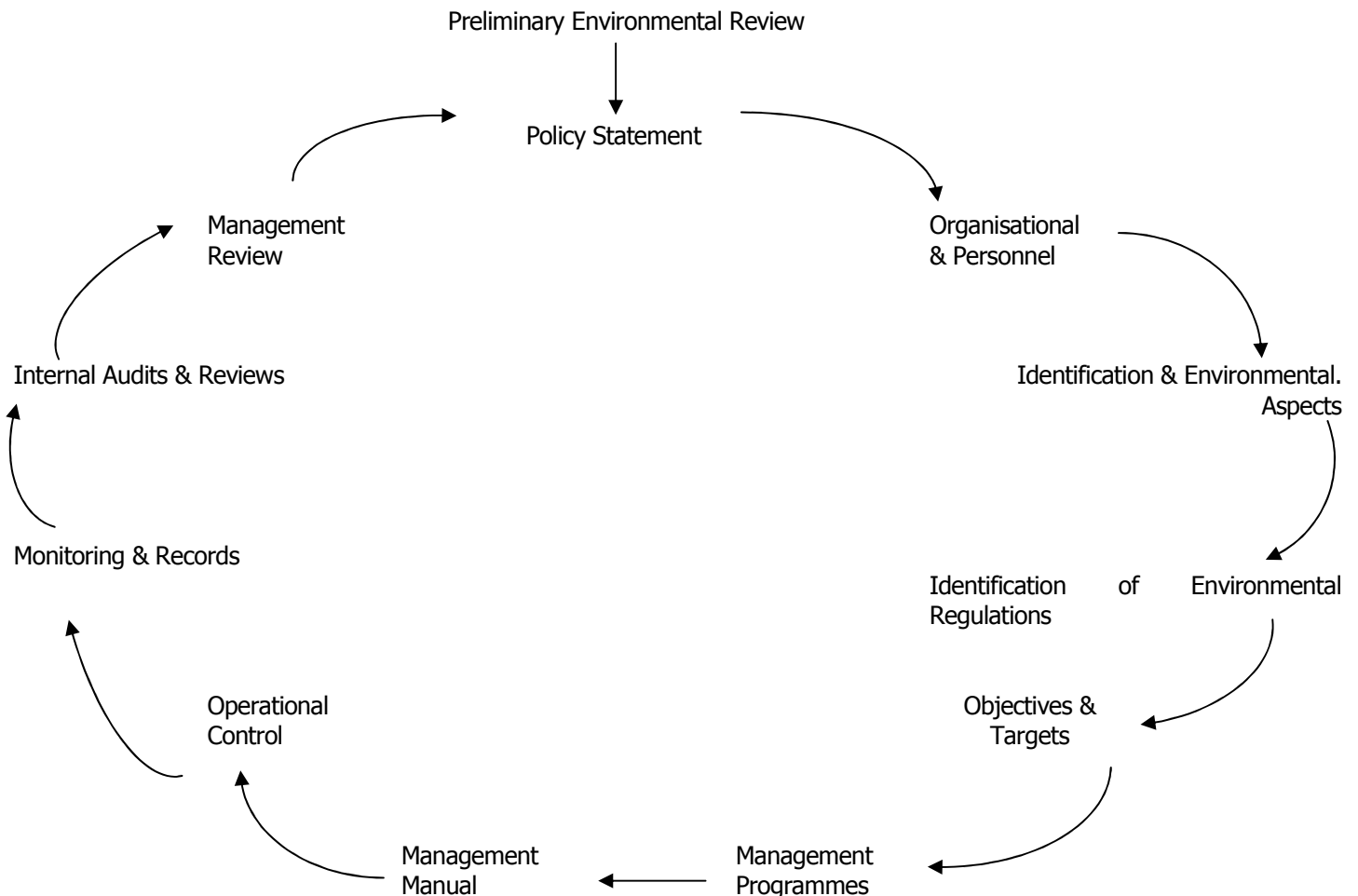
#### 3.1. ENVIRONMENTAL POLICY

It is the policy of Wyeth Newbridge 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 Environmental, Health and Safety Policy, presented overleaf.

#### 3.2. ENVIRONMENTAL MANAGEMENT SYSTEM

Wyeth Newbridge has developed its Environmental Management System (EMS) based on the requirements of ISO 14001. The Environmental Management System (Figure 3.1) allows for continuous, structured and quantifiable improvement in Wyeth Newbridge’s environmental performance.

Figure 3.1 Environmental Management System



## Environmental, Health and Safety Policy

It is the Policy of Wyeth, its divisions and subsidiaries to conduct business in a responsible way and in a manner designed to protect the health and safety of our employees, customers, the public and the environment. As a good corporate citizen, we must be conscious of the effects of our operations on the environment. We, therefore, will continually evaluate and assess our products and processes in order to reduce adverse environmental and safety impacts as we strive toward being a more sustainable Company and fulfilling our vision of "leading the way to a healthier world".

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

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

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

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.

### The Company shall carry out this 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 to 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.
- Conduct training for EHS personnel within the Company.
- Evaluate the performance 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.
- Understand and consider stakeholder points of view in the development of EHS policy.
- Add value to the Company by coordination EHS initiatives with business objectives.
- Participate in trade associations and professional organizations regarding EHS issues.



Robert Esner  
President and Chief Executive  
August 2002

The key aims of the system are to identify the significant environmental aspects of the Wyeth Newbridge business, to ensure that Wyeth Newbridge operations are controlled to prevent avoidable impact, and to help Wyeth Newbridge to continually improve environmental performance over the lifetime of the system. The EMS defines the working procedures and control necessary to manage the environmental aspects of Wyeth Newbridge activities and provides the framework for continual improvement through the setting of Targets and Objectives. In 1998 the Wyeth Newbridge EMS was audited and independently certified as complying with the requirements of ISO 14001 by SGS United Kingdom Ltd. Building on this success certification to the European Eco-Management and Audit Scheme (EMAS) was achieved in May 2004.

