Novartis Ringaskiddy Limited

Annual Environmental Report 2009

01-April-2010

EMAS

Novartis Ringaskiddy Limited

Annual Environmental Report 2009

IPPCL Register Number P0006-03

Schedule of Environmental Objectives and Targets - 2009

Environmental Management Programme - Proposal

Environmental Management Programme - Report

Section 4: Licence Specific Reports:

Groundwater Monitoring Summary

Noise Monitoring Report

Report on List I and II Substance Reductions

Tank and Pipeline Testing and Inspection Report

Energy Audit Report

Effluent Toxicity Report

Environmental Liability Risk Assessment (Update)

Novartis Ringaskiddy Limited

Annual Environmental Report 2009

IPPCL Register Number P0006-03

Section 1: Introduction:

IPPCL Register Number

Name and Location of the Site

Description of Activities at the Site

Company Environmental Policy

Company Organisation Chart for Environmental Management

Current Site Plan

IPPCL Register Number: P0006-03

Name and Location of Site:

Novartis Ringaskiddy Limited

Ringaskiddy

County Cork

Ireland

Description of Activities at the Site:

Industry Sector (NACE Code): D24.41

Activity: Manufacture of basic pharmaceutical products

Novartis Ringaskiddy Limited is engaged in the manufacture of active substances for speciality drugs used in the treatment of immunologic, dermatologic, cardiovascular, oncological and central nervous system diseases.

Identification of the relevant activities in the First, Third or Fourth Schedule of the Protection of the Environment Act 2004 to which the activity relates:

Schedule: 1
Class: 5.16
Description: The use of a chemical or biological process for the production of basic pharmaceutical products

Schedule: 1
Class: 11.1
Description: The recovery or disposal of waste in a facility, within the meaning of the Waste Management Act of 1996, which facility is connected or associated with another activity specified in this Schedule in respect of which a licence or a revised licence under Part IV is in force or in respect of which a licence under the said Part is or will be required

Company Environmental Policy:

The company's environmental policy is reproduced in full on the following page.

Novartis Ringaskiddy Limited Health, Safety and Environment Policy

As a member of the Novartis Group of companies Novartis Ringaskiddy Limited wants to be known for being a responsible corporate citizen. This means that we do everything that we can to operate in a manner that is sustainable: Economically, socially and environmentally - in the best interest of long-term success for our enterprise. We expect all our employees to implement this policy and the Group policy on Corporate Citizenship.

We integrate Health, Safety and Environmental Protection into our business strategies to add value to the enterprise, to manage risk and to enhance the reputation of the company.

- The health and safety of our employees, neighbours, customers and consumers, and the protection of the environment are company priorities consistently pursued at all levels in the organisation.
- We take HSE into account in all business decisions and activities. All departments establish proper structures and allocate sufficient resources in order to live up to this policy.
- Each employee shall comply with the HSE guidelines and the laws applicable to their area of operational responsibility.

We want to be a leader in Health, Safety and Environmental Protection by managing these disciplines actively, consistently and efficiently.

- We strive for continual improvement in our HSE performance. We measure progress and verify compliance with Novartis Corporate HSE guidelines and National regulatory requirements through audits and management reviews. To this end we set clear annual objectives and targets, which are assessed on an on-going basis.
- We foster awareness and a sense of responsibility for HSE among our employees; to this end we provide appropriate information and training and develop their HSE skills.
- We optimise the use of natural resources and minimise the environmental impact of our activities so as to conduct our business in as sustainable a manner as is possible.
- We assess HSE implications to ensure that the benefits of manufacturing new products and introducing new technologies and processes outweigh remaining risks.

We care about the expectations and concerns of our stakeholders.

- We provide our employees with safe workplaces. We promote programmes to maintain or improve the health of our employees.
- We cooperate with our suppliers and contractors and offer assistance to enable them to achieve an HSE performance matching our own.
- We recognise the interest of our employees, neighbours, customers, the authorities and the public at large in our societal behaviour; and the HSE impacts of our business. We provide relevant information and actively listen to stakeholders. We openly communicate and provide the information necessary to understand the risks and effects of our operations on health, safety and the environment.

J. B. Alexander

J. Alexander, 10-Mar-2006
Managing Director, Novartis Ringaskiddy Limited

Company Organisation Chart for Environmental Management:

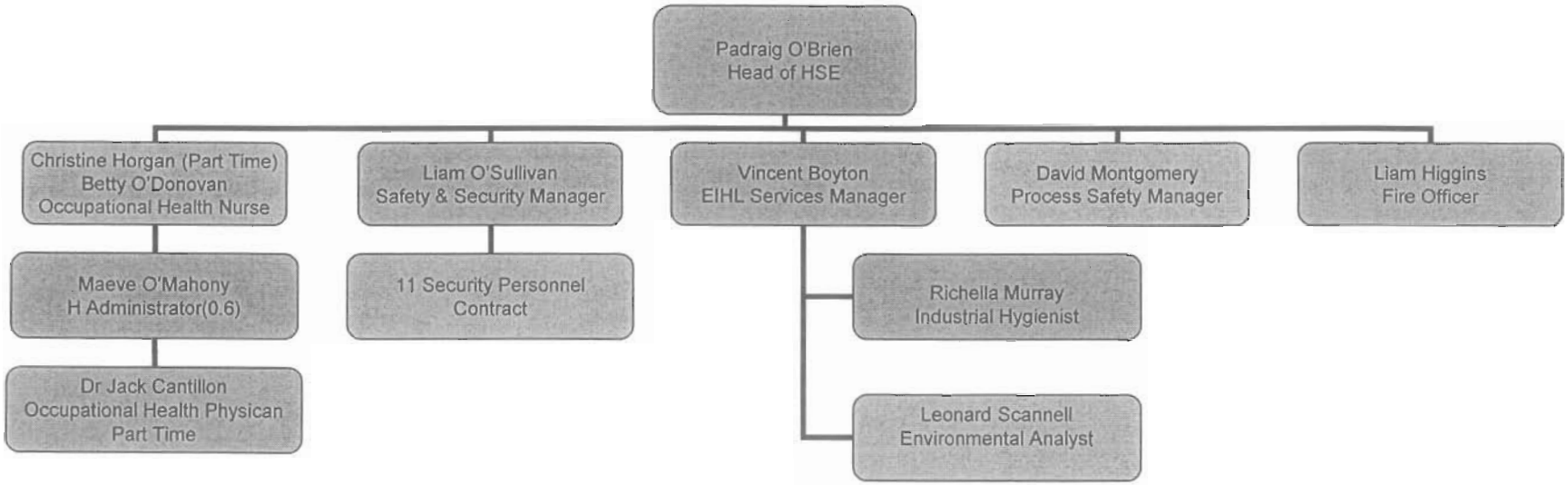
An overall company organisation chart is reproduced on the following page. Organisation charts follow this in turn for the two functions involved in day-to-day environmental management:

The Health, Safety and Environmental Protection (HSE) Function, which is involved in regulatory aspects of environmental management; and

The Technical Services Function, which is involved in the day-to-day operation of environmental protection modules at the facility.

Novartis Ringaskiddy Limited
Health Safety & Environment (HSE)

Issue Date: 16 Jan 2009
Revision Number: 25
Approved By: Padraig O'Brien



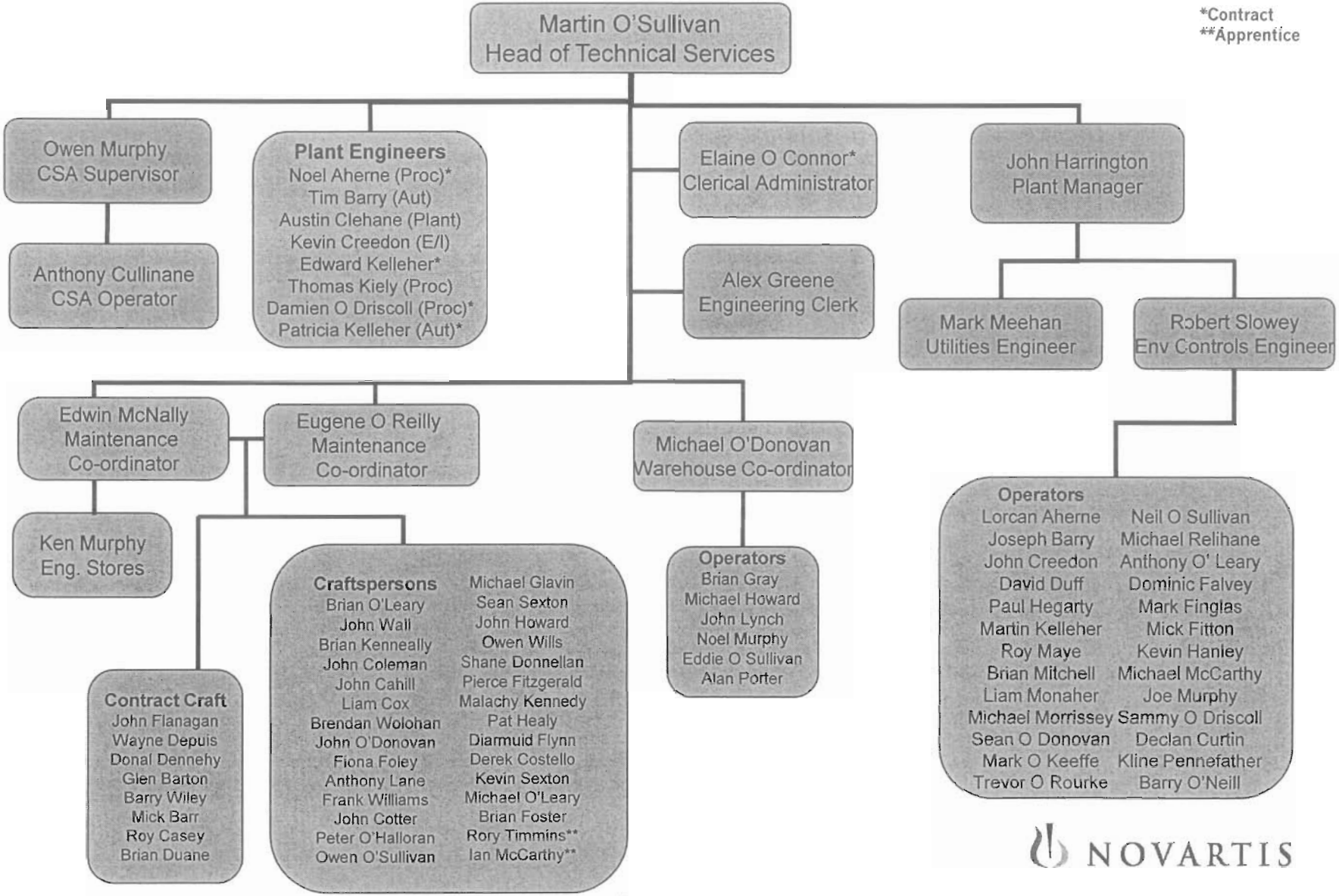
NOVARTIS

Novartis Ringaskiddy
Technical Services

Issue date: 25-Feb-2010

Prepared by: Alex Greene

*Contract
**Apprentice



NOVARTIS

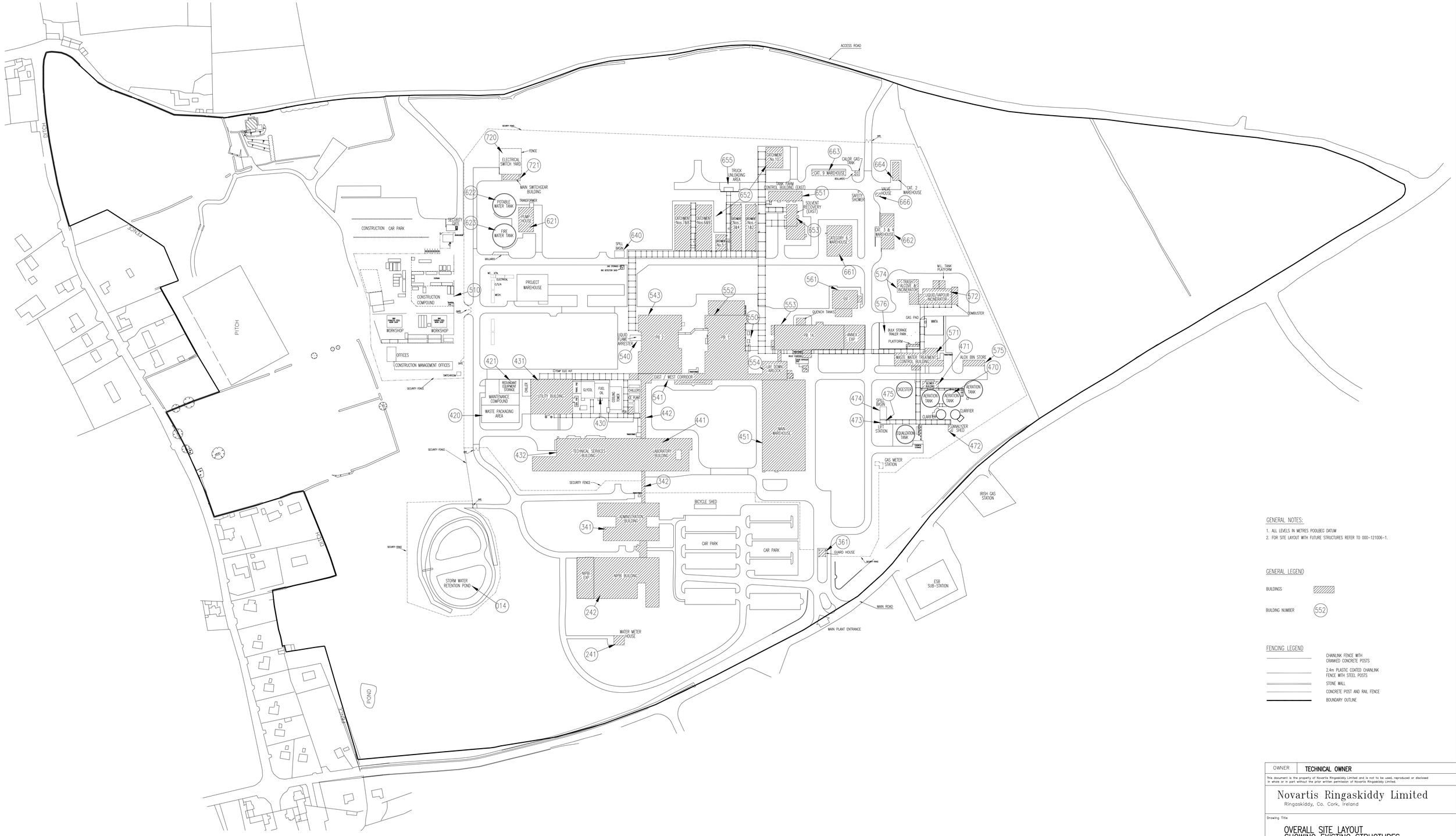
Updated Site Plan

The current site plan (drawing number 000-121005-1 Rev 16) is reproduced as an insert overleaf.

Also included are:

Drawing Number 000-517043-1 Rev 1 'Main Emission Points with Irish Grid Projection; and

Drawing Number 000-517044-1 Rev 0 'Main Sampling and Monitoring Points with Irish Grid Projection.



GENERAL NOTES:

1. ALL LEVELS IN METRES POOLBEG DATUM
2. FOR SITE LAYOUT WITH FUTURE STRUCTURES REFER TO 000-121006-1.

GENERAL LEGEND

BUILDINGS

BUILDING NUMBER (552)

FENCING LEGEND

- CHAINLINK FENCE WITH CRANKED CONCRETE POSTS
- 2.4m PLASTIC COATED CHAINLINK FENCE WITH STEEL POSTS
- STONE WALL
- CONCRETE POST AND RAIL FENCE
- BOUNDARY OUTLINE

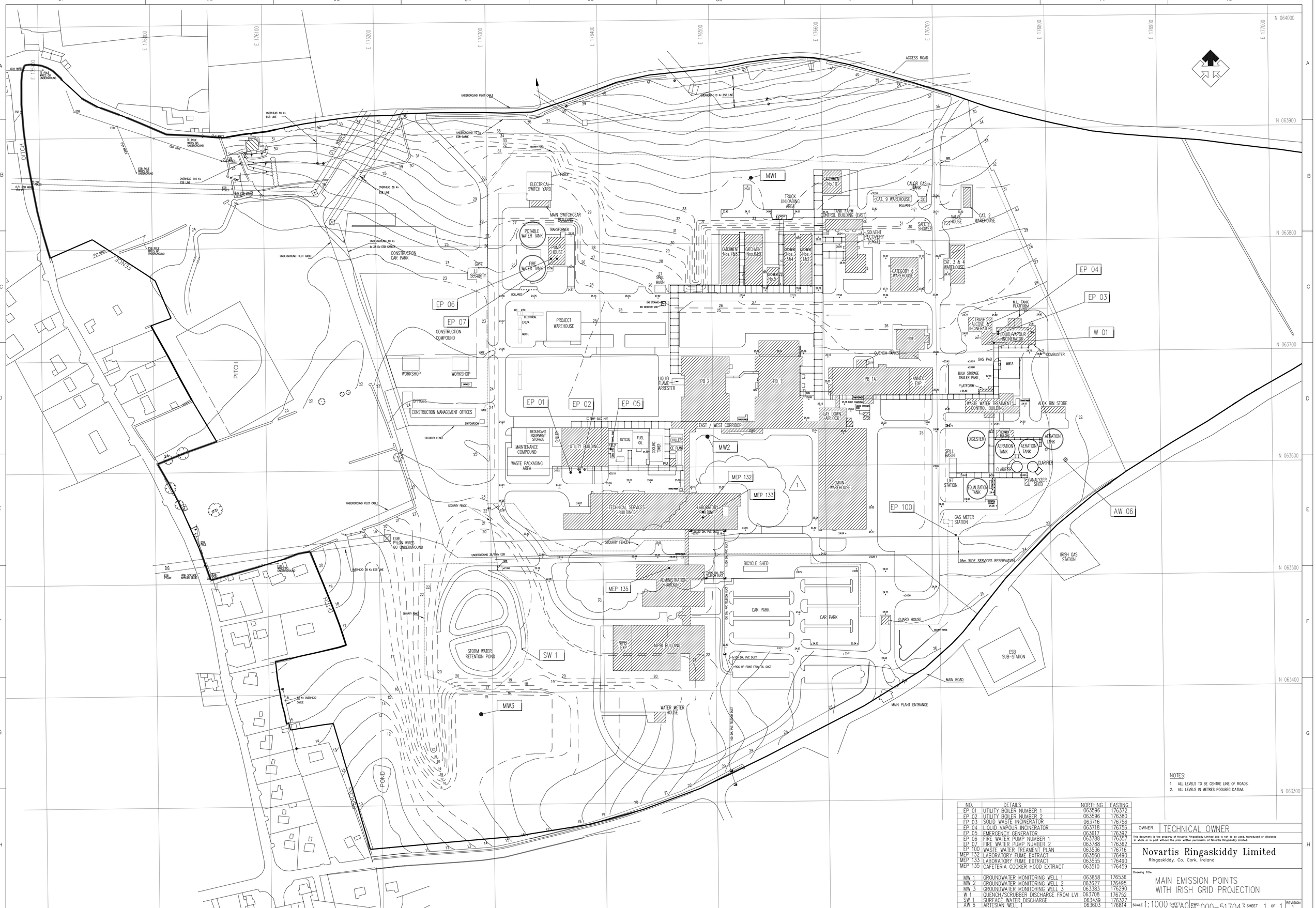
OWNER	TECHNICAL OWNER

Novartis Ringaskiddy Limited
Ringaskiddy, Co. Cork, Ireland

Drawing Title

OVERALL SITE LAYOUT
SHOWING EXISTING STRUCTURES

SCALE	SHEET SIZE	DWG. NO.	SHEET	OF	REVISION
1:1250 DO NOT SCALE	A0	000-121005	1	1	17



NOTES:

1. ALL LEVELS TO BE CENTRE LINE OF ROADS.
2. ALL LEVELS IN METRES POOLBEG DATUM.

NO.	DETAILS	NORTHING	EASTING
EP 01	UTILITY BOILER NUMBER 1	063596	176372
EP 02	UTILITY BOILER NUMBER 2	063596	176380
EP 03	SOLID WASTE INCINERATOR	063716	176756
EP 04	LIQUID VAPOUR INCINERATOR	063718	176756
EP 05	EMERGENCY GENERATOR	063617	176392
EP 06	FIRE WATER PUMP NUMBER 1	063788	176357
EP 07	FIRE WATER PUMP NUMBER 2	063788	176362
EP 100	WASTE WATER TREAMENT PLAN	063536	176716
MEP 132	LABORATORY FUME EXTRACT	063560	176490
MEP 133	LABORATORY FUME EXTRACT	063555	176490
MEP 135	CAFETERIA COOKER HOOD EXTRACT	063510	176459
MW 1	GROUNDWATER MONITORING WELL 1	063858	176536
MW 2	GROUNDWATER MONITORING WELL 2	063627	176495
MW 3	GROUNDWATER MONITORING WELL 3	063383	176290
W 1	QUENCH/SCRUBBER DISCHARGE FROM LVI	063708	176752
SW 1	SURFACE WATER DISCHARGE	063439	176327
AW 6	ARTESIAN WELL 1	063603	176814

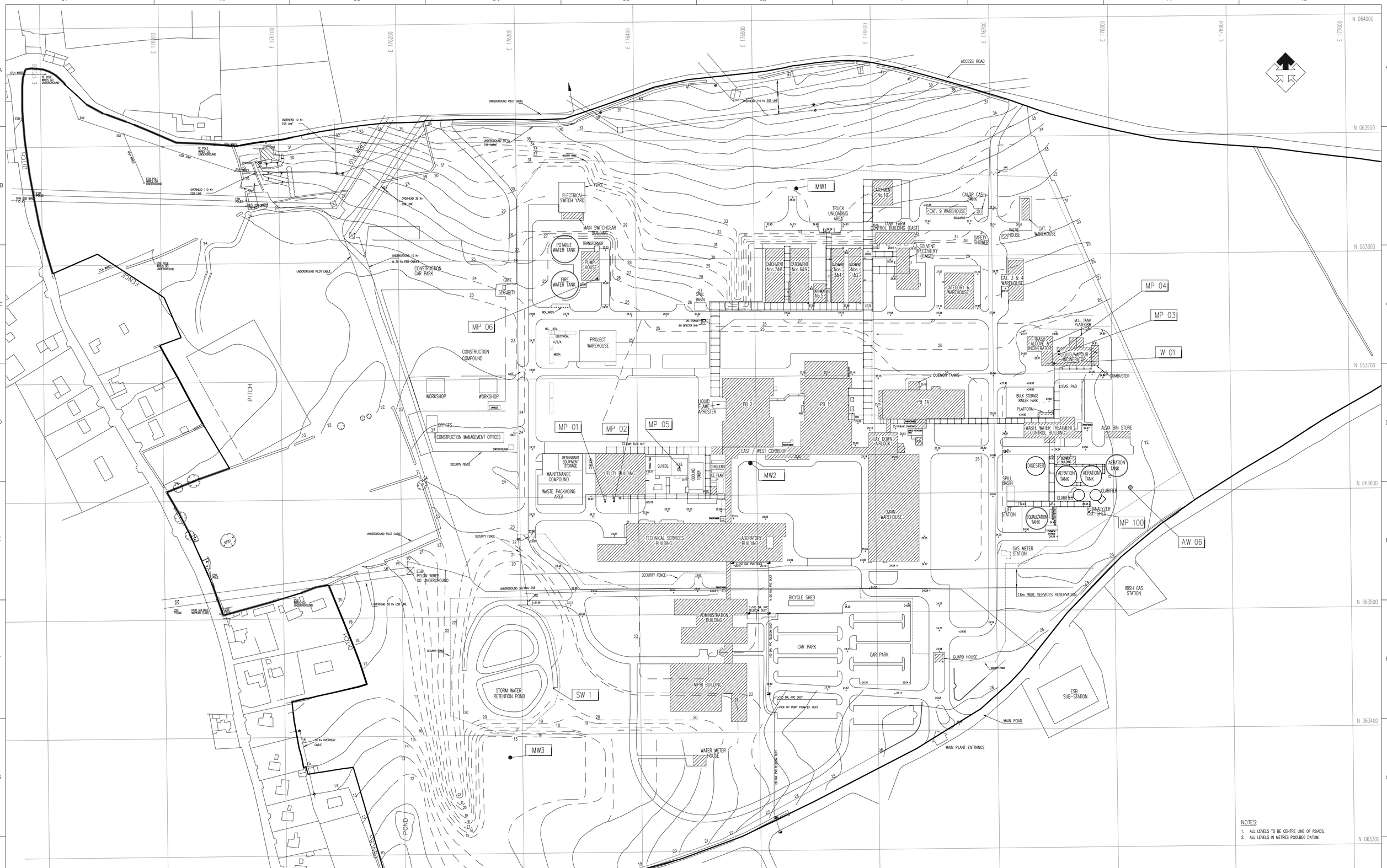
OWNER TECHNICAL OWNER

Novartis Ringaskiddy Limited
Ringaskiddy, Co. Cork, Ireland

Drawing Title

MAIN EMISSION POINTS
WITH IRISH GRID PROJECTION

SCALE 1:1000 DO NOT SCALE | SHEET SIZE A0 | DWG. NO. 000-517043 | SHEET 1 OF 1 | REVISION 1



NOTES:

1. ALL LEVELS TO BE CENTRE LINE OF ROADS.
2. ALL LEVELS IN METRES POOLBEG DATUM.

NO.	DETAILS	NORTHING	EASTING
MP 01	UTILITY BOILER NUMBER 1	063596	176372
MP 02	UTILITY BOILER NUMBER 2	063596	176380
MP 03	SOLID WASTE INCINERATOR	063716	176756
MP 04	LIQUID VAPOUR INCINERATOR	063718	176756
MP 05	MAIN FUEL TANK IN SERVICE YARD FOR EP 05 EMERGENCY GENERATOR	063624	176434
MP 06	MAIN FUEL OIL FOR EP 06 & EP 07 FIRE WATER PUMPS	063788	176381
MP 100	WASTE WATER TREAMENT PLAN	063583	176779
MW 1	GROUNDWATER MONITORING WELL 1	063858	176536
MW 2	GROUNDWATER MONITORING WELL 2	063627	176495
MW 3	GROUNDWATER MONITORING WELL 3	063383	176290
W 1	QUENCH/SCRUBBER DISCHARGE FROM LVI	063708	176752
SW 1	SURFACE WATER DISCHARGE	063439	176327
AW 6	ARTESIAN WELL 1	063603	176814

OWNER TECHNICAL OWNER

Novartis Ringaskiddy Limited
Ringaskiddy, Co. Cork, Ireland

Drawing Title

MAIN SAMPLING & MONITORING POINTS WITH IRISH GRID PROJECTION

SCALE 1:1000 DO NOT SCALE | SHEET SIZE A0 | DWG. NO. 000-517044 | SHEET 1 OF 1 | REVISION 0

Novartis Ringaskiddy Limited

Annual Environmental Report 2009

IPPCL Register Number P0006-03

Section 2: Summary Information:

Emission to Atmosphere Summary

Emissions to Sewer Summary

Surface Water Emissions Report

Agency Monitoring and Enforcement

Waste Management Report

Summary of On-Site Incineration Record

Resource Consumption Record

Complaints Summary

Reported Incidents Summary

Novartis Ringaskiddy Limited

Emission Point Reference Number 3 (Solid Waste Incinerator)

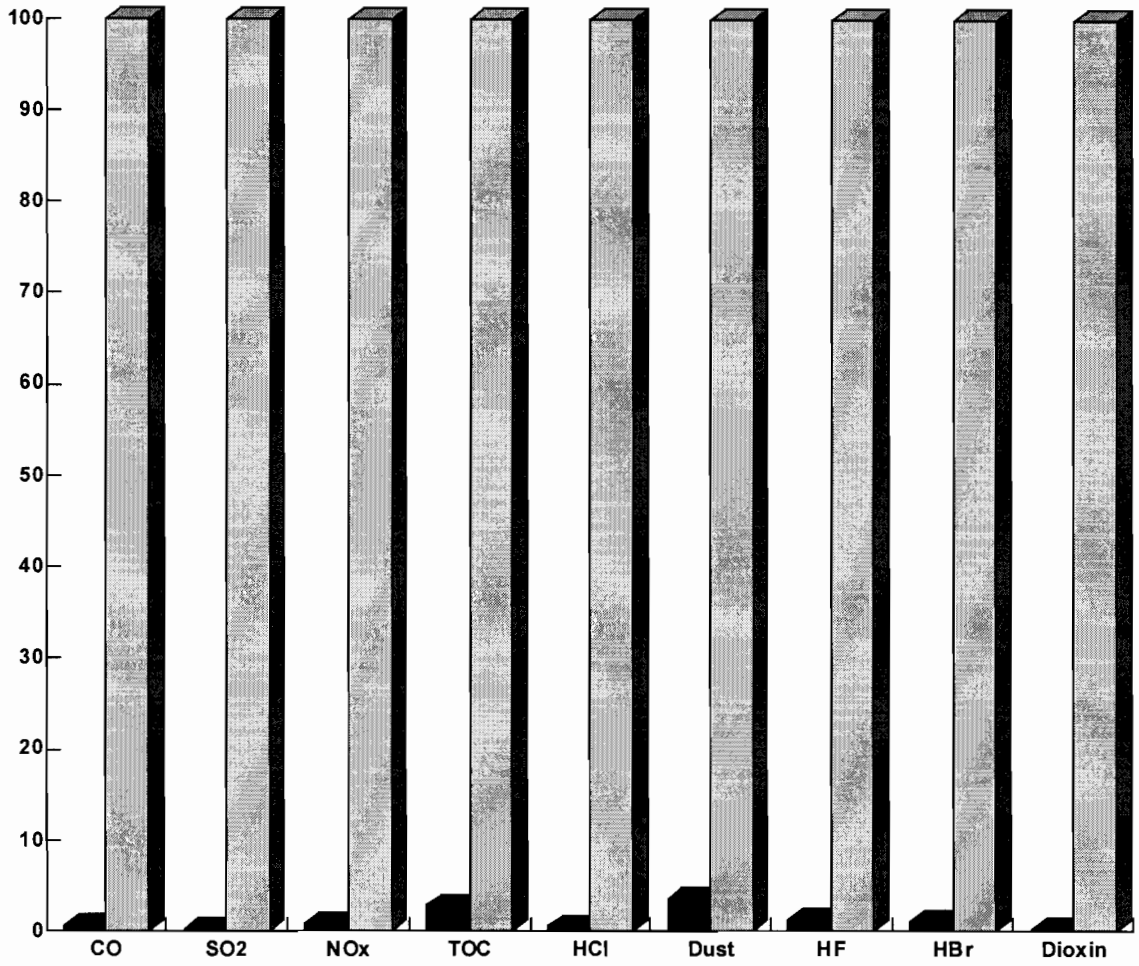
Emissions to Atmosphere Summary 2009

IPPCL Register Number P0006-03

Parameter	Mass Emission (kg)	Controlled Discharge (kg)
Carbon Monoxide	26	3,833
Sulphur Dioxide	6	3,833
Oxides of Nitrogen	238	30,660
Total Organic Carbon	21	767
Hydrochloric Acid	4	767
Total Particulates	27	767
Hydrogen Fluoride	1	77
Hydrogen Bromide	2	153
Dioxins and Dibenzofurans	0.000000023	0.000007665

Notes: A summary of the non-compliances reported for Emission Point Reference Number 03 to the Agency during 2009 is presented on the page after next. More detailed information on these non-compliances is contained in the Reported Incidents Summary section of this AER

Emission Point Reference Number 3



Mass Discharges from Solid Waste Incinerator (first column) Expressed as a Percentage of the Discharge Regulated Under IPPCL Register Number P0006-03 (second column): 2009

Legend:	CO:	Carbon Monoxide
	SO_2:	Sulphur Dioxide
	NOx:	Oxides of Nitrogen
	TOC:	Total Organic Carbon
	HCl:	Hydrochloric Acid
	Dust:	Particulates
	HF:	Hydrogen Fluoride
	HBr:	Hydrogen Bromide
	Dioxin:	Dioxins and Dibenzofurans

Novartis Ringaskiddy Limited Monitoring Data: Emission Point Reference No. 3 Solid Waste Incinerator: January to December 2009

Continuous monitoring data submitted to the Environmental Protection Agency for the period of January to December 2009:

Valid 10 minute means:	**8,050**	Complying 10 minute means:	**8,050**
Valid 30 minute means:	**18,646**	Complying 30 minute means:	**18,644**
Valid 24 hour means:	**770**	Complying 24 hour means:	**770**

Excursions above Emission Limit Values as outlined in Schedule B 1, IPPCL Register Number P0006-03:

Twenty-eight Carbon Monoxide (CO) ten-minute means exceeded the relevant ELV for CO during the period of January to December 2009. The mass discharges of CO associated with the aforementioned readings were less than the amount regulated under IPPCL Register Number P0006-03. A total of **8,050** ten-minute means were recorded for CO during the period of January to December 2009. Note that 95% of all 10 minute means recorded for CO to during the period of January to December 2009 remained less than 150 mg/Nm^3.