### **3.3. ENVIRONMENTAL MANAGEMENT PROGRAMME**

The Environmental Management Programme (EMP) forms part of the strategic environmental planning process for Wyeth Newbridge. The purpose of the EMP is to ensure that the requirements of the Environmental, Health and Safety 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 environmental management system.

#### **3.3.1. Environmental Management Programme: Report 2003**

A review of the status of the individual Objectives and Targets detailed in the Environmental Management Programme for 2003 are outlined as follows.

##### **(i) Objective 1 - IPC Licence Requirements**

**Objective:** To achieve 100% compliance with Wyeth Newbridge IPC Licence requirements.

**Status:** During 2003 compliance was as follows:

- Wastewater 96.7%
- Air 99.6%
- Surface Water 100%
- Groundwater 100%

In the case of all of the exceedances observed relating to emissions to sewer and emissions to atmosphere, works are ongoing in order to further improve compliance with IPC licence emissions limit values for these discharges and emissions.

## **(ii) Objective 2 - Emissions to Sewer**

**Objective:** To investigate the best method(s) of reducing OC and HRT active amounts in wastewater discharge to sewer.

**Status:** An evaluation of potential treatment technologies for the reduction of Oral Contraceptive and Hormone Replacement Therapy actives in wastewater discharged to sewer was conducted. The technology selected for further investigation via a pilot plant trial is a combination of membrane bioreactor and ozone oxidation technologies.

The selection process for a laboratory capable of developing standardized wastewater extraction methods and analytical method development for the OC and HRT compounds is near completion. The implementation of this project is on schedule for completion as per the deadline specified in Condition 6.2 of IPC Licence Register No. 673 i.e. January 01/01/2006.

## **(iii) Objective 3 - Environmental Awareness**

**Objective:** To hold an Environmental Week (Quarter 4 2003) to promote environmental awareness on site. Projects to be designed by employee representative groups (Green Teams).

**Status:** To further heighten ongoing environmental awareness on site an Energy Efficiency/Environment Week was run from 6-10/10/2003. The week was organised to relay environmental information to both Wyeth Newbridge employees and contractors enlightening them of the current Irish situation and how important their continued contribution is to influencing Wyeth Newbridge environmental ethos. The week was highly successful with a range of events taking place each day.

Wyeth Newbridge non-hazardous waste contractors IPODEC Ireland Ltd., and hazardous waste contractors MinChem Environmental Services Ltd., supplied two information stands with free information leaflets. Quality Green Team/EHS assembled a further information stand providing more practical based information leaflets pertaining to composting, recycling facilities in the surrounding counties, simple methods of saving energy etc.

A most prestigious award was presented to a Wyeth Newbridge employee following nominations during environmental week for 'An Environmental Person of the Year Award'. The employee was presented with a substantial holiday voucher sponsored by IPODEC in recognition of their environmental contribution to Wyeth Newbridge.

Daily lunchtime competitions were run consisting of a word search, energy efficiency/environmental survey and crossword with prizes on offer. An art competition was organised and was open to children and grandchildren of both Wyeth Newbridge employees and contractors and also Wyeth Newbridge employees.

It is considered that every Wyeth Newbridge employee and contractors alike acquired some valuable information from Energy Efficiency/Environmental week and in some way applied it both within Wyeth Newbridge and the home.

## (iv) Objective 4 - Energy Management

**Objective:** To carry out an audit of the energy efficiency of the site and to continue to investigate energy improvement options. To meet the Energy Performance Index targets set for energy efficiency set by Sustainable Energy Ireland.

**Status:** As part of its commitment to energy efficiency on site, Wyeth Newbridge conducted an energy audit in 2003 which:

- Identified individual cost effective energy savings projects and quantified the scope for energy conservation at the site.
- Investigated the calculation of an energy performance indicator.

Wyeth Newbridge aims to implement a number of energy saving projects developed as a result of the energy efficiency audit over the period 2003 - 2006.

## (v) Objective 5 – Supply Chain Management

**Objective:** To audit Wyeth Newbridge key suppliers and investigate initiatives aimed at encouraging them to operate their businesses in an environmentally positive manner.

**Status:** The review of the response of key suppliers to a detailed Wyeth Newbridge environmental questionnaire is ongoing. Areas which have been identified for improvement in environmental are to be scheduled for discussion with these suppliers.

## (vi) Objective 6 – Communication

**Objective:** To develop a policy of open communication with interested parties through the publication of an Environmental Management Statement.

**Status:** As part of its commitment to continuous improvement, Wyeth Newbridge is committed to fulfilling the requirements of the European Eco-Management and Audit Scheme (EMAS). Following the EMAS verification conducted in November 2003, final approval was received from the Irish National Accreditation Board in May 2004. Interim statements will be produced on an annual basis as part of the EMAS verification process.

## (vii) Objective 7 – Water Recycling

**Objective:** To investigate the recycling of on site purified water for use in the water cooling towers to maintain water usage at agreed levels on site.

**Status:** A study of the potential to reuse ultra pure reject water within the cooling towers was conducted. This project has temporarily been put on hold in order to consider the viability of same. It is proposed to revisit and review this project as part of the OC and HRT wastewater treatment project.

### 3.3.2. Environmental Management Programme: Proposal 2004

Environmental objectives and targets are generated through Environmental Management System standard operating procedures. Objectives and targets are identified following identification of environmental aspects and reviewed on an annual basis as part of the Environmental Management Programme. The Wyeth Newbridge environmental objectives proposed for 2004 are outlined as follows.

- Objective 1: IPC Licence Compliance
- Objective 2: Treatment of Emissions to Sewer
- Objective 3: Environmental Awareness
- Objective 4: Energy Management
- Objective 5: Incident Elimination
- Objective 6: Efficiency of Raw Materials Use

#### (i) Objective 1: IPC Licence Compliance

It remains Wyeth Newbridge policy to aim for more than minimal compliance with IPC licence requirements and thereby demonstrate commitment to continual improvement.