Two CO thirty-minute means exceeded the relevant ELV for CO during the period of January to December, 2009. The mass discharges of CO associated with the aforementioned readings were less than the amount regulated under IPPCL Register Number P0006-03. A total of **2,664** thirty-minute means were recorded for CO during the period of January to December, 2009.

One Total Organic Carbon (TOC) thirty-minute mean exceeded the relevant ELV for TOC during the period of January to December 2009. The mass discharge of TOC associated with the aforementioned reading was less than the amount regulated under IPPCL Register Number P0006-03. A total of **2,662** thirty-minute means were recorded for TOC during the period of January to December 2009. Note that 97% of all thirty-minute means recorded for TOC during the period of January to December 2009 remained less than 10 mg/Nm^3.

Compliance with IPPCL Register Number P0006-03 in terms of ELVs (10 minute; 30 minute; and 24 hour means) was 100 %, %, with the exception of CO (30-minute (concentration) mean, which was in > 99% compliance.

Mass discharges of all parameters (10 minute; 30 minute; and 24 hour means) were in 100 % compliance.

Quarterly and Bi-annual monitoring data submitted to the Environmental Protection Agency for the period of January to December 2009:

Hydrogen fluoride and hydrogen bromide emissions were in 100% compliance.

Novartis Ringaskiddy Limited

Emission Point Reference Number 04 (Liquid Vapour Incinerator)

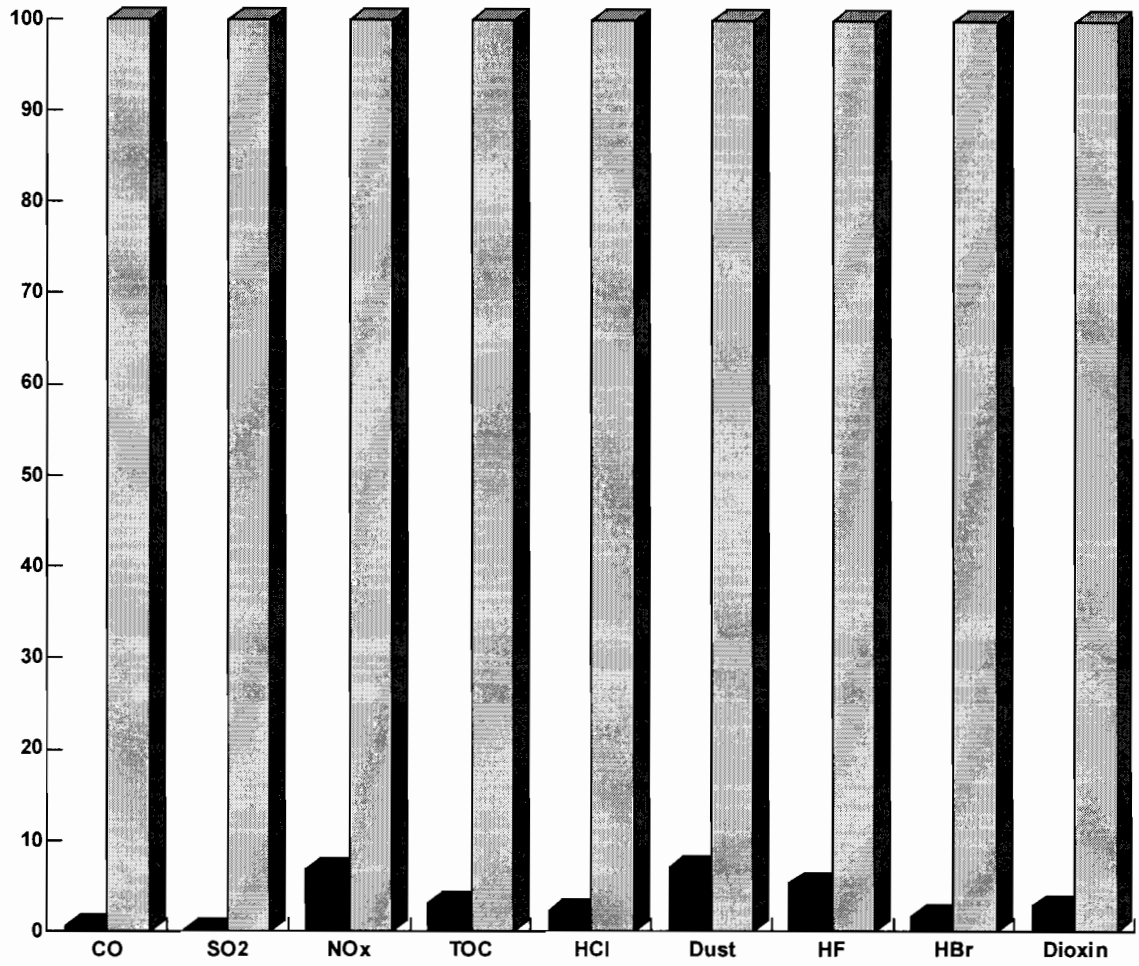
Emissions to Atmosphere Summary 2009

IPPCL Register Number P0006-03

Parameter	Mass Emission (kg)	Controlled Discharge (kg)
Carbon Monoxide	135	18,250
Sulphur Dioxide	34	18,250
Oxides of Nitrogen	9,929	146,000
Total Organic Carbon	113	3,650
Hydrochloric Acid	83	3,650
Total Particulates	257	3,650
Hydrogen Fluoride	19	365
Hydrogen Bromide	<13	730
Dioxins and Dibenzofurans	0.000001013	0.0000365

Notes: A summary of the non-compliances reported for Emission Point Reference Number 04 to the Agency during 2009 is presented on the page after next. More detailed information on these non-compliances is contained in the Reported Incidents Summary section of this AER

Emission Point Reference Number 4



Mass Discharges from Liquid Vapour Incinerator (first column) Expressed as a Percentage of the Discharge Regulated Under IPPCL Register Number P0006-03 (second column): 2009

Legend:	CO:	Carbon Monoxide
	SO_2:	Sulphur Dioxide
	NOx:	Oxides of Nitrogen
	TOC:	Total Organic Carbon
	HCl:	Hydrochloric Acid
	Dust:	Particulates
	HF:	Hydrogen Fluoride
	HBr:	Hydrogen Bromide
	Dioxin:	Dioxins and Dibenzofurans

Novartis Ringaskiddy Limited Monitoring Data: Emission Point Reference No. 4 Liquid Vapour Incinerator: January to December 2009

Continuous monitoring data submitted to the Environmental Protection Agency for the period of January to December 2009:

Valid 10 minute means:	**51,170**	Complying 10 minute means:	**51,170**
Valid 30 minute means:	**121,564**	Complying 30 minute means:	**121,564**
Valid 24 hour means:	**2,553**	Complying 24 hour means:	**2,551**

Excursions above Emission Limit Values as outlined in Schedule 1 (i), IPPCL Register Number P0006-03:

Eight Carbon Monoxide (CO) ten-minute means exceeded the relevant ELV for CO during the period of January to December 2009. The mass discharges of CO associated with the aforementioned readings were less than the amount regulated under IPPCL Register Number P0006-03. A total of **51,170** ten-minute means were recorded for CO during the period of January to December 2009. Note that 95% of all 10 minute means recorded for CO during the period of January to December 2009 remained less than 150 mg/Nm^3.

One Hydrochloric Acid (HCl) thirty-minute mean exceeded the relevant ELV for HCl during the period of January to December 2009. The mass discharge of HCl associated with this reading was less than the amount regulated under IPPCL Register Number P0006-03. A total of **17,347** thirty-minute means were recorded for HCl during the period of January to December, 2009. Note that 97% of all thirty-minute means recorded for HCl to the end of December 2009, remained less than 10 mg/Nm^3.

Four Total Organic Carbon (TOC) thirty-minute means exceeded the relevant ELV for TOC during the period of January to December 2009. The mass discharges of TOC associated with the aforementioned readings were less than the amount regulated under IPPCL Register Number P0006-03. A total of **17,315** thirty-minute means were recorded for TOC during the period of January to December, 2009. Note that 97% of all thirty-minute means recorded for TOC to the end of December 2009, remained less than 10 mg/Nm^3.

Seventy-one Particulate thirty-minute means exceeded the relevant ELV for Particulates during the period of January to December 2009. The mass discharges of Particulates associated with fifty of the aforementioned readings were less than the amount regulated under IPPCL Register Number P0006-03. A total of **17,345** thirty-minute means were recorded for Particulates during the period of January to December, 2009. Note that 97% of all thirty-minute means recorded for Particulates to the end of December 2009, remained less than 10 mg/Nm^3.

Two Particulate twenty-four hour means exceeded the relevant ELV for Particulates during the period of January to December 2009. The mass discharges of Particulates associated with the aforementioned readings were less than the amount regulated under IPPCL Register Number P0006-03. A total of **365** twenty-four hour means were recorded for Particulates during the period of January to December, 2009.

Emission Point Reference Number 100

Emissions to Sewer Summary 2009

IPPCL Register Number P0006-03

Parameter	Mass Emission (kg)	Controlled Discharge (kg)
Total Suspended Solids	11,283	82,125
Chemical Oxygen Demand	32,510	229,950
Total Phosphorus	519	3,650
Total Nitrogen	899	11,680
Total Ammonia	21	1,825
Biochemical Oxygen Demand	4,792	82,125
Copper	1	183
Zinc	20	365

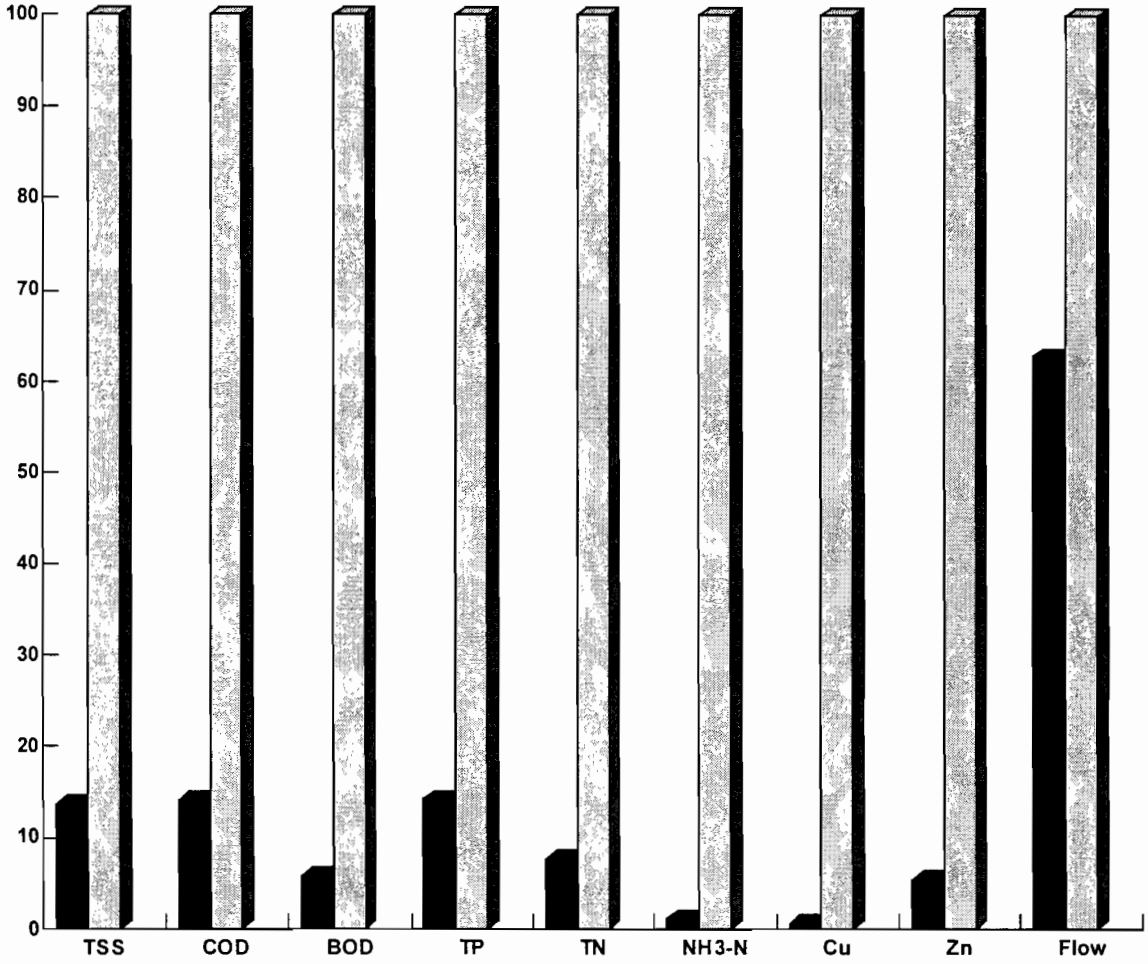
Parameter	Discharge (m^3)	Controlled Discharge (m^3)
Flow	206,415	328,500

Parameter	Values	Controlled Values
pH	6 to 9	6 to 9
Toxicity (Fish)	< 3.1 Toxic Units	10 Toxic Units
Toxicity (Invertebrate)	< 3.1 Toxic Units	10 Toxic Units
Toxicity (Bacteria)	2.8 Toxic Units	10 Toxic Units

Notes: Neither copper nor zinc is used in production processes at Novartis Ringaskiddy Limited

A detailed summary of the non-compliances reported to the Agency for Emission Point Reference Number 100 during 2009 is presented in the Reported Incidents Summary section of this AER

Emission Point Reference Number 100



Mass Discharges from Wastewater Treatment Plant (first column) Expressed as a Percentage of the Discharge Regulated Under Integrated Pollution Prevention and Control Licence Register Number P0006-03 (second column): 2009

Legend:	TSS:	Total Suspended Solids
	COD:	Chemical Oxygen Demand
	BOD:	Biochemical Oxygen Demand
	TP:	Total Phosphorus
	TN:	Total Nitrogen
	NH_3-N:	Total Ammonia
	Cu:	Copper
	Zn:	Zinc
	Flow:	Flow

Novartis Ringaskiddy Limited

Surface Water Emissions Summary 2009

IPPCL Register Number P0006-03

A total of 12 monthly reports were prepared and held on site for Agency inspection in relation to surface water emissions from the facility during 2009. All discharges of surface water from the facility were compliant with the requirements of IPPCL Register Number P0006-03.

A description of the facility's Surface Water Protection System is included on the following pages.

Novartis Ringaskiddy Limited: Surface Water Protection System

1. General Overview

A significant contribution to environmental protection can be achieved by incorporating the principle of **CONTAINMENT**, in addition to the principles of **AVOID**, **REDUCE**, **REUSE** and **RECYCLE**, in the design of production facilities. At Novartis Ringaskiddy Limited this has been achieved from a total concept with contributions from all areas.