#### (ii) Objective 2: Treatment of Emissions to Sewer

Wyeth Newbridge aims, during Quarter 2-3 2004, to complete a pilot plant trial on the reduction of Oral Contraceptive and Hormone Replacement Therapy actives in wastewater discharged to sewer. This investigation will involve a review of results generated on the removal efficiency of a pilot plant which incorporates membrane bioreactor and ozone oxidation technologies.

#### (iii) Objective 3: Environmental Awareness

Following the success of the Environmental Week conducted in October 2003, Wyeth Newbridge, through its employee environmental groups (Green Teams), aims to supplement ongoing environmental awareness initiatives on-site by holding an Environmental, Health and Safety Week in Quarter 4 2004.

#### (iv) Objective 4: Energy Management

Wyeth Newbridge aims to reduce water and energy consumption and improve the efficiency of on-site operations. As an objective, Wyeth Newbridge aims to continue the implementation of a number of energy saving projects developed as a result of the energy efficiency audit conducted in 2003 including:

- Optimisation of MTHW controls.
- Upgrading of Boiler controls.
- Installation of variable speed drive combustion fans.
- Optimisation of HVAC set points.
- Chiller and cooling tower sequencing.
- Upgrading of high frequency lighting.

The following feasibility studies will be conducted in 2004:

- Potential for recycling of on site treated water for use in the water cooling towers.
- Monitoring programme for energy usage and water consumption at each operational building or manufacturing area at Wyeth Newbridge.

**(v) Objective 5: Incident Elimination**

Wyeth Newbridge aims to prepare a specification and test programme for the Solvent Recovery System which will significantly reduce the potential of accidents and/or incidents with the potential for environmental consequences.

**(vi) Objective 6: Efficiency of Raw Materials Use**

Wyeth Newbridge aims to ascertain if more sustainable forms of production and raw material consumption can be adopted at the site (product and process improvement). To this end it is proposed to identify opportunities to improve the environmental aspects of products at various points in the product life cycle from raw material acquisition to final disposal.

## 4. ENVIRONMENTAL MONITORING DATA

### 4.1. EMISSIONS TO SEWER

The overall wastewater discharge from the Wyeth facility (WP1) is made up of contributions from two separate wastewater streams, namely process (WP3) and domestic wastewaters. *Schedule 2(iii) Monitoring of Emissions to Sewer* of IPC Licence Register No. 581 required Wyeth Newbridge to monitor emissions to sewer at Emission Point Reference No. WP1 and WP3.

Flowrates and contaminant concentration levels/ranges were generally within the emission limit values specified within *Schedule 2(i) Emissions to Sewer* of the IPC licence apart from selected isolated exceedances. In 2003 Wyeth Newbridge recorded 53 individual exceedances out of 1587 determinations (refer to Table 4.1a and 4.1b).

Table 4.1a: Summary of Emissions to Sewer (WP1) Non-Compliances 2003

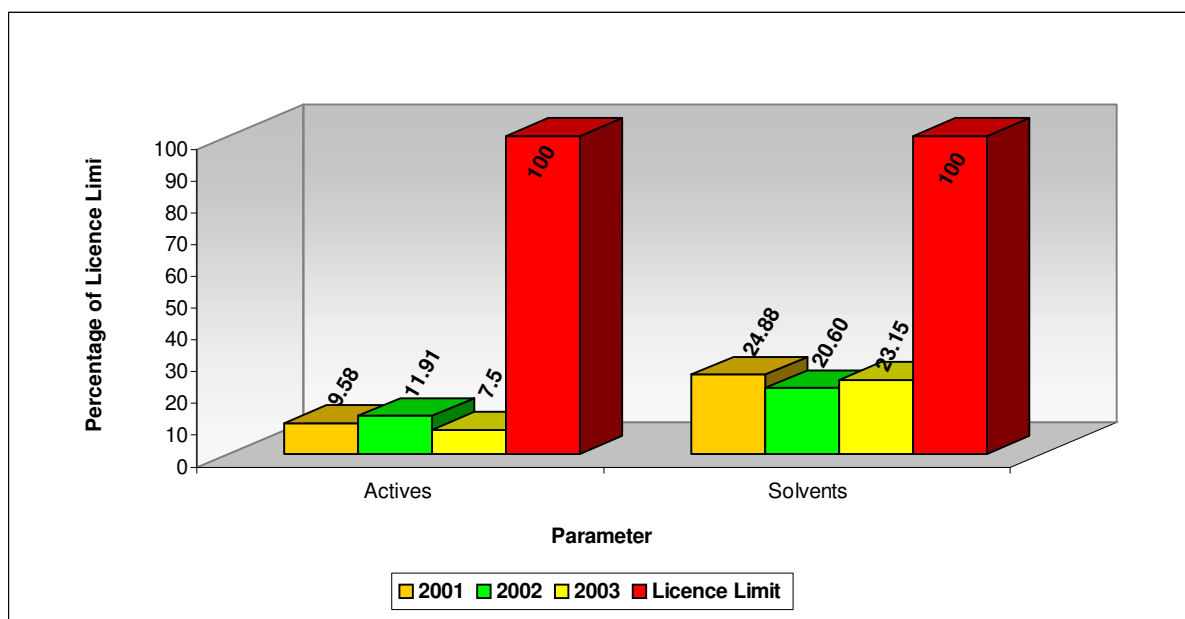
Date	Non-Compliance	Cause	Corrective Action
<b>Temperature</b>			
01/07/03, 03/07/03, 05/07/03, 31/07/03, 06/08/03, 12/08/03, 20/08/03, 22/08/03, 26/08/03, 28/08/03,	02/07/03, 04/07/03, 08/07/03, 01/08/03, 07/08/03, 19/08/03, 21/08/03, 23/08/03, 27/08/03, 29/08/03.	36 v. 30°C, 36 v. 30°C, 38 v. 30°C, 36 v. 30°C, 36 v. 30°C, 32 v. 30°C, 32 v. 30°C, 34 v. 30°C, 34 v. 30°C, 35 v. 30°C, 31 v. 30°C, 35 v. 30°C, 34 v. 30°C, 32 v. 30°C, 32 v. 30°C, 30.5 v. 30°C, 32 v. 30°C, 32 v. 30°C, 30°C, 31 v. 30°C, 33 v. 30°C.	Temporary increase in water temperature required to ensure maintenance of validated cleaning in processing.
Engineering solutions currently under review. Issue has been discussed with EPA and Kildare County Council.			
<b>Ammonia</b>			
29/01/03	31 mg/l v. 30 mg/l	Unknown	Additional monitoring carried out for days following exceedance. No reoccurrence of elevated levels during this period.
<b>Sodium</b>			
26/02/03	278 mg/l v. 250 mg/l 69.2 kg/l v. 45 kg/d	Backwashing of new purified water system with salt solution in combination with discharge from existing water treatment unit operating during the same period.	These operations to be timed so that they will not operate simultaneously.
27/08/03	59.7 kg/d v. 45 kg/d.	On investigation cause not apparent.	Detailed monitoring programme initiated.
22/10/03, 19/11/03	05/11/03, 66.7 kg/d v. 45 kg/d. 49.9 kg/d v. 45 kg/d. 63.4 kg/d v. 45 kg/d.	Backwashing of purified water system identified.	Detailed monitoring programme initiated. Mass balance of the use of salt for softening carried out. Dosing Parameters changed on units.

Table 4.1b: Summary of Emissions to Sewer (WP1) Non-Compliances 2003 (continued)

Date	Non-Compliance	Cause	Corrective Action
<b>Chloride</b>			
26/02/03	407 mg/l v. 150 mg/l. 101 kg/d v. 45 kg/d.	Backwashing of new purified water system with salt solution in combination with discharge from existing water treatment unit operating during the same period.	These operations to be timed so that they will not operate simultaneously.
27/08/03	47.5 kg/d v. 45 kg/d.	On investigation cause not apparent.	Detailed monitoring programme initiated.
18/10/03, 19/11/03.	05/11/03, 153.2 mg/l v. 150 mg/l 50.7 kg/d v. 45 kg/d. 156.6 mg/l v. 150 mg/l 54.4 kg/d v. 45 kg/d.	Backwashing of purified water system identified.	Detailed monitoring programme initiated. Mass balance of the use of salt for softening carried out. Dosing Parameters changed on units.
<b>Sulphate</b>			
27/08/03	116.4 mg/l v. 100 mg/l 40.4 kg/d v. 30 kg/d	Overdosing of sulphuric acid at pH neutralisation station.	New control system installed came into operation in January 2004.
10/09/03	35.2 kg/d v. 30 kg/d	Overdosing of sulphuric acid at pH neutralisation station.	New control system installed came into operation in January 2004.
19/11/03	31.5 kg/d v. 30 kg/d.	Overdosing of sulphuric acid at pH neutralisation station.	New control system installed came into operation in January 2004.

A comparison of individual parameters expressed as a percentage of the licensed yearly mass emission value is presented in Figure 4.1, 4.2, 4.3 and 4.4 respectively. These graphs indicate that, as for 2001 and 2002, the mass emission for the parameters monitored in 2003 continue to be significantly within the IPC Licence emission limit values.

Figure 4.1 Emissions to Sewer (Actives & Solvents <sup>Note 1</sup>) as a Percentage of IPC Licence Limit - Yearly Mass Emissions



**Note 1** Solvents refer specifically to Dichloromethane for which an Emission Limit Value is specified in *Schedule 2(i) Emissions to Sewer* of IPC Licence Register No. 581.

Figure 4.2 Emissions to Sewer (BOD, COD, SS, OFG) as a Percentage of IPC Licence Limit - Yearly Mass Emissions

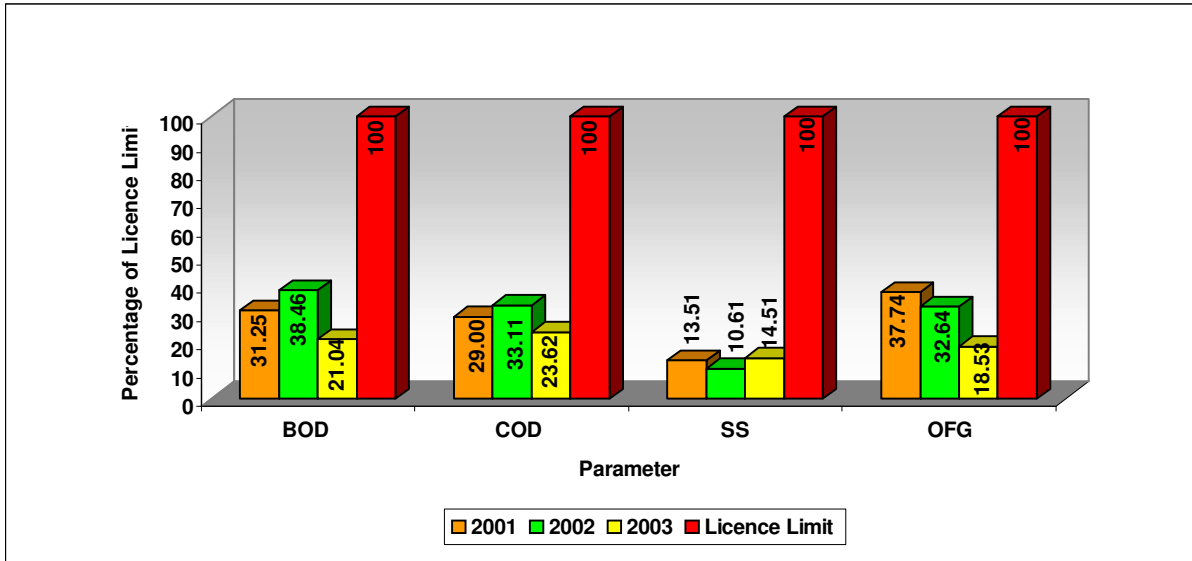


Figure 4.3 Emissions to Sewer (Total Phosphate, Total Nitrogen, Ammonia) as a Percentage of IPC Licence Limit - Yearly Mass Emissions