The design of the Novartis Ringaskiddy Limited facility incorporates detailed attention to the prevention of contamination of surface water. Bunded and segregated drainage systems form a major part of this strategy. Areas where spillage of liquid is possible, such as the Tank Farm or Solvent Recycling Unit, are bunded to retain spilled material. The bunded water sewer is a stainless steel pipe that drains spillages from the Tank Farm bunds to one of two Spill Basins, each with a capacity of 500 m^3. This allows the interception of large spillages, which could incapacitate the Wastewater Treatment Plant. This material can then be treated in an appropriate manner.

The concept adopted for the draining and discharge of storm water run off is aimed at minimising the possibility of surface water contamination and preventing the release of contaminated material from a spillage, fire fighting or other incident. All buildings where a fire risk exists are surrounded by an impermeable apron to intercept any spillages or fire fighting water in the event of an incident. Run off is collected by a buried concrete gravity sewer which feeds a Storm Water Protection Pond (SWRP). The SWRP is sized to hold two hours of the largest fire water demand, in addition to 20 mm of rainfall over the site paved area, in a total holding capacity of 5,000 m^3. The SWRP is lined with a 2 mm HDPE liner and is divided into two compartments for operational and maintenance purposes.

Uncontaminated storm water routinely discharges, via one of the two compartments, to the storm outfall sewer, which is located on the opposite ends of the SWRP compartments. The second compartment is maintained empty and in standby mode. In the event of possible contamination, a deviation above the background level is sensed by the continuous monitors located on the inlet to the compartments of the SWRP. This results in the outlet valve of the operational compartment to the storm sewer automatically closing. Potentially contaminated water can then be gathered in the sealed compartment and subject to more detailed laboratory assessment. If necessary, this water can be pumped to the site's Wastewater Treatment Plant for biodegradation.

The flow of surface water run off can be routed to the second compartment of the SWRP once the continuous analysers have indicated that the quality of the run off has returned to specified levels. This means that the surface water protection system remains operational even in the event of a potential problem having been intercepted and quarantined.

Retention capacity monitoring was installed during 2005 t o provide for rapid determination of the available retention capacity in the two 2,500 m^3 compartments of the Storm Water Retention Pond. The system uses radar probes in each compartment to calculate the volume of water present and this information is fed back in real time to the Environmental Controls Department (ECD) control room. The information is also available at other control rooms throughout the facility.

2. Warning and Action Levels

Storm water run off from the site to the SWRP is continuously analysed for Total Organic Carbon (TOC) and pH. Information from both TOC and pH analysers is continuously fed back to the ECD Control Room through the site's Distributed Control System (DCS). The DCS enables the ECD to automatically close the outlets from the SWRP compartments once predefined **Action Levels** have been recorded by one or both of the analysers located at the inlet of the SWRP. These **Action Levels** have been notified to the Environmental Protection Agency and are set as outlined on the following table:

SURFACE WATER PROTECTION ACTION LEVELS		
Total Organic Carbon	: Action Level	: 40 mg/L TOC
pH	: Action Levels	: Less than 6.5 and greater than 9.5

The **Action Levels** also trigger an audible alarm in the ECD Control Room. This serves to notify ECD personnel that there may be a potential change in the quality of storm water running off site and that this water is being gathered and quarantined in one of the SWRP's compartments. This alarm has to be acknowledged by ECD personnel before it is inactivated. Responding to the alarm does not result in the outlets from the SWRP automatically opening.

A sample of the water gathered and quarantined in the SWRP can then be taken for more detailed laboratory analysis. ECD personnel may activate the second standby compartment of the SWRP if the output from the continuous analysers indicates that the quality of the storm water no longer exceeds the **Action Levels**. Water can only be released from the quarantined compartment to the storm water sewer based on a detailed laboratory analysis.

The surface water protection system also incorporates **Warning Level** alarms for TOC and pH. These **Warning Levels** have been set as follows:

SURFACE WATER PROTECTION WARNING LEVELS		
Total Organic Carbon	: Warning Level	: 20 mg/L TOC
pH	: Warning Levels	: 7.0 to 6.5 and 9.0 to 9.5

The purpose of setting a **Warning Level** is to indicate to ECD personnel that there is a potential drift in the quality of the storm water running off the site. Once these predefined **Warning Levels** have been reached, by one or both analysers at the inlet of the SWRP, an audible alarm is activated, via the DCS, in the ECD Control Room. ECD personnel are then required to acknowledge the alarm and to continue monitoring the output from the TOC and pH analysers. ECD personnel may then close the outlet from the operational

compartment of the SWRP if there is a continuous drift towards the **Action Levels**. This anticipates the automatic response effected by the DCS when the **Action Levels** are reached. Again, once storm water has been gathered and quarantined in one of the SWRP's compartments a more detailed laboratory analysis is required before a decision can be made as to whether the water can be released to the storm water sewer.

3. Reference Drawing Numbers

020-114001-1 that details the site underground storm sewer pipe layout and Storm Water Retention Pond.

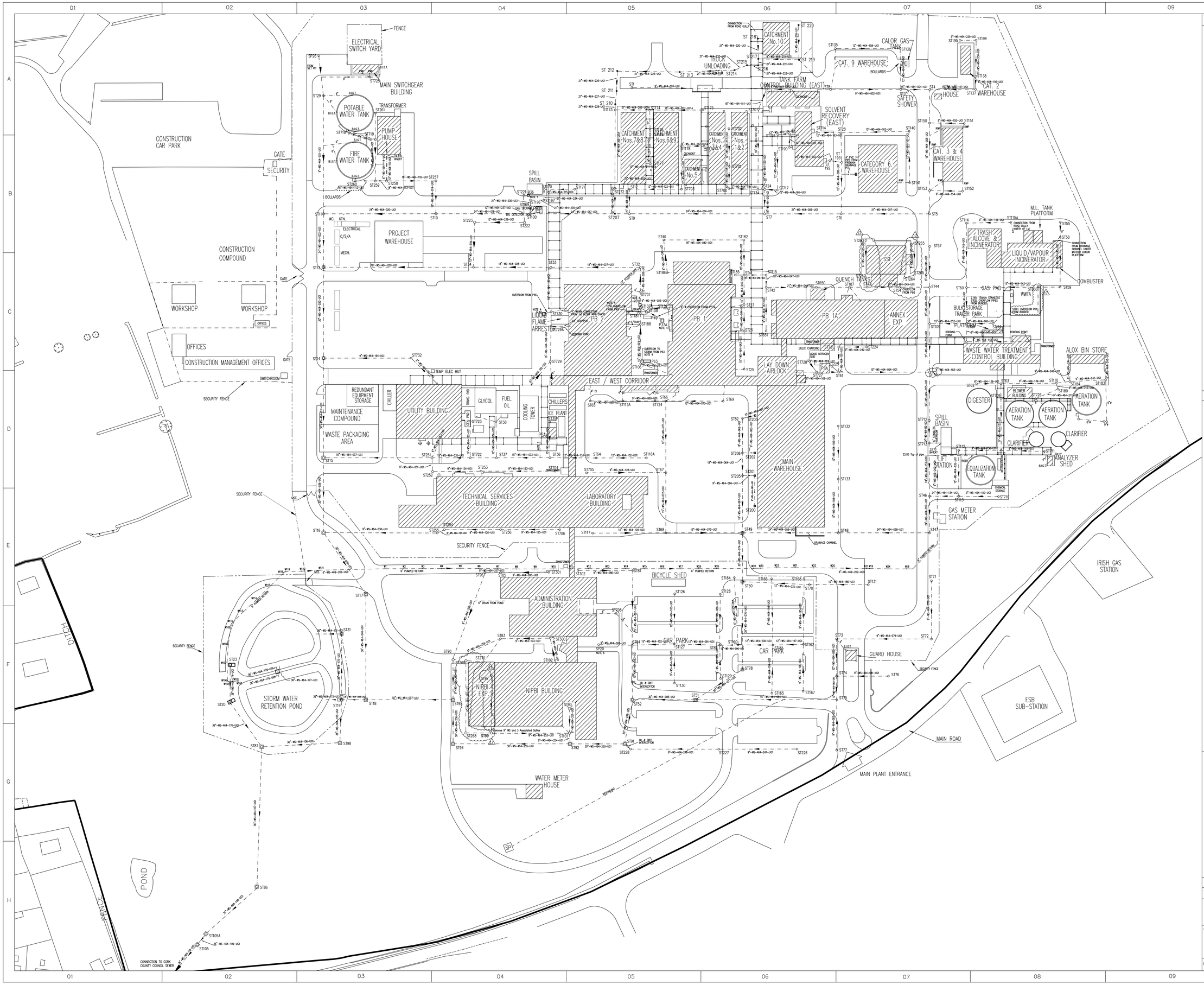
020-114005-1 that details the site underground bunded sewer pipe layout and the Spill Basin.

Both drawings were included in **SANDOZ** (now Novartis) Ringaskiddy Limited's Application to the Environmental Protection Agency for an Integrated Pollution Control Licence: Attachment Number 2: Complete application documentation (including drawings) for Water Licence Register Number WP (S) 7/93 (R).

Up-to-date copies are also included as in insert in the document:

020-114001-1 Rev 17

020-114005-1 Rev 29



NOTES

STORM SEWER NOTES:

1. ALL PIPES ARE CONCRETE WITH NOMINAL INTERNAL DIAMETERS SHOWN ABOVE
2. ALL JOINTS ARE SPIGOT & SOCKET WITH CHLOROPRENE SEAL
3. FOR STORM SEWER SCHEDULES SEE DRG. No. 020–114012
4. PROCESS SEWERS SHOWN ON THIS DRAWING ARE FOR INFORMATION ONLY. REFER TO DRAWING 020–114006–1 FOR PROCESS SEWER LAYOUT.
5. BUNDED SEWERS SHOWN ON THIS DRAWING ARE FOR INFORMATION ONLY. REFER TO DRAWING 020–114005–1 FOR BUNDED SEWER LAYOUT.
6. SILT PITS SHOWN ON THIS DRAWING ARE FOR INFORMATION ONLY. REFER TO DRAWING 020–114007–1 FOR LAND DRAIN LAYOUT.
7. 9" CONCRETE PIPE CAPPED AT P.3.

STORM SEWER LEGEND

STORM SEWER — 30"-WS-464-094-UCI

STORM SEWER MANHOLE (PRECAST) — ST100

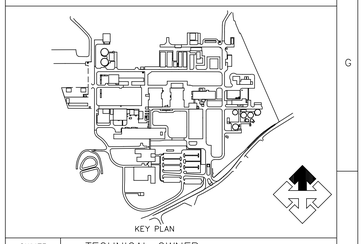
STORM SEWER MANHOLE (CAST INSITU) — ST53

STORM SEWER PUMPED RETURN — 6"-WS-469-202-UCI

CL =

RWP = RAIN WATER PIPE

REFERENCE DRAWINGS



KEY PLAN

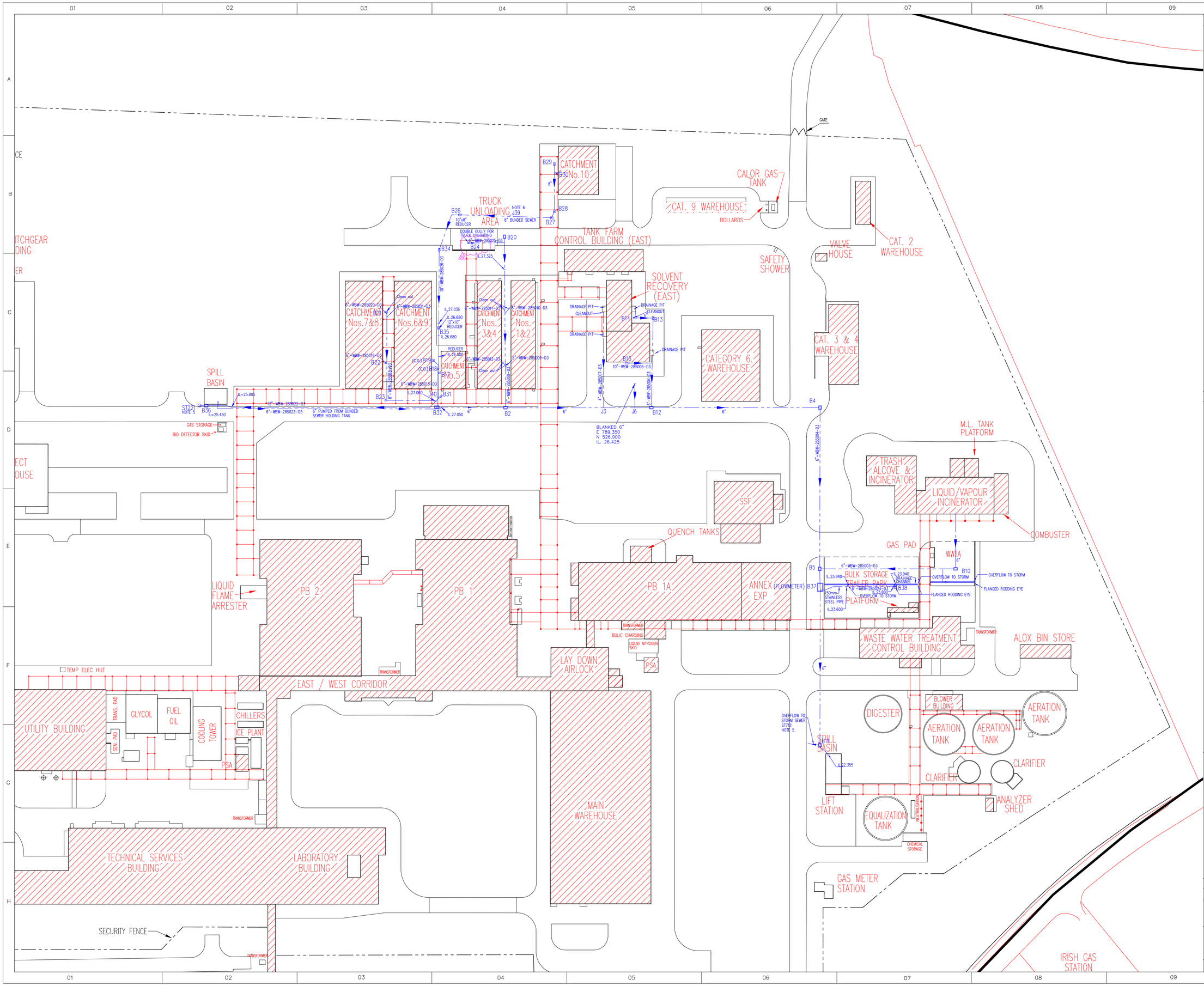
OWNER	TECHNICAL OWNER

Novartis Ringaskiddy Limited
Ringaskiddy, Co. Cork, Ireland

Drawing Title

SITE – UNDERGROUND PIPING
STORM SEWER LAYOUT

SCALE	SHEET SIZE	DWG. NO.	SHEET	REVISION
1:750 DO NOT SCALE	A0	020–114001	1 OF 1	17



NOTES

BUNDED SEWER NOTES:

1. ALL PIPES ARE STAINLESS STEEL SCHEDULE 10S GRADE TP 316L
2. FOR DETAILS OF BUNDED MANHOLES REFER TO DRAWING No. 020-114009
3. FOR DETAILS OF FLOWMETER CHAMBER REFER TO DWG. 020-114009
4. DELETED.
5. STORM SEWERS ON THIS DRAWING ARE SHOWN FOR INFORMATION ONLY. REFER TO DRAWING 020-114001-1 FOR STORM SEWER LAYOUT.
6. FLAT PLATE WELDED ON TEE. TEE IS FACING UPWARDS IN DIRECTION.

BUNDED SEWER LEGEND

BUNDED SEWER

BUNDED MANHOLES/CLEANOUTS — B2

BUNDED MANHOLES/CLEANOUTS — J6

REFERENCE DRAWINGS

SCHEDULE OF BUNDED MANHOLES/CLEANOUTS

Manhole Junction Number	Cover Level	Invert Level	Northing	Easting
B1	27.928	27.049	516.770	706.113
B2	–	26.861	516.770	734.550
J3	–	26.471	516.800	776.125
B4	27.874	25.888	516.800	867.800
B5	25.310	23.603	448.500	867.705
J6	–	26.368	516.800	789.275
B10	25.008	23.963	448.500	925.200
B11	24.772	22.407	373.876	867.742
B12	27.645	26.170	516.720	796.350
B13	28.443	27.100	554.750	797.100
B14	28.525	27.170	554.800	789.350
B15	28.450	27.980	535.640	785.865
B17	28.190	27.118	531.500	706.540
B18	28.181	27.125	533.530	706.090
B19	28.176	27.644	536.880	703.880
B20	34.483	31.850	586.607	734.096
B21	28.199	27.488 27.462	557.485	683.370
B22	28.132	27.372	536.097	683.440
B23	28.051	27.170	520.192	683.440
B24	34.330	–	584.031	720.438
B26	24.827	31.410	598.470	715.260
B27	33.510	32.365	597.275	754.150
B28	33.437	32.383	600.000	755.255
B29	33.386	32.593	620.000	755.255
B30	33.395	32.549	616.000	756.100
B31	28.076	26.285	522.190	707.730
B32	27.926	27.020	517.000	705.290
B34	34.582	31.235	583.960	706.530
B35	28.284		550.575	706.300
B36	26.700	25.535	517.575	607.800
B37	25.400	23.490	440.600	867.730
B38	24.500	23.800	440.985	899.665
J39			597.828	736.150
J40			521.202	705.931

KEY PLAN

OWNER: TECHNICAL OWNER

Novartis Ringaskiddy Limited
Ringaskiddy, Co. Cork, Ireland

Drawing Title

SITE – UNDERGROUND PIPING
BUNDED SEWER LAYOUT

SCALE	SHEET SIZE	DWG. NO.	SHEET	REVISION
1:500 DO NOT SCALE	A0	020-114005	1 OF 1	29

Novartis Ringaskiddy Limited

Agency Monitoring and Enforcement Summary 2009

IPPCL Register Number P0006-03

The Environmental Protection Agency undertook unannounced emission sampling and analysis for the following emission points during 2009:

Emission Point Reference Number 100 (Discharge from Wastewater Treatment Plant):

24-Mar-2009; 29-Apr-2009; 05-Aug-2009; and 03-Nov-2009

Emission Point Reference Number SW1 (Surface Water Discharge Point):

24-Mar-2009; 29-Apr-2009; 05-Aug-2009; and 03-Nov-2009

Emission Point Reference Number W1 (Incinerator Effluent Discharge Point):

24-Mar-2009; 29-Apr-2009; 05-Aug-2009; and 03-Nov-2009

The results reported for the various samples were compliant with the requirements of IPPCL Register Number P0006-03.

The Agency issued one Notification of Non-Compliance on 27-Apr-2010, which followed an Agency inspection on 16-Apr-2009. It is worth noting that the notification was in respect of number of previously notified short-term emission deviations from the company's Wastewater Treatment Plant, Solid Waste Incinerator and Liquid Vapour Incinerator – none of which resulted in any adverse environmental impact. The overall performance of the company's environmental control modules was excellent during 2009 (refer to the graphs in the sections of this AER detailing Emissions to Atmosphere and Emissions to Sewer). A copy of the inspection report and the company's response are enclosed on the following pages.

The Agency undertook an inspection of the facility on 19-Jun-2009, which followed notification of the Agency by the company of a small localised fire on the waste conveyor system that feeds the company's Solid Waste incinerator. A copy of the inspection report and the company's response are enclosed on the following pages.

The Agency undertook an audit of the facility on 30-Sep-2009. The company noted the Agency's general comment that Novartis Ringaskiddy Limited has a well established system of managing the day to day issues associated with the IPPC Licence and that the company has been proactive in a number of areas and in particular optimisation of processes on site, which has led to significant reductions in the quantities of raw solvent being used and waste solvent being sent off site. Two audit observations were followed up one of which forms part of an environmental management programme for 2010. A copy of the audit report; and a copy of the company's response are enclosed on the following pages.

The Agency issued one Notification of Non-Compliance on 03-Dec-2009, which was in respect of a previously notified short-term particulate emission deviation from the company's Liquid Vapour Incinerator, which did not result in any adverse environmental impact. The overall performance of the company's environmental control modules was excellent during 2009 (refer to the graphs in the section of this AER detailing Emissions to Atmosphere).

Agency Inspection Report of 27-Apr-2009

Office of
Environmental
Enforcement

South/South West Region
Environmental Protection Agency
Regional Inspectorate, Inniscarra
County Cork, Ireland

Cigireacht Réigiúnach, Inis Cara
Contae Chorcaí, Éire

T: +353 21 487 5540
F: +353 21 487 5545
E: info@epa.ie
W: www.epa.ie

LoCall: 1890 33 55 99

Dr. Vincent Boyton
Environmental and Industrial Hygiene Services Manager
Novartis Ringaskiddy Limited
Ringaskiddy
County Cork

27th April 2009 Our Ref: P0006-03/nc05ld

Notification of Non-Compliance

Dear Dr. Boyton,

Please find enclosed a Site Inspection Report detailing the Agency's findings following an inspection of Novartis Ringaskiddy Limited on 16/04/09.

Novartis Ringaskiddy Limited has been found to be in non-compliance with the conditions of the IPPC Licence as set out in the Site Inspection Report. You are required to undertake the corrective actions specified to close out the non-compliance raised in the Site Inspection Report or further enforcement action may be taken by the Agency. You are required to submit a corrective action proposal and timeframe where relevant within 14 working days of the date of this letter.

Please quote the above reference number in any future correspondence in relation to this Site Inspection Report. If you have any further queries please contact Linda Dalton at 021 4875540.

Yours sincerely,

Linda Dalton
Office of Environmental Enforcement

Site Inspection Report

Office of Environmental Enforcement

South/South West Region
Environmental Protection Agency
Regional Inspectorate, Inniscarra
County Cork, Ireland

Cigireacht Réigiúnach, Inis Cara
Contae Chorcaí, Éire

T: +353 21 487 5540
F: +353 21 487 5545
E: info@epa.ie
W: www.epa.ie

LoCall: 1890 33 55 99

Dr. Vincent Boyton
Environmental and Industrial Hygiene Services Manager
Novartis Ringaskiddy Limited
Ringaskiddy
County Cork

Date of issue of Inspection Report: 27th April 2009

Licence Register No:	P0006-03	**Inspection Reference No:**	(P0006-03)09si02ld
Date of Inspection:	16/04/2009	**Inspectors:**	Ms. Linda Dalton
Photographs Taken:	Yes	**Announced:**	Yes

F.A.O: Dr. Vincent Boyton

This Site Inspection Report details the Agency's findings following an inspection of Novartis Ringaskiddy Limited on 16/04/2009.

NOTIFICATION OF NON-COMPLIANCE

Novartis Ringaskiddy Limited has been found to be in non-compliance with the conditions of the IPPC Licence as set out in this Site Inspection Report. You are required to undertake the corrective actions specified to close out the Non-Compliances and Observations raised in this Report or further enforcement action may be taken by the Agency.

In view of the above you are required to submit a schedule to the Agency within 14 working days of receipt of this Report detailing how the non-compliance and observations specified therein are to be rectified. Please quote the above Inspection Reference Number in any future correspondence in relation to this Report. If you have any further queries please contact Linda Dalton **at** 021 487 5540.

1. SITE INSPECTION AND ASSESSMENT

The Site Inspection commenced at 9:30am and the following were in attendance:

Representing Novartis Ringaskiddy Limited:

Dr. Vincent Boyton	Environmental and Industrial Hygiene Services Manager
Mr. Padraig O'Brien	Head of HSE

Representing the Environmental Protection Agency:

Linda Dalton	Inspector

An Inspection of the site was conducted, special attention was paid to the:

- stormwater retention ponds and storm water monitoring point SW1
- waste water treatment plant and emission point 100
- liquid vapour incinerator and emission point W1
- solid waste incinerator
- storage warehouses
- tank farm

Interview

The following representatives were interviewed during the Inspection:

Name	Position	Issue
Dr. Vincent Boyton	Environmental and Industrial Hygiene Services Manager	All licence conditions
Mr. Padraig O'Brien	Head of HSE	Site layout and up-coming projects

Documentation

The following documentation was requested for review:

Record	Condition No.	Comment
Emissions to Air Monitoring Records (emission monitoring points 3 and 4) – Monthly summary reports for January and February 2009	6.1, 11.7, Sch. C.1.2	See Non-Compliance
Storm Water Monitoring Records (emission monitoring point SW1) – Monthly summary reports for January and February 2009	6.1, 11.7, Sch. C.2.3	Satisfactory
Emission to Sewer Monitoring Records (emission monitoring point 100 and W1) - Monthly summary reports for January and February 2009	6.1, 11.7, Sch. C.3.2	Satisfactory
Weather Station Data - Monthly summary reports for January and February 2009	3.14, 11.7	Satisfactory
Solid Waste Incinerator Inventory - Monthly summary reports for January and February 2009	NA	Satisfactory
Waste Tracking System (viewed electronically)	NA	Satisfactory

General Comment

This was a routine compliance site inspection, and was the first visit for the new Inspector. A detailed site tour was taken, followed by a brief documentation review. It was noted that since December 2008, a number of breaches of the emission limit value for carbon monoxide at the air emission monitoring locations No. 3 and No. 4, and for total

suspended solids and COD at monitoring location 100, have occurred. These are outlined in greater detail in Non-Compliance 1 below. Furthermore, two observations were noted on the day of Inspection. The licensee is required to carry out the corrective actions outlined in the sections below to ensure compliance with the IPPC licence.

During the site tour, the Inspector noted that the licensee has implemented two of the recommendations outlined in the 2008 ELRA at the waste water treatment plant. These involved installing new tanks in both the waste water lift station and neutralisation basin. These infrastructural improvements are welcomed by the Agency. Additionally, the Agency acknowledges the receipt of a Parent Company Guarantee from the licensee as financial provision for the amount identified in the ELRA. This was discussed on the day of the Inspection, and will be responded to by the Agency under a separate cover.

The licensee was briefed on the Agency's reporting procedures and was advised that a Site Inspection Report would be issued.

Finally, the licensee was thanked for the courteous and co-operative manner of the staff, and the assistance and co-operation extended during the Inspection.

2. INSPECTION FINDINGS

Inspection Non-Compliances

The site inspection process is a random sample on a particular day of a facility's compliance with some of its licence conditions. Where a non-compliance against a particular condition has not been reported, this should not be construed to mean that there is full compliance with that condition of the licence.

The licensee was found to be in non-compliance with the requirements of the Licence in respect of the following on the day of the Inspection (Schedule and Condition numbers refer to the Licence):

TABLE OF NON COMPLIANCES

1. **Breaches of Emission Limit Values (ELV's) at Emission Reference Points No 3, No. 4 and 100**

Emissions to Air

There have been three breaches of the licence ELV for carbon monoxide (30 minute average) at air emission reference points No. 3 and No.4 as outlined in the table below. Each of these exceedences were reported to the Agency as incidents by the licensee as required in the licence. An investigation into the exceedences of the ELV for CO in the solid waste incinerator on the 19/03/09 and 29/03/09 is on-going.

Date of Breach	Emission Monitoring Ref.	Parameter	Licence ELV (mg/Nm^3)	Result (mg/Nm^3)	Date Notified to Agency
22/12/08	No. 4	CO	100	106	23/12/08
19/03/09	No. 3	CO	100	111	20/03/09
29/03/09	No. 3	CO	100	120	31/03/09

Emission to sewer

A number of exceedences of the licence ELV's for total suspended solids and COD at emission reference point 100 were noted on the 30/01/09, 31/01/09, 01/02/09 and 02/02/09 (as notified to the Agency on the 02/02/09 and 03/02/09). A follow up incident report relating to these exceedences was received by the Agency on the 04/03/09.

This is in non-compliance with **CONDITION 5.1**

Corrective Action Required

The licensee is required to:

- Comply with the emission limit values of your licence.
- Submit an follow up report on the exceedence of the emission limit values for Carbon monoxide at emission reference No. 3 as soon as practicable.

Inspection Observations

These observations should be addressed, or where relevant noted, by the licensee in order to ensure compliance, improve environmental performance of the facility and provide clarification on certain issues, as required. Where requested the actions taken and clarifications requested should be reported back to the Agency.

1. **Skip**

An ash skip was located to the north of the Category 9 and Category 2 warehouses. The skip was empty at the time of Inspection.

Corrective Action Required

Move the ash skip to a designated waste storage area. Ensure that all wastes are stored in designated areas as required in Condition 8.4 of your licence.

2. **AER**

The licensee was finalising the AER for 2008 at the time of Inspection. An electronic copy of the AER was received by the Agency via email on the 20/04/09

Corrective Action Required

Submit three hard copies of the completed 2008 AER to the Agency as soon as practicable.

3. FOLLOW-UP ACTIONS

The licensee shall take the actions required to close out the non-compliance and observations raised in this Site Inspection Report. These actions will be verified during subsequent Inspections.

Please quote the above Inspection Reference Number in any future correspondence in relation to this Report.

Report prepared by Inspector: Linda Dalton

Date: 27/4/09

Linda Dalton

27th April 2009

E + IH Services Manager
Health, Safety and
Environmental Protection

Ringaskiddy
Co. Cork
Ireland

Tel +353-21-4862324
Fax +353-21-4862358

NOVARTIS

OEE Regional Office
Environmental Protection Agency
Inniscarra
County Cork

21 May 2009

IPC10354.doc

Re: Corrective Actions Arising From Agency Report Dated 27-Apr-2009

To whom it may concern,

Novartis Ringaskiddy Limited wishes to update the Agency on the schedule of corrective actions listed in the Agency's report on the site inspection undertaken on 16-Apr-2009 and as documented in the Agency's correspondence dated 27-Apr-2009.

1. Attachment Number 1 contains the follow up report on the exceedence of the emission limit value for Carbon Monoxide (CO) at Emission Point Reference Number 3 between 16:30 and 17:00 on Thursday, 19-Mar-2009.

2. Attachment Number 2 contains the follow up report on the exceedence of the emission limit value for Carbon Monoxide (CO) at Emission Point Reference Number 3 between 06:30 and 07:00 on Sunday, 29-Mar-2009.

3. The empty ash skip that was observed north of the Category 2 and category 9 warehouses was removed on the date of the site inspection to a appropriate storage location.

NOVARTIS

4. The hard copies of the 2008 Annual Environmental Report were submitted to the Agency on 20-Apr-2009. The softcopy of this document in .pdf format is currently nearing completion and will be forwarded once to hand.

Trusting that this information is to the Agency's satisfaction,

yours sincerely,

Vincent Boyton
21-May-2009

Attachment Number 1

Section 1:- Description of Event:

Date of Event:	19 Mar 2009	**Time of Event:**	16:30-17:00
Date reported:	23 Mar 2009	**Time Reported:**	17:00

Person(s) Reporting Event: Robert Slowey

Overview of Event:
The Continuous Emission Monitor (CEM) analysing Carbon Monoxide (CO) emissions from the Solid Waste Incinerator (Emission Point Reference Number 3) at Novartis Ringaskiddy Limited registered one thirty-minute (concentration) mean, which exceeded the Emission Limit Value (ELV), stipulated for Emission Point Reference Number 3, in Schedule B.1, of the aforementioned licence on Thursday, 19-Mar-2009.

HSE Ref. 20mr0901

Which System is affected

Area number: 574	**Module number: 381**	**Equipment number: 001**

EXTENT data

IPC License parameter and Limit value as specified in IPCL	CO (30min): 100mg/Nm3
Actual Value recorded	111 mg/Nm3
Duration of out of specification event	30 minutes
Specify any known related events:	N.A.