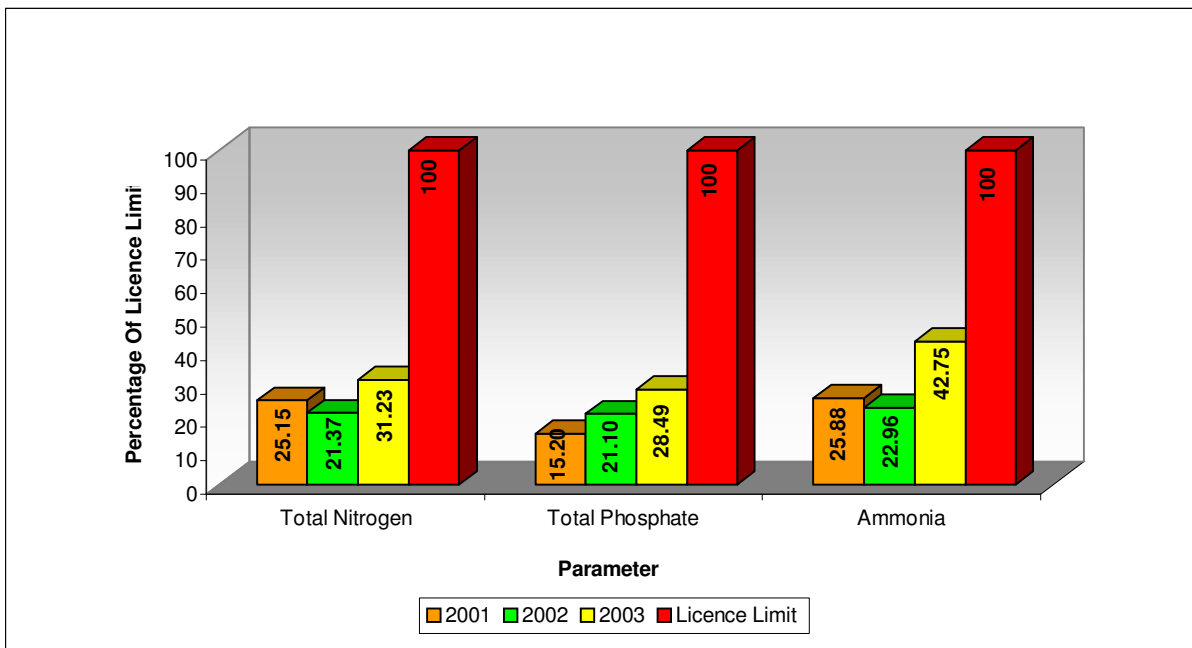
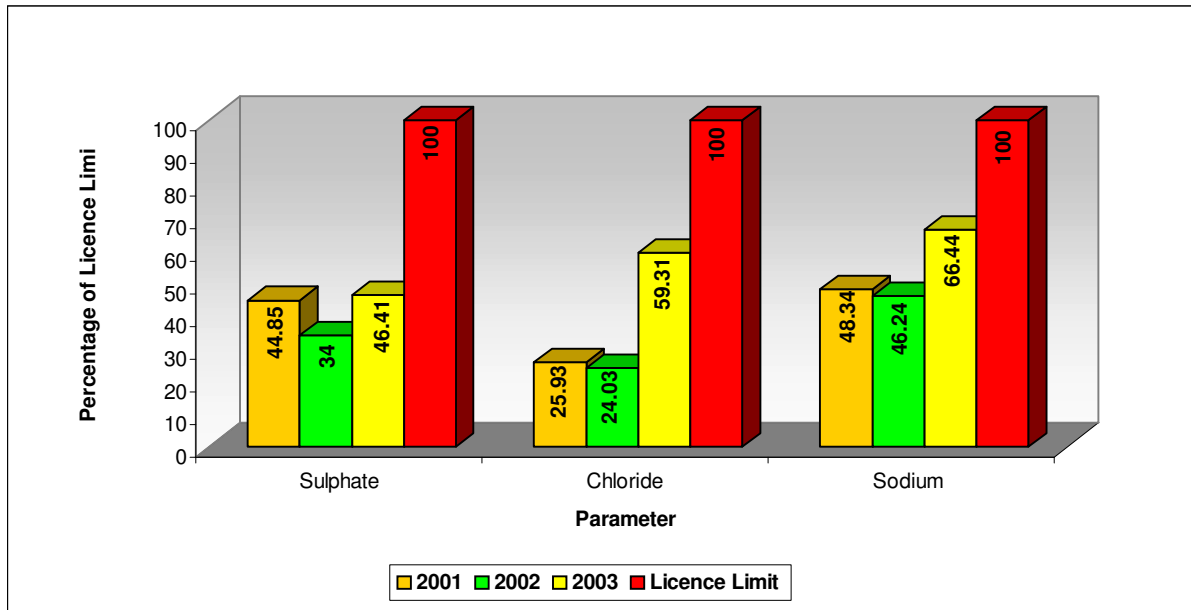


Figure 4.4 Emissions to Sewer (Sulphate, Chloride, Sodium) as a Percentage of IPC Licence Limit - Yearly Mass Emissions



All wastewater arisings (treated) from the Wyeth Newbridge facility are discharged to Osberstown municipal wastewater treatment plant. In summary, results indicate that the effluent discharge from the Wyeth Newbridge facility is unlikely to have a significant impact on the performance of the municipal sewage treatment works.

**4.2. SURFACE WATER DISCHARGE**

*Schedule 4(i) Surface Water Discharge Monitoring* of IPC Licence Register No. 581 required Wyeth Newbridge to monitor the final discharge point of surface water from the site (Emission Point Reference No. WP2). Results indicate that the surface water discharge (surface water run-off from hardstanding areas following a rainfall event) from the Wyeth Newbridge facility is unlikely to impact on the receiving waters into which it ultimately discharges (i.e. River Liffey).

**4.3. GROUNDWATER**

*Schedule 4(ii) Groundwater Monitoring* of IPC Licence Register No. 581 required Wyeth Newbridge to monitor the groundwater quality at Emission Point Reference No. MW1S, MW2S, MW3S and MW4S on a bi-annual basis. Results indicate groundwater of good chemical quality with no pharmaceutical actives or organic solvents detectable.