Section 2:- Remedial Action

Possible Consequences if no remedial action taken:
Further OOS on 30min mean values.
Immediate Action Taken:
Burning stopped by operator.
Loader lock-out activated, preventing material from being burned.
Formal notification made to the EPA
Long Term Action Recommended
To be determined at review.

Section 3:- Preliminary Investigation of Incident

Cause of Incident (Tick Boxes closest to the initial suspected cause)

Unsafe Actions by personnel		Plant Failure	
Unsafe Conditions of plant / equipment		Sitewide implications	
Pipe/Joint failure		Incorrect Plant Operation.	
Plant Malfunction/Failure	√	Override Safety Features	

Preliminary Description of Cause of Incident

19/03/2009 16:41	4.1	Empty Tetrazolyl drums and liners	6.56	Fibre Drum	150110
19/03/2009 16:59	4.2	Contaminated Diovan Floor waste	5.32	Plastic Bag	150202

Material being incinerated at the times in question.

Further follow up Incident review Meeting
Further report Yes X No Signature & Date: Robert Slowey Robert Slowey
23 Mar 2009 23 MAR 2009

Complete parts 1- 3 and circulate to:- Head of Technical Services, Head of HSE, Environmental and Industrial Hygiene Manager within 24 hours or on the Monday following a week-end event.

Section 4:- Root Cause of Incident

Root Cause of Incident (Tick all applicable boxes):

1. Plant Reliability		**2. Operator Reliability**	
Hardware failure		Failure to follow Instruction or Procedure	
Emission analyser Failure		Deficient Training / Skills / Competence / Experience	
Software Fault DCS		Operator interaction with Machines	
Software Fault CCS (HIMA)		Operator interaction DCS/Control System	
Equipment Malfunction (Pumps / fans/ valves			
Repeated Equipment Failure Trend			

3. Failure of Communication / Feedback		**4. Organisation / Management Issues**	
Deficient Procedure		Responsibility	√
Batch Record / SOPs.		Supervision	√
Method Statement / Risk Assessment		Sitewide implications	
Failure of Permit System			
Information from Statutory Instructions			
Shift Logs / Documentation			
Verbal Dialogue			
Custom / Practice			

5. System / Climate Issues		**6. Incident Category**	
Production Priorities		Start-up	
Production Support Priorities		Training	
Legislative Requirements		Engineering or equipment	
Maintenance Regime		Procedural	

Description of Root Cause

On investigation of SWI parameters on time in question, it was noted that the impact on the CO occurred after the last load of waste at 16:59 was inputted. This would indicate that the material in the load had a very high calorific value.

Supervisor :	**Robert Slowey**	**Date**	25 MAR 2005
Plant Manager/Function Head:	**John Harrington**	**Date**	25 MAR 2005

Circulate within 10 days to: Head of Technical Services, Head of HSE, Environmental and Industrial Hygiene Manager and Supervisor/Plant Manager,.

Section - 5 Recommended Follow-up actions and Comments (follow up action & task list number).

Re-iterate to the building in question on the importance of correct packaging of wastes.

Section 5 implemented on 22 May 05 (Date) **Checked by: -** (Plant Manager.)

Circulate to: Head of Technical Services, Head of HSE, Environmental and Industrial Hygiene Manager and Supervisor/Plant Manager,.

Attachment Number 2

Section 1:- Description of Event:

Date of Event:	29 Mar 2009	**Time of Event:**	06:30-07:00
Date reported:	31 Mar 2009	**Time Reported:**	17:00

Person(s) Reporting Event: Robert Slowey

Overview of Event:
The Continuous Emission Monitor (CEM) analysing Carbon Monoxide (CO) emissions from the Solid Waste Incinerator (Emission Point Reference Number 3) at Novartis Ringaskiddy Limited registered one thirty-minute (concentration) mean, which exceeded the Emission Limit Value (ELV), stipulated for Emission Point Reference Number 3, in Schedule B.1, of the aforementioned licence on Sunday, 29-Mar-2009.

HSE Ref. 30mr0902

Which System is affected

Area number: 574	**Module number: 381**	**Equipment number: 001**

EXTENT data

IPC License parameter and Limit value as specified in IPCL	CO (30min): 100mg/Nm3
Actual Value recorded	120 mg/Nm3
Duration of out of specification event	30 minutes
Specify any known related events:	N.A.

Section 2:- Remedial Action

Possible Consequences if no remedial action taken:
Further OOS on 30min mean values.
Immediate Action Taken:
Burning stopped by operator.
Loader lock-out activated, preventing material from being burned.
Formal notification made to the EPA.
Long Term Action Recommended
To be determined at review meeting.

Section 3:- Preliminary Investigation of Incident

Cause of Incident (Tick Boxes closest to the initial suspected cause)

Unsafe Actions by personnel		Plant Failure	
Unsafe Conditions of plant / equipment		Sitewide implications	
Pipe/Joint failure		Incorrect Plant Operation.	
Plant Malfunction/Failure	√	Override Safety Features	

Preliminary Description of Cause of Incident

29/03/2009 06:32	4.10	Contaminated Floor Waste	9.22	Fibre Drum	150202
29/03/2009 06:40	4.1	Empty Tetrazolyl drums and liners	7.11	Fibre Drum	150110
29/03/2009 06:54	4.20	FIBC Bag (One)	6.66	Plastic Bag	150110

Material being incinerated at the times in question.

A meeting was held between 15:30 and 16:00 on Tuesday, 31-Mar-2009, to review a number of suggested corrective actions in light of recently recorded deviations for Carbon Monoxide. Attendees were John Harrington, Robert Slowey, Noel Aherne and Vincent Boyton. These items are being followed up today Wednesday 01-Apr-2009.

Further follow up Incident review Meeting

Further report **Yes X** **No** **Signature & Date:** **Robert Slowey** Robert Slowey
31 Mar 2009 31 MAR 2009

Complete parts 1- 3 and circulate to:- Head of Technical Services, Head of HSE, Environmental and Industrial Hygiene Manager within 24 hours or on the Monday following a week-end event.

Section 4:- Root Cause of Incident

Root Cause of Incident (Tick all applicable boxes):

1. Plant Reliability

Hardware failure	
Emission analyser Failure	
Software Fault DCS	
Software Fault CCS (HIMA)	
Equipment Malfunction (Pumps / fans/ valves	
Repeated Equipment Failure Trend	

2. Operator Reliability

Failure to follow Instruction or Procedure	
Deficient Training / Skills / Competence / Experience	
Operator interaction with Machines	
Operator interaction DCS/Control System	

3. Failure of Communication / Feedback

Deficient Procedure	
Batch Record / SOPs.	
Method Statement / Risk Assessment	
Failure of Permit System	
Information from Statutory Instructions	
Shift Logs / Documentation	
Verbal Dialogue	
Custom / Practice	

4. Organisation / Management Issues

Responsibility	√
Supervision	√
Sitewide implications	

5. System / Climate Issues

Production Priorities	
Production Support Priorities	
Legislative Requirements	
Maintenance Regime	

6. Incident Category

Start-up	
Training	
Engineering or equipment	
Procedural	

Description of Root Cause

Initial causes of mechanical issues with machine have been ruled out after extensive testing.
Root cause seems to be with the waste from the production building – the way it is being packaged and labelled.

Supervisor :	**Robert Slowey**	**Date**	**31 Mar 2009**
Plant Manager/Function Head:	**John Harrington**	**Date**	**31 Mar 2009**

Circulate within 10 days to: Head of Technical Services, Head of HSE, Environmental and Industrial Hygiene Manager and Supervisor/Plant Manager,.

Section - 5 Recommended Follow-up actions and Comments (follow up action & task list number).

1. **Pull and clean/check oxygen analyser on stage 3 of the SWI**
2. **Check operation of the fan**
3. **Chek reburn tunnel injection pipework for blockages.**
4. **Rod out all air holes on hearth**

1. O2 Probe and Analyser were checked by E & I -(Donal Dennehy & Kevin Sexton) - analyser/probe removed from Stage 3, found to be in perfect condition, calibration carried out and found to be in Cal.

2. Stage 2 & 3 blower air flows checked (Ken Hayes from Eirdata) - see attached results - all readings were higher than SWI upgrade design recommendations by Basic International (John N Basic Snr) (note Low Flow and High Flow settings are normal operating ranges)

3. Reburn Tunnel combustion air injection pipe bowbacks have been checked and are operational.

4. Rodding of Pulse Hearth combustion air injection pipes - completed by ECD (R. Slowey).

After all these checks completed and found to be OK, we re-looked at the waste that was incinerated at the time. A check of all the wastes involved in recent OOS's was taken and one buildings waste was found to be the reason in all cases.
A meeting was held with the building in question and they took on board all our findings and made a commitment to rectify same.
With that, they have now dedicated one person from the building to physically pack and check all wastes coming down for incineration.
Since this has been in place, instances of OOS's have greatly reduced.

Section 5 implemented on 22/11/04 (Date) **Checked by: -** [signature] (Plant Manager.)
Circulate to: Head of Technical Services, Head of HSE, Environmental and Industrial Hygiene Manager and Supervisor/Plant Manager,.

Agency Inspection Report of 23-Jun-2009

Office of
Environmental
Enforcement

South/South West Region
Environmental Protection Agency
Regional Inspectorate, Inniscarra
County Cork, Ireland

Cigireacht Réigiúnach, Inis Cara
Contae Chorcaí, Éire

T: +353 21 487 5540
F: +353 21 487 5545
E: info@epa.ie
W: www.epa.ie

LoCall: 1890 33 55 99

Dr. Vincent Boyton
Environmental and Industrial Hygiene Services Manager
Novartis Ringaskiddy Limited
Ringaskiddy
County Cork

23rd June 2009 Our Ref: P0006-03/gc10ld

Dear Dr. Boyton,

Attached for your attention is a site inspection report following a site visit to Novartis Ringaskiddy Limited by Agency Personnel on the 19/06/09.

You are required to submit a schedule to the Agency within 10 working days of receipt of this letter detailing how the observations raised in the attached report are to be rectified.

If you have any queries please contact Linda Dalton at 021 487 5540.

Please quote the above reference in future correspondence in relation to this matter.

Yours sincerely,

Linda Dalton
Office of Environmental Enforcement

Site Inspection Report

Office of Environmental Enforcement

South/South West Region
Environmental Protection Agency
Regional Inspectorate, Inniscarra
County Cork, Ireland

Cigireacht Réigiúnach, Inis Cara
Contae Chorcaí, Éire

T: +353 21 487 5540
F: +353 21 487 5545
E: info@epa.ie
W: www.epa.ie

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Dr. Vincent Boyton
Environmental and Industrial Hygiene Services Manager
Novartis Ringaskiddy Limited
Ringaskiddy
County Cork

Date of issue of Inspection Report: 23rd June 2009

Licence Register No:	P0006-03	**Inspection Reference No:**	(P0006-03)09sm03ld
Date of Inspection:	19/06/2009	**Inspectors:**	Ms. Linda Dalton
Photographs taken:	Yes	**Announced:**	No

F.A.O: Dr. Vincent Boyton

This Site Inspection Report details the Agency's findings following an inspection of Novartis Ringaskiddy Limited on 19/06/2009. Novartis Ringaskiddy Limited was found to be in compliance with the conditions of your Licence on the date of the Site Inspection.

In view of the above you are required to submit a schedule to the Agency within 10 working days of receipt of this Report detailing how the observations specified therein are to be rectified. Please quote the above Inspection Reference Number in any future correspondence in relation to this Report. If you have any further queries please contact Linda Dalton **at** 021 487 5540.

1. BACKGROUND

This unscheduled Site Inspection was undertaken as a result of an incident notification to the Agency from the licensee outlining a fire on site during the night of the 18th/19th June 2009.

2. SITE INSPECTION AND ASSESSMENT

The Site Inspection commenced at 10:40am and the following were in attendance:

Representing Novartis Ringaskiddy Limited:

Dr. Vincent Boyton	Environmental and Industrial Hygiene Services Manager

Representing the Environmental Protection Agency:

Ms. Linda Dalton	Inspector

An Inspection of the site was conducted and special attention was paid to the:

- solid waste drum storage area
- conveyor system for the solid waste incinerator
- firewater/stormwater retention system
- spill basin adjacent to the waste water treatment plant.

Interview

The following representatives were interviewed during the Inspection:

Name	Position	Issue
Dr. Vincent Boyton	Environmental and Industrial Hygiene Services Manager	Fire incident 19/06/09
Mr. Tim Barry	Engineer, Technical Services	CCTV footage of fire on 19/06/09

Documentation

The following documentation was requested for review:

Record	Condition No.	Comment
Continuous monitoring records for pH, TOC and flow at influent to firewater/stormwater retention lagoons	6.1 and Sch. C.2.3	Satisfactory

General Comment

The licensee contacted the Agency by telephone at 06:08am on the 19/06/09 and left a voicemail on the Agency telephone system advising that there had been a Category 3 incident in the early hours of the morning and that a fax would be submitted to Inspector Linda Dalton as Enforcement Inspector for the site. An email containing a copy of this fax was sent to Inspector Dalton by Dr. Boyton at 5:47am and a follow up email was sent at 7:00am.

Upon receipt of the above, I undertook a Site Inspection to gather information regarding the incident. Upon arrival at the site I met with Dr. Boyton who provided me with the following details regarding the incident; a small fire had taken place on the conveyor system for the Solid Waste Incinerator on site, which is contained within a small building to the East/North East of the site. The throughput for the incinerator was low in the week leading up to the incident and therefore several drums had been resting on the conveyor belt system for a short period of time. Liquid had leaked from one of these drums, and this liquid caught fire prior to entering the incinerator. The plastic conveyor unit carrying the drum subsequently caught fire. The fire firstly spread upwards and then laterally through the conveyor system (away from the incinerator). Electronic records for the loading of waste into the Solid Waste Incinerator on site indicate that the fire began at 00:43am on the morning of the 19/06/09. The operator stationed in the control room at the time saw the fire on CCTV cameras in the building in question and immediately activated the emergency stop control and a fire response. The sprinkler system was automatically activated within the building. The internal fire response team was mobilised within 3 minutes and began hosing the exterior of the building. Subsequently, a team was dispatched to extinguish the fire within the building. External Emergency Response Agencies were notified and the external fire fighting services arrived on site at approximately 1am. In total, 4 fire fighting units and a number of Garda units attended the incident. The fire units remained on site until approximately 3:30am. Fire water from fire fighting actions within the building was mainly collected in a bunded area located under the conveyor/incinerator. Some fire water escaped the building through a door to the North of the building and entered the surface water drainage system, where it was collected in either the firewater/stormwater retention pond or the spill basin adjacent to the waste water treatment plant. During the incident, the sprinkler system in the Liquid Vapour Incinerator on site was manually activated as a preventative measure. Again, water produced as a result was retained in the firewater/stormwater retention pond or the spill basin.

During the Site Inspection, I viewed the CCTV footage and the electronic waste loading records for the Solid Waste Incinerator, which showed that the fire began at 00:45 (on CCTV) or 00:43 (on waste records log which Dr. Boyton advised was a more accurate representation of the time). The liquid that had spilt was clearly visible on the CCTV footage I viewed, as was the initiation of the fire. From a visual inspection of the building in which the fire took place, I noted that a minimum of 12 plastic conveyor units, and the drums containing solid waste therein, were destroyed by the fire. Dr. Boyton advised me that information regarding exactly what material was contained within each drum in the plastic conveyor units is stored electronically, though this would not be accessible until at least Monday 22/06/09 as an operator from the company's headquarters would be required to access it. The housing of the Solid Waste Incinerator appeared to be fully intact and unaffected by the fire. However, I noted some charring around 2 passive roof vents. Dr. Boyton advised that the a flue adjacent to the conveyor system has a slight negative extraction to allow for a constant flow of air through the building in which the incident occurred, and that it is possible that some smoke would have escaped through this flue.

A number of queries regarding the incident on site were received by the Agency on the morning of the 19/06/09. Therefore, the Agency issued a notification of this incident on the Agency website, www.epa.ie, on the afternoon of the 19/06/09.