**4.4. EMISSIONS TO ATMOSPHERE**

*Schedule 1(iii) Monitoring of Emissions to Atmosphere* of IPC Licence Register No. 581 required Wyeth Newbridge to monitor various air emission points (major emissions and boiler emissions) for parameters including Dust, Flue Gas Emissions (NO<sub>x</sub>, CO) and Volatile Organic Compounds (VOCs - TA Luft Class I, TA Luft Class III). Summary details (total mass emissions for Dust, NO<sub>x</sub>, CO, and VOCs) for air emissions for the period January - December 2003 are presented Figures 4.5 – 4.6. As indicated Newbridge has maintained or restored compliance with the annual mass emission limits for the Dust, NO<sub>x</sub>, CO, and VOCs parameters.

In 2003 Wyeth Newbridge recorded 2 individual exceedances out of 554 determinations which were recorded for the gas fired CHP plant boiler emission (Table 4.2) for the CO and NO<sub>x</sub> parameters. These exceedances are attributable to the CHP plant burning inefficiently. Engineering works are ongoing in order to improve the efficiency of the CHP plant. It should be noted that the CHP plant is not considered as a boiler/burner unit but rather an engine as the technology works by generating power in association with low grade heat. Therefore, imposing of emission limit values relevant to boilers is not appropriate for CHP.

Table 4.2: Summary of Emissions to Atmosphere Non-Compliances 2003

Date	Non-Compliance	Cause	Corrective Action
25/06/03	CO - ELV (963 mg/Nm <sup>3</sup> ) v. 100 mg/nm <sup>3</sup>	CHP burning inefficiently.	Review with service engineers and increase efficiency.
	NO <sub>x</sub> as NO <sub>2</sub> - ELV (277 mg/Nm <sup>3</sup> ) v. 200 mg/nm <sup>3</sup>	CHP burning inefficiently.	Review with service engineers and increase efficiency.

Figure 4.5 Emissions to Air (TA Luft Class I, TA Luft Class III) as a Percentage of IPC Licence Limit - Yearly Mass Emissions

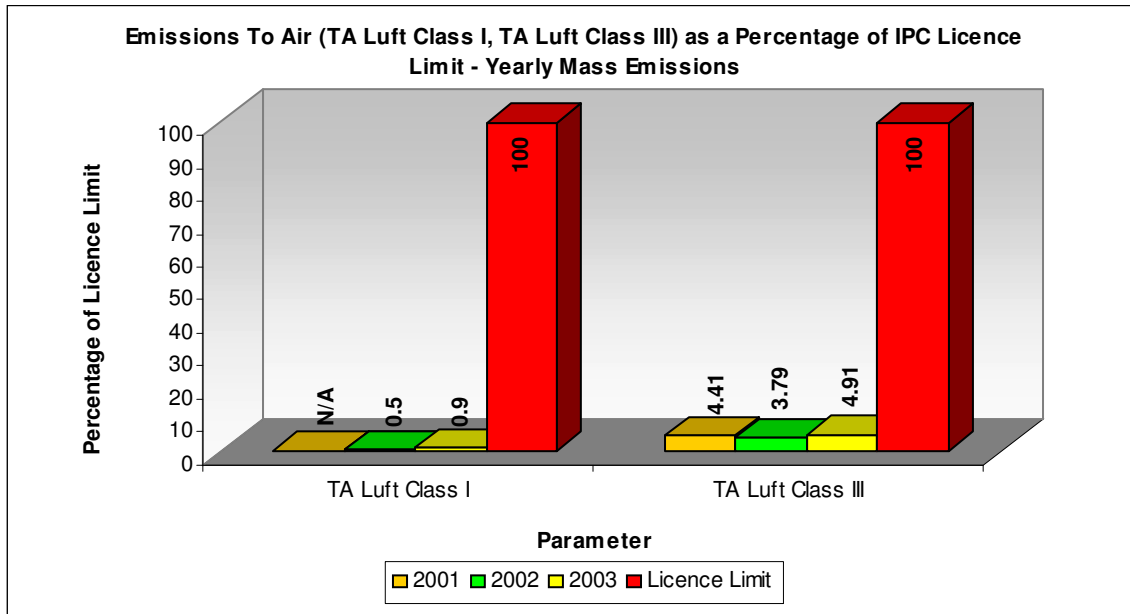
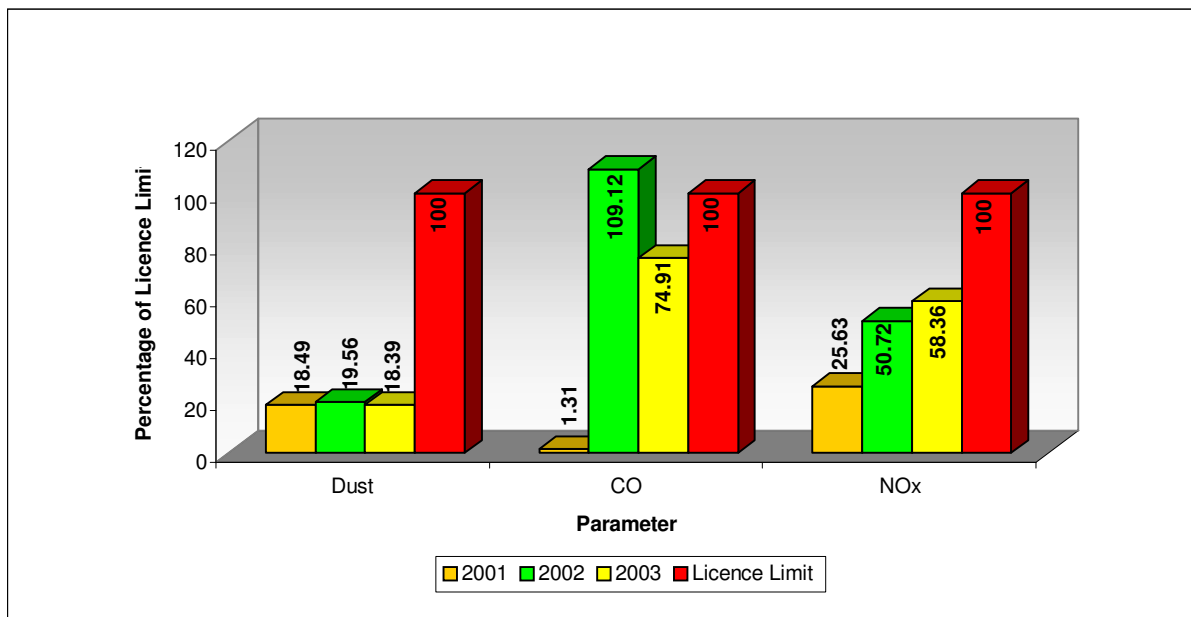


Figure 4.6 Emissions to Air (Dust, CO, NO<sub>x</sub>) as a Percentage of IPC Licence Limit - Yearly Mass Emissions



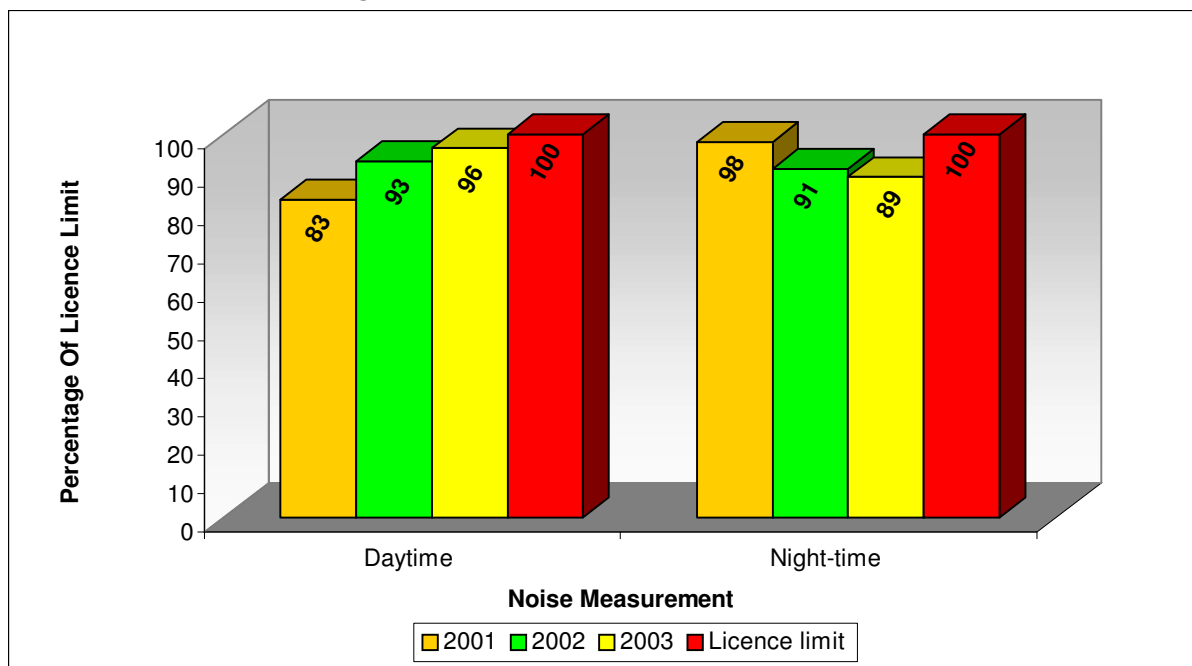
**4.5. NOISE**

*Condition 8 Noise* of IPC Licence Register No. 581 required Wyeth Newbridge to undertake a noise survey at the site on an annual basis. Results indicate that the noise generated at the Wyeth Newbridge site does not have any undesirable effects on the existing neighbouring environment i.e. daytime and night-time limits [ $L_{eq, 15 mins}$  55dB(A) and 45 dB(A) respectively] are maintained at the nearest sensitive locations (Noise Monitoring Locations N1, N2 and N3).

No audible tonal or impulsive component from noise emissions emanating from the Wyeth Newbridge facility was recorded at Noise Monitoring Locations N1, N2 and N3 during the noise survey.

Over the last 3 years, 2001 – 2003, Wyeth Newbridge has consistently maintained noise emission levels from the site below the required IPC licence daytime and night-time limit levels (refer to Figure 4.7).

Figure 4.7 Daytime and Night-time Noise Emissions at the Nearest Noise Sensitive Monitoring Location N1 as a Percentage of IPC Licence Limits



**4.6. WASTE MANAGEMENT DATA**

Details of the individual waste fractions sent off-site for treatment including disposal and recycling by appropriately licenced waste management contractors, for the period January - December 2002 and 2003 are presented in Table 4.3. A review of waste management records confirms that certificates of destruction are available for all hazardous waste transported off-site.

Table 4.3 Waste Volumes Sent Off-Site for Treatment 2002 - 2003

Description of Waste	Quantity (Tonnes) 2002	Quantity (Tonnes) 2003
<b>Hazardous</b> <sup>Note 1</sup>		
Disposed	1529	2083
Recovered	122 <sup>Note 3</sup>	516 <sup>Note 4</sup>
<b>Non-Hazardous</b> <sup>Note 2</sup>		
Disposed	1239	694
Recovered	689	627

**Note 1** This waste fraction comprises of solid and liquid hazardous waste including out of specification tablets/granulate, packaging in contact with actives/tablets, disposable masks and gloves and material cleaned or vacuumed from the processing area as well as solvent waste, coating/rinse waters containing active, engineering maintenance oils and clinical waste.

**Note 2** This waste fraction comprises of solid and liquid non-hazardous waste including canteen waste, paper and cardboard, plastics and metal, which include aluminium foil, aluminium cans and general metals.

**Note 3** This waste fraction comprises of non-hazardous and hazardous sugar solution.

**Note 4** This waste fraction comprises of waste oil, lead-acid batteries, spent fluorescent tubes, and contaminated soil.