Upon conclusion of the Site Inspection above, the licensee was briefed on the Agency's reporting procedures and was advised that a Site Inspection Report would be issued. Finally, the licensee was thanked for the courteous and co-operative manner of the staff, and the assistance and co-operation extended during the Inspection.

3. INSPECTION FINDINGS

Inspection Observations

These observations should be addressed, or where relevant noted by the licensee, in order to ensure compliance, improve environmental performance of the facility and provide clarification on certain issues, as required. Where requested the actions taken and clarifications requested should be reported back to the Agency.

1. **Incident Record**

During the Site Inspection, I was advised by Dr. Boyton that a full investigation into the fire would take place the week beginning the 22/06/09.

Corrective Action Required

The licensee is required to submit a full incident record, which shall include the details outlined in Conditions 11.5 and 9.3 (vi) of the licence, within one month of date of the incident (or by the 19/07/09).

2. **Possible Air Emissions**

Charring around 2 roof vents and the slight negative pressure applied to the flue in the building in which the fire occurred indicates that some air emissions may have escaped the building during incident, though the licensee advised that there was little or no smoke emanating from the building during or following the incident.

Corrective Action Required

In addition to the Incident Report required in Observation 1 above, the licensee shall:

- Identify the contents of all of the drums destroyed in the fire.
- Investigate any possible air emissions from the facility as a result of the incident and submit a report on the same to the Agency within one month of the date of this report.

3. **Operation of Solid Waste Incinerator**

The licensee has advised the Agency that the Solid Waste Incinerator is currently not being operated as a result of the incident above.

Corrective Action Required

The licensee is requested to notify the Agency via fax and telephone prior to recommencement of operation of the Solid Waste Incinerator.

3. Follow-Up Actions

The licensee shall take the actions required to close out the and observations raised in this Site Inspection Report. These actions will be verified during subsequent Inspections.

Please quote the above Inspection Reference Number in any future correspondence in relation to this Report.

Report prepared by Inspector:	Linda Dalton	**Date:** 23/6/09
	Linda Dalton	23rd June 2009

Vincent Boyton
E + IH Services Manager
Health, Safety and
Environmental Protection

Novartis Ringaskiddy Limited
Ringaskiddy
Co. Cork
Ireland

Tel +353-21-4862324
Fax +353-21-4862358

NOVARTIS

OEE Regional Office
Environmental Protection Agency
Inniscarra
County Cork

22 Jul 2009

IPC10356.doc

Re: Update to schedule to rectify observations raised in Inspection Report (P0006-03)09sm03ld

To whom it may concern,

Novartis Ringaskiddy Limited wishes to submit an update to the schedule to rectify the observations raised in the Agency's Inspection Report of 23-Jun-2009 (your reference (P0006-03)09sm03ld) as required by the Agency's letter dated 23-Jun-2009 (your reference P0006-03/gc10ld).

1. *The licensee is required to submit a full incident record, which shall include details outlined in Conditions 11.5 and 9.3 (vi) of the licence, within one month of the date of the incident (or by 19-Jul-2009).*

A full programme to investigate the incident commenced on Monday 22-Jun-2009 – details as follows:

Monday (full afternoon): Walkdown of unit with relevant personnel and commencement of incident review.

Tuesday (morning): Root cause analysis (Failure Mode and Effect Analysis (FMEA))(part 1).

Tuesday (afternoon): Initial meeting with Veolia (waste management company) to scope management plan for solid waste until the Solid Waste Incinerator is operational again.

Wednesday (morning): Full review of the implementation of the company's emergency management system during and immediately after the incident.

Wednesday (afternoon): On site review of incident scene by Cantwell Keogh (fire/safety engineers).

Thursday (full day): Walkdown of all solid waste producing areas on-site by Veolia (waste management company) - audit report to give recommendations on ways to avoid a repeat of this incident.

Friday (morning): Root cause analysis (FMEA)(part 2).

The key (FMEA) report arising from this body of work is included in Attachment Number 1. All other reports arising from the investigative work of the week commencing Monday 22-Jul-2009 will be held on-site and available for inspection by the Agency.

Two key corrective actions arising from this work are/were to:

Undertake an in depth waste audit of the solid waste being presented for treatment in the Solid Waste Incinerator. This work has been completed in association with the company's main waste management contractor Veolia. As a consequence a new system of solid hazardous waste segregation is currently being implemented in the waste generating areas on-site. This will be complimented by full retraining off all personnel responsible for labelling solid waste with the company's Waste Tracking System. Use of the Waste Tracking System for labelling waste for on-site solid incineration will be contingent on satisfactory completion of the training.

The complete report of the fire/safety engineers is still to be issued. However, it is reasonably clear that at this point in time that additional active and passive risk mitigation measures will need to be put in place at the Solid Waste Incinerator to compliment the root cause corrective action outlined above. These will probably included both active risk mitigation in the form of local fire suppression near the point where this incident occurred; and also passive risk mitigation to segregate operational personnel from the direct point where solid waste is fed into the Solid Waste Incinerator.

2. *In addition to the Incident Report required in Observation 1 above, the licensee shall:*

Identify the contents of all of the drums destroyed in the fire.

Investigate any possible air emissions from the facility as a result of the incident and submit a report on the same to the Agency within one month of the date of this report (23-Jun-2009)

A description of the eight drums and contents destroyed in the fire is included in Attachment Number 2. A total of eight lots of solid waste were destroyed in the fire (total weight of 64.24 kgs); together with a similar number of plastic buckets that formed part of the conveyor system. Three lots of waste (on bucket numbers 39, 9 and 10 would have contained some non-chlorinated solvent in adsorbent material); one lot of waste was inert chromatography packing (bucket number 38) and the remaining four lots of waste was either lightly contaminated packing material or general floor waste (bucket numbers 1, 2, 3 and 8). A total of 18 out of 39 conveyor buckets remained intact following the fire and a total of 21 buckets were destroyed in the fire.

An estimation of the emissions arising from the burning of the eight lots of solid waste can be made using typical conversion factors for heavy fuel oil (which would be conservative and probably overstate the emission):

Sulphur Dioxide:	0.2 kg/t	Estimated emission of 0.01 kg
Nitrogen Oxides:	2.7 kg/t	Estimated emission of 0.17 kg
Particulates:	0.2 kg/t	Estimated emission of 0.01 kg

The controlled daily emission of these parameters from the Solid Waste Incinerator is:

Sulphur Dioxide:	10.5 kg/day
Nitrogen Oxides:	84 kg/day
Particulates:	2.1 kg/day

Given the quick spread of the conflagration and the ensuing speed in which it was brought under control it is possible to state with reasonable certainty that there was neither immediate off-site environmental impact during the incident; nor any long-term environmental impact either on-site or off-site following the incident.

NOVARTIS

3. *The licensee is requested to notify the Agency via fax and telephone prior to recommencement of operation of the Solid Waste Incinerator.*

Recommencement of operations at the Solid Waste Incinerator will meet the above requirement.

Trusting that this information is to the Agency's satisfaction,

yours sincerely,

Vincent Boyton

NOVARTIS

Attachment Number 1

Find Root Cause Worksheet 1

IQP
INNOVATION - QUALITY - PRODUCTIVITY

Date: 22-Jun-2009

Attendees: Padraig O'Brien (Head HSE), Vincent Boyton (Env. Health), David Montgomery (Process Safety), Tim Barry (Plant Engineer), Noel Aherne (Plant Engineer), John Harrington (Env. Engineer), Eamonn Burke (IQP), Martin O'Sullivan (Head TS), Liam Higgins (Fire Officer), Brian Daly (G/F PU)

	Is	Is Not
Problem Statement		
What?	Fire on Conveyor at Solid Waste Incinerator (SWI)	SWI
Object?	Conveyor 574.381.001	SWI, other equipment in buidling
Defect?	Fire due to flammable liquid being present	N.A.
Where?		
Geographically?	On Conveyor at SWI	Elsewhere in SWI
On the object	On tipping bucket	Not SWI itself.
When?		
When first?	Friday 19th June 2009 00:43	N.A.
When since?	No occurrence	N.A.
When in the lifecycle?	27 of 39 (number of drum in burning sequence)	Not on earlier drums in the group
# of objects?	1 drum ignited	Not other drums (others were burned as a knockon effect only)
# of defects?	1	N.A.
What is the trend?	refer to Reject Report	

Develop Possible Root causes

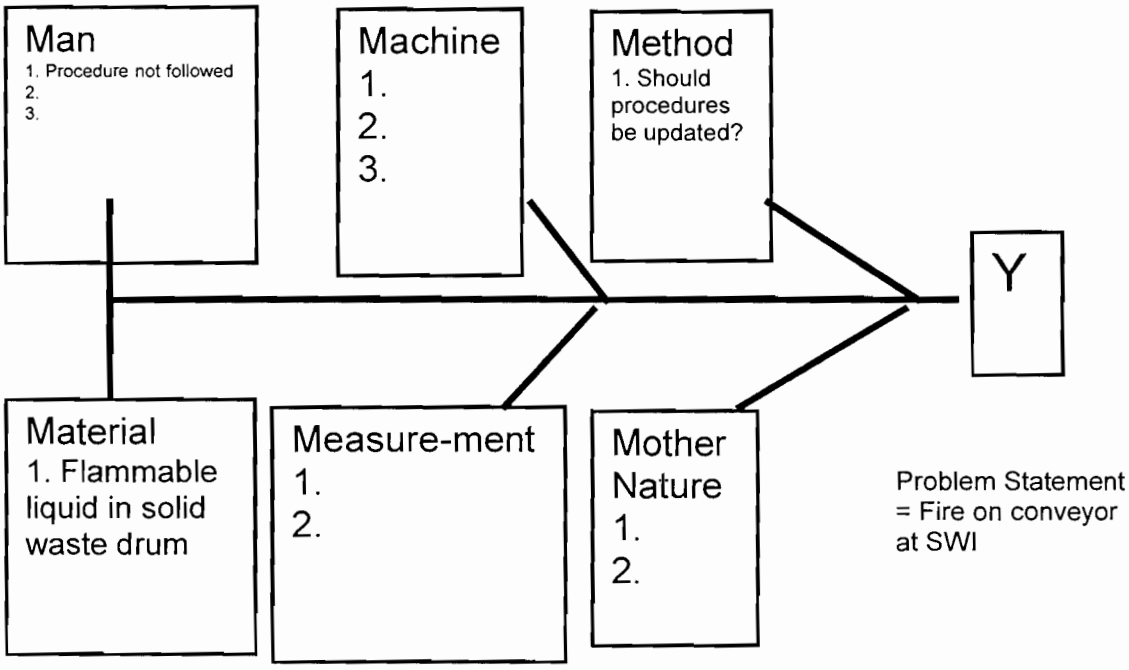
Most Probable Cause? Ignition is visible in CCTV footage from area. Waste as delivered to SWI for incineration is solid waste and should not contain liquids.CCTV however clearly shows lwet area at base of drum and liquid at the base of the carrier bucket having leaked from drum.This
What other damage could this cause create? Explosion, Serious injury or potential fatality.EPA out of spec.
Where else could this Cause create problems? SWI, offiste disposal facility, Manual loading area, waste transportation, fugitive emissions, non-compliance (HSA/EPA) Structural damage
What caused the Cause? Flammable liquid present in solid waste drum lead to ignition indicating a failure to follow procedure on the segretation of waste in production. Possible lack of clarity on procedure for wet waste.
What Fix has been put in place? Initially SWI is out of action.No incineration at the SWI pending root cause analysis and remediation plan. Alternate waste disposal required in short term. Need to review handling procedures for waste.
What identical things need the same Fix? Offsite disposal vendor.

What problems could this Fix cause? Backlog of waste for disposal, Cost of disposal may rise.

Find Root Cause Worksheet 2

IQP
INNOVATION - QUALITY - PRODUCTIVITY

Date: 22-Jun-2009



Possible Causes

Ref #	Description	Probability	Verified

Project	SWI Incident	Prepared By	Eamonn Burke
Team leader	Padraig O'Brien	Original date	22 June 2009
IQP Champion	Eamonn Burke	Last update	26 June 2009

Failure Mode and Effects Analysis

Item / Process steps	Possible Failure Mode(s)	Potential Cause(s)/ Mechanism(s) of Failure	Potential Effect(s) of Failure	Current Detectability Controls Mechanism	Initial criticality				Recommended Action(s)	Responsibility & Target Completion Date	Actions Taken	Final criticality			
					Impact	Frequency	Detectability	RPN				New Impact	New Frequency	New Detect.	New RPN
1	Flammable liquid waste included in Solid Waste drums	Not following procedure (following existing)	Fire, fatality, Out of spec	Observation by TS operator	10	1	8	**80**	Review fire suppression (can we reduce or minimise impact local to the	Liam Higgins to review with Cantwell Keogh	Open	8	1	8	**64**
2	Flammable liquid waste included in Solid Waste drums	lack of clarity in procedure	Fire, fatality, Out of spec	Observation by TS operator	10	5	10	**500**	Revise and update procedures. Train all relevant personnel. More at-source segregation of solid waste materials	John Harrington	open	10	1	10	**100**
3	Unknown waste in drum	Incorrect labelling of waste	Fire, fatality, Out of spec	No control... Full trust in the label as delivered to SWI (or to offsite disposal company)	10	5	10	**500**	Random inspection of drums (select @ SWI and put to side for review by PU)	Martin O'Sullivan	Open	10	3	8	**240**
4	Flammable liquid waste included in Solid Waste drums	Lack of understanding on potential impact, consequences	Fire, fatality, Out of spec	No control... Full trust in the label as delivered to SWI (or to offsite disposal company)	10	5	8	**400**	Show CCTV footage from incident to all operations personnel . Include in the revised training	John Harrington	Open	10	2	8	**160**
5	Unknown waste in drum	Different operator loads and labels drum	Fire, fatality, Out of spec	No control... Full trust in the label as delivered to SWI (or to offsite disposal company)	10	1	10	**100**	Revise procedure to ensure ownership of waste from collection/loading of drum and labelling @ WTS	Martin O'Sullivan	Open	10	1	8	**80**

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Attachment Number 2

Individual lots of solid waste destroyed in fire of 19-Jun-2009:

Date of generation	Location	WasteID	Bucket	WasteType	Description	EWC Code	Weight (kgs)	DrumType
13/06/2009 18:53	PB2	15154968	38	SOLID-SITE	Waste Amres (chromatography column packing)	070510	7.32	Fibre Drum
11/06/2009 16:20	PB2	15154823	39	SOLID-SITE	Ciclo Filter Waste from Clarifier	070510	9.31	Fibre Drum
13/06/2009 16:41	PB2	15154958	1	SOLID-ALL	Contaminated Floor Waste	150202	9.68	Fibre Drum
13/06/2009 12:15	PB2	15154947	2	SOLID-ALL	Empty FIBC Bag (One bag only)	150110	6.91	Plastic Bag
16/06/2009 12:13	PB1	15155188	3	SOLID-ALL	PB1 General Floor Waste	150202	9.15	Fibre Drum
13/06/2009 02:05	PB2	15154922	8	SOLID-ALL	Contaminated Floor Waste	150202	5.97	Plastic Bag
17/06/2009 15:15	PB1	15155280	9	SOLID-ALL	Gaff Filter Material	070510	5.90	Fibre Drum
17/06/2009 11:28	PB1	15155260	10	SOLID-ALL	Gaff Filter Material	070510	10.00	Fibre Drum

Note: 18 buckets in tact after incident ==> 21 buckets destroyed **Total weight: 64.24**

Estimated emissions using Novartis Corporate HSE emission factors for heavy fuel oil (conservative factors):

Sulphur Dioxide: 0.2 kg/t Estimated emission of 0.01 kg
Nitrogen Oxides as NOx: 2.7 kg/t: Estimated emission of 0.17 kg
Particulates: 0.2 kg/t: Estimated emission of 0.01 kg

Agency Audit Report of 08-Oct-2009

Office of
Environmental
Enforcement

South/South West Region
Environmental Protection Agency
Regional Inspectorate, Inniscarra
County Cork, Ireland

Cigireacht Réigiúnach, Inis Cara
Contae Chorcaí, Éire

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Dr. Vincent Boyton
Environmental and Industrial Hygiene Services Manager
Novartis Ringaskiddy Limited
Ringaskiddy
County Cork

8th October 2009 Our Ref: P0006-03 /gc11mor.doc

Dear Dr. Boyton

The observations with IPPC licence Register No. P0006-03 as detailed in the attached audit report have been noted by the Agency.