Wyeth Newbridge’s long-term objective is, where possible, to decrease raw material usage and increase the recycling of the waste materials thereby reducing the quantities of waste requiring disposal and/or treatment.

Over the period 2001-2003 Wyeth Newbridge has put in place various mechanisms to maximise the quantity of waste undergoing recycling. The success of these programmes is reflected in the continued improvements in the quantity of material being recycled over this period. While the initial programme was very much focused on the recycling of paper and cardboard current programmes include the recycling of metal, plastics, batteries, fluorescent tubes and wood pallets.

645 tonnes of domestic/canteen waste was generated at Wyeth Newbridge during the year 2003. This represents a 45% decrease on the 2002 canteen waste arisings. This decrease is partly attributable to the canteen’s procurement programme on foodstuffs which aims to purchase smaller quantities of foodstuffs on a more frequent basis thereby reducing the requirement to dispose of expired product.

Wyeth Newbridge has introduced new initiatives for the logging and labelling of both its liquid (solvent, hazardous and non-hazardous liquids) and solid hazardous waste. All waste generated in each area is logged on a daily basis with a monthly summary report produced. This monthly report forms the basis for the allocation of costs to the Focus Factory based on the volume and cost of the waste produced for each area.

**4.7. ENERGY & WATER CONSUMPTION**

Tables 4.4, 4.5 and 4.6 show a summary of the energy and water usage at Wyeth Newbridge for January – December 2002 and 2003. A significant quantity of water is consumed in daily washdown activities, namely wet washing of blending bins/pans, washing of utensils/small items and washing of pallets.

Table 4.4: Gas Usage 2002 - 2003

User	Site Consumption (MWh)	
	2002	2003
Boilers	53,313	60,308
CHP	34,914	27,268
<b>Total</b>	<b>88,226</b>	<b>87,576</b>

Table 4.5: Electricity Usage 2002 - 2003

User	Site Consumption (MWh)	
	2002	2003
Purchased Electricity	30,937	38,584
CHP Generated Electricity <sup>Note 1</sup>	12,085	9,240
<b>Total</b>	<b>43,022</b>	<b>47,824</b>

**Note 1** Calculated on the basis of a 2.7 MWh electricity output for the CHP plant

Table 4.6: Water Usage 2002 – 2003

Source	Site Consumption (m <sup>3</sup> /yr)	
	2002	2003
Municipal Water	158,412	160,888

**4.8. ENVIRONMENTAL INCIDENTS / COMPLAINTS & EPA ENFORCEMENT**

**4.8.1. Environmental Incidents**

***Incident No. 1***

On 25/03/2003, there was a discrete release of insulating oil to ground, from a tank on one of the transformers within the ESB substation site located on the Wyeth Newbridge facility. Wyeth Newbridge immediately notified the EPA and engaged Bord na Móna Environmental Ltd., to investigate the nature and extent of the release. In conjunction with the ESB the contaminated material (subsurface sediments) was removed. The results of the soil sampling undertaken indicated low levels of oil within the subsurface and no levels were detected in the groundwater samples taken from on-site monitoring boreholes. Following agreement with the EPA the contaminated soil was transferred off-site to Atlas Oil for treatment/disposal.

## ***Incident No. 2***

An emission to air occurred on 08/10/2003 when there was a malfunction in the HEPA Filter associated with the Fluid Bed Dryer serving the tranquilliser production area (TB-6). The malfunction was recorded on the Building Management System and resulted in the shut down of this emission. The EPA was immediately informed and the incident was documented. It was noted there was no significant discharge of material to atmosphere.

### **4.8.2. Environmental Complaints**

Wyeth Newbridge have received no complaints of any nature in 2003.

### **4.8.3. EPA Enforcement**

An EPA Inspector carried out a site inspection of the Wyeth Newbridge facility on 19/09/2003. There were no non-compliances reported in the IPC Licence Site Inspection Report.

## **5. CONCLUDING REMARKS**

The Wyeth Newbridge facility has been designed and is operated in such a manner that the potential emissions (wastewater, surface water, air) to the environment are reduced or eliminated. In addition, the BAT principle continues to be implemented during the operation phase of the site with respect to the management of the facility. It is contended that the risk of environmental contamination as a result of both existing activities and potential accidental or emergency situations at the Wyeth Newbridge facility are minimised or eliminated by adherence to the existing protection programmes. The Environmental Monitoring Programme carried out over the 2003 reporting period shows no adverse environmental impact on the environmental media into which discharges from the Wyeth Newbridge facility are made.

All of the objectives and targets set out in the company's schedule of Environmental Objectives for 2003 were achieved.

It is the policy of Wyeth Newbridge 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 and Safety Policy. The success of this policy is reflected by:

- The accreditation of the Wyeth Newbridge facility to the EMAS Regulation;
- Ongoing compliance with ISO14001 Environmental Management System certification; and,
- The 2003 EPA inspection conducted at the site which was fully compliant.

## **6. VERIFIERS DECLARATION**

Further to consideration of the documentation, data and information resulting from internal procedures examined during the verification process at Wyeth Medica Ireland, it is evident that the Environmental Policy Programme Management System Review (or Audit Procedure) and Environmental Statement meet the requirement of Regulation 761/01 (the EMAS Regulation).

**Signed:**

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Amanda Thorpe

SGS United Kingdom Ltd.,  
 SGS House,  
 217/221 London Road,  
 Camberley, Surrey, GU15 3EY,  
 United Kingdom.

(Accreditation No: UK-V-0007)

**Date:**

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This EMAS Statement will be updated annually. The next full Environmental Statement will be submitted to the verifier no later than November 2006.

### **Site Details**

**Company Name:** Wyeth Medica Ireland

**Site Area:** 120 acres

**Industry Sector (NACE Code):** DG 24.2

**Activity:** Formulation and packaging of pharmaceutical tablets, capsules and vial / ampoule packing.

**Further Information:** Further information regarding the contents of this Environmental Statement is available from Dr. Michael Donlon or Dr Edward Molyneaux at 00353-45-447000