ACTION REQUIRED

- Submit a schedule to the Agency within ten working days which details how and when the observations specified within the audit report will be rectified.

This notification has been placed on the public file and may be the subject of further enforcement action by the Agency. If you have any queries please contact the Lead Auditor specified in the report.

Please quote the above reference in future correspondence in relation to this matter.

Yours sincerely

Martin O' Reilly
Office of Environmental Enforcement

Encl.

Licence Audit Report

Office of Environmental Enforcement

South/South West Region
Environmental Protection Agency
Regional Inspectorate, Inniscarra
County Cork, Ireland

Cigireacht Réigiúnach, Inis Cara
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LoCall: 1890 33 55 99

Dr. Vincent Boyton
Environmental and Industrial Hygiene Services Manager
Novartis Ringaskiddy Limited
Ringaskiddy
County Cork

Date of Issue of Audit Report: **8th October 2009**

Lead Auditor:	Mr. Martin O'Reilly	**Licence Register No:**	P0006-03
Auditor:	Ms. Michelle Purcell	**Audit Reference No:**	(P0006-03)09AR1MOR
Audit Criteria:	Licence Reg. No. P0006-03	**Scheduled:**	23rd September 2009
Audit No:	4	**Date of Audit:**	30th September 2009

F.A.O: Dr. Vincent Boyton

This Licence Audit Report details the Agency's findings following an audit at Novartis Ringaskiddy Limited on 30/09/2009.

You are required to undertake the corrective actions specified to close out the Observations raised in this Report or further enforcement action may be taken by the Agency. In view of the above you are required to submit a schedule to the Agency within 14 working days of receipt of this Report detailing how the observations specified therein are to be rectified. Please quote the above Audit Reference Number in any future correspondence in relation to this Report. If you have any further queries please contact Linda Dalton at 021-4875540.

1. OPENING MEETING

The opening meeting commenced at 09:30 and the following were in attendance:

Representing Novartis Ringaskiddy Limited:

Dr. Vincent Boyton	Environmental and Industrial Hygiene Services Manager
Mr. Martin O' Sullivan	Head of Technical Services
Mr. John Harrington	Plant Manager Technical Services

Representing the Environmental Protection Agency:

Mr. Martin O'Reilly	Lead Auditor

Ms. Michelle Purcell Auditor

Martin O'Reilly gave a brief introduction to the objectives and scope of the audit and the procedure to be followed for the remainder of the audit.

2. ON-SITE ASSESMENT

2.1 Review of Progress of EMP Implementation

A presentation on the progress of implementation of the Environmental Management Programme was given by Dr. Vincent Boyton

The licensee outlined that progress had been made in relation to the following: solvent recovery, reduction in fugitive emissions, energy conservation, optimising surface water management,

Progress on EMP implementation was considered satisfactory by the Audit team.

2.2 Site Inspection and Assessment

An inspection of the site was conducted, special attention was paid to bunding, the storm water pond, the waste water treatment plant, the liquid vapour incinerator, the solid waste incinerator and the environmental laboratory.

2.3 Interview

The following representatives were interviewed during the audit:

Name	Position	Issue
Dr. Vincent Boyton	Environmental and Industrial Hygiene Services Manager	All
Mr. Martin O' Sullivan	Head of Technical services	Bund testing.
Mr. Len Scannell	Environmental Analyst	Effluent testing.

2.4 Documentation

The following documentation was requested for review:

Record	Condition No.	Comment
Bund test reports.	3.6.5	See observations.
Effluent monitoring results.	6.1 and Schedule C3.2	Satisfactory.
Calibration Records.	6.4	See observations.
Underground tank and pipeline assessment.	6.8	Satisfactory.
Inspection records for storm water.	6.9.1	Satisfactory.
Incident reports.	11.5	Satisfactory
Waste records.	11.10	Satisfactory.

3. GENERAL COMMENT

I found that the site is well managed and there is a well established system of managing the day to day issues associated with the IPPC licence. The licensee has been proactive in a number of areas and in particular optimisation of processes on site which has led to significant reductions in the quantities of raw solvent being used and waste solvent being sent off site.

During the audit I carried out an assessment of the testing that is carried out in the laboratory to assess licence compliance for emissions to sewer. The licensee has started work on reviewing the laboratory test methods and this is an area which should be progressed.

4. CLOSING MEETING

The closing meeting commenced at 15:30 and the attendees were as at the opening meeting with the exception of Mr. John Harrington.

I gave a summary of the audit result. Observations made during the audit (listed below), were discussed.

The licensee was briefed on the Agency's reporting procedures and was advised that an audit report would be issued.

Finally, the licensee was thanked for the courteous and co-operative manner of the staff, and the assistance and co-operation extended during the audit.

5. AUDIT FINDINGS

The audit process is a random sample on a particular day of a facility's compliance with some of its licence conditions. Where a non-compliance against a particular condition has not been reported, this should not be construed to mean that there is full compliance with that condition of the licence.

5.1 Audit Observations

These observations should be addressed or where relevant noted by the licensee in order to ensure compliance, improve environmental performance of the facility and provide clarification on certain issues. Where requested the actions taken and clarifications requested should be reported back to the Agency.

1. **Laboratory Procedures.**

I carried out an assessment of the laboratory test procedures for parameters which are reported to the Agency for compliance purposes. The following tests are carried out by the laboratory for compliance reporting purposes pH, BOD, COD, Suspended solids, total nitrogen, ammonia and total phosphorous. The remainder of tests are carried out by external laboratories which are accredited. I noted the following points during the laboratory assessment.

pH

- There is no annual calibration carried out for temperature for the pH probe.
- Quality control graphs are not in place for analytical quality controls (AQCs).

BOD

- Daily calibration details for the dissolved oxygen meter are not recorded.
- There is no annual calibration carried out for temperature on the DO probe.
- There is no calibration programme in place for the incubator used for BOD samples.
- The daily temperature for the BOD incubator is not recorded.
- Quality control graphs are not in place for AQCs.

COD

- The COD vials being used are in the range 0-1,500 mg/l. The COD in the final effluent is typically <100mg/l.
- The temperature of all positions in the digester block is not checked on an annual basis.

- There is no calibration programme in place for the spectrophotometer.
- Quality control graphs are not in place for AQCs.

Suspended Solids

- The analytical balance used for weighing filter papers is calibrated on an annual basis by Masons, the calibration details are recorded on a Novartis template and the label on the balance is a Novartis one.
- A daily check is not carried out on the balance.
- The oven used for drying suspended solids filter papers is not on a programme for calibration.
- There is no daily check carried out on the oven to verify it is at the correct operating temperature.
- Quality control graphs are not in place for AQCs.

Ammonia (Ion Selective Electrode)

- Two ammonia standards are used as checks on the instrument.
- Quality control graphs are not in place for AQCs.
- There is no calibration programme in place for the ion selective electrode instrument.

Total Phosphorous

- A blank and a standard are used as checks on the instrument.
- Quality control graphs are not in place for AQCs.
- There is no calibration programme in place for the instrument.

Total Nitrogen

- Quality control graphs are not in place for AQCs.
- There is no calibration programme in place for the instrument.

General

- The performance characteristics of the test methods were determined when the tests were initially established in 1993 but have not been examined since.
- The majority of instrumentation is not part of an ongoing service/maintenance programme with servicing only being carried out when needed or when instrument needs repair.

Corrective Action Required

General

- The licensee shall establish a calibration programme for all equipment used for testing and analysis purposes.
- The licensee shall establish quality control graphs for AQCs used for all test methods. The control graphs shall have appropriate warning and action limits.
- Performance characteristics for all test methods should be re-examined to assess their appropriateness.

BOD

- Daily calibration details shall be recorded and acceptable criteria established.
- The temperature of the BOD incubator shall be recorded on a daily basis when samples are being

incubated.

COD

- The vials used for analysing the final effluent should be in a more appropriate range such as 0 – 150mg/l.
- The temperature for all positions on the block digester shall be verified on an annual basis.

Suspended Solids

- The licensee shall maintain calibration certificates which the external calibration company should supply.
- A daily check shall be carried out on the balance using an appropriate check weight and this shall be recorded in a log book or worksheet.

Ammonia

- The ion selective electrode should be calibrated using a minimum of 5 standards across the range of the test method.
- Analytical quality control standards shall be used and shall be prepared from separate stock to the calibration solution.

2. Bund Testing.

During the audit I carried out a review of the most recent bund test report. I found that the report stated that photos were taken over the testing period for the glycol and fuel bund. The photos were not included in the report and no depth measurements were provided. I was informed by the licensee that these were available but had not been included in the report.

Corrective Action Required

The licensee shall include full details of measurements that were taken during the bund testing event. The inclusion of photographs may be made as supplementary information.

6. Follow-Up Actions

The licensee shall take the actions required to close out the non-compliances and observations raised in this Licence Audit Report. These actions will be verified during subsequent site inspections/audits.

Please quote the Audit Reference Number in any future correspondence in relation to this Report.

Report prepared by:	Martin O' Reilly	**Reviewed by:**	Niamh O' Donoghue
Date:	8th October 2009	**Date:**	8th October 2009

Vincent Boyton
E + IH Services Manager
Health, Safety and
Environmental Protection

Novartis Ringaskiddy Limited
Ringaskiddy
Co. Cork
Ireland

Tel +353-21-4862324
Fax +353-21-4862358

Martin O'Reilly.
Office of Environmental Enforcement.
EPA Regional Inspectorate.
Inniscarra,
County Cork,
Ireland.

10 Nov 2009

IPC10358.doc

Re: Schedule In Respect of Agency Audit P0006-03/gc11mor.doc

Dear Mr. O'Reilly,

further to the Agency's audit of 30-Sep-2009 and the subsequently issued report (your reference P0006-03/gc11mor.doc) the company wishes to submit the following schedule of corrective actions:

1. Laboratory Procedures

1.1 In respect of BOD, Ammonia, Total Phosphorus and Total Nitrogen

The company proposes to have those samples that are analysed for these parameters for compliance reporting purpose be carried out by an external accredited laboratory/laboratories.

1.2 In respect of COD

The company's IPPCL emission limit value in respect of COD is 700 mg/l – therefore the correct range to use is 0 to 1,500 mg/l. The point was made during the audit that the typical treated effluent readings for COD are certainly at the lower end of this

scale, however, the 0 to 1,500 mg/l range is most appropriate for confirmation of IPPCL compliance.

The temperature for all positions on the block digester will be verified on an annual basis and this will be ensured by scheduling the work in the company's computerised maintenance management programme (with additional items of laboratory equipment that need scheduled maintenance).

1.3 In respect of Suspended Solids

A hard copy of the calibration certificates that are supplied by the external calibration company will be maintained locally and made available for inspection.

A daily check will be carried out on the balance using an appropriate weight check and this will be recorded in a worksheet.

1.4 General Items

The company will establish a calibration programme for all equipment used for testing and analysis where the results are used for compliance reporting purposes. This programme will be scheduled in the company's computerised maintenance management programme. The test methods of relevance are pH, COD and Suspended Solids.

The company will establish quality control graphs for AQCs used for those test methods where the results are used for compliance reporting purposes. The test methods of relevance are pH, COD and Suspended Solids.

Performance characteristics for those test methods where the results are used for compliance reporting purposes will be re-examined to assess their appropriateness. However, the company does not that it has been an on-going participant in LGC Standards Proficiency Testing scheme since 1994 when the company commenced submitting results to the Agency for compliance reporting purposes. This together with the Agency's own routine analysis of samples from the company should provide a modicum of assurance that the test methods are still fit for purpose.

2. Bund Testing

Full details of the measurements that were taken during the bund testing have been incorporated into the revised report on the testing and inspection of the underground

bunded sewer system and bunded areas; and updated copies will be forwarded to the Agency.

Novartis Ringaskiddy Limited proposes to have all items fully implemented by the end of the current year and available for verification during a subsequent site inspection/audit.

Trusting that this information is to the Agency's satisfaction,

yours sincerely,

Vincent Boyton

Novartis Ringaskiddy Limited

Waste Management Record 2009

IPPCL Register Number P0006-03

Further to Condition 10.10.; and Schedules C.4 and D.; of IPPCL Register Number P0006-03, Novartis Ringaskiddy Limited wishes to submit the relevant data for waste management operations, during 2009, to the Environmental Protection Agency (EPA). This information is listed in the relevant waste summary pages from the Agency's electronic reporting proforma, which forms Attachment 1 to this section of the AER. An analysis of this data is included in Attachment 2 to this section to allow a clearer differentiation to be made between on- and off-site recovery, treatment and disposal.

Results from the analyses of the company's wastewater treatment plant sludge to meet the requirements of Schedule C.4 of IPPCL Register Number P0006-03 are presented in Attachment Number 3 of this report. All other relevant waste analytical data will be held at the facility for inspection by the Agency

Attachment Number 1

5. ONSITE TREATMENT & OFFSITE TRANSFERS OF WASTE | PRTR# : P0006 | Facility Name : Novartis Ringaskiddy Limited | Filename : P0006_2009.xls | Return Year : 2009 | 18/05/2010 09:25

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Transfer Destination	European Waste Code	Hazardous	Quantity (Tonnes per Year) --	Description of Waste	Waste Treatment Operation	Method Used M/C/E	Method Used 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)
Within the Country	07 05 04	Yes	318.747	Solvent vapours	R1	E	Volume Calculation	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03,Ringaskiddy,.,County Cork,.,Ireland	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	07 05 04	Yes	442.651	Solvent waste	D8	C	Volume Calculation	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03,Ringaskiddy,.,County Cork,.,Ireland	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	07 05 04	Yes	6222.178	Solvent waste	R2	M	Volume Calculation	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03,Ringaskiddy,.,County Cork,.,Ireland	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	07 05 04	Yes	1534.934	Solvent waste	R1	M	Volume Calculation	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03,Ringaskiddy,.,County Cork,.,Ireland	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	07 05 01	Yes	342.696	Solvent waste	D10	M	Volume Calculation	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03,Ringaskiddy,.,County Cork,.,Ireland	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	07 05 01	Yes	5.369	Solvent waste	D8	M	Volume Calculation	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03,Ringaskiddy,.,County Cork,.,Ireland	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	07 05 04	Yes	0.17974	Solvent waste	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03,Ringaskiddy,.,County Cork,.,Ireland	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	07 05 10	Yes	6.32824	Other filter cakes and spent absorbents	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03,Ringaskiddy,.,County Cork,.,Ireland	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	07 05 13	Yes	1.54195	Solid wastes containing dangerous substances	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03,Ringaskiddy,.,County Cork,.,Ireland	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	13 02 05	Yes	0.03252	Non-chlorinated lubricating oil	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03,Ringaskiddy,.,County Cork,.,Ireland	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	15 01 10	Yes	40.32986	Contaminated packaging	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03,Ringaskiddy,.,County Cork,.,Ireland	Ringaskiddy, ,County Cork, ,Ireland

Transfer Destination	European Waste Code	Hazardous	Quantity (Tonnes per Year)	Description of Waste	Waste Treatment Operation	Method Used M/C/E	Method Used 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)
Within the Country	15 02 02	Yes	20.31248	Contaminated absorbents and filter materials	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03,Ringaskiddy,.,County Cork,.,Ireland	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	16 05 06	Yes	7.93169	Laboratory waste	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03,Ringaskiddy,.,County Cork,.,Ireland	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	15 01 01	No	0.129	Paper and cardboard packaging	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland		
Within the Country	15 01 02	No	0.22372	Plastic packaging	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland		
Within the Country	15 01 03	No	0.36811	Wooden packaging	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland		
Within the Country	15 01 06	No	0.014	Mixed packaging	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland		
Within the Country	15 02 03	No	0.50652	Non-contaminated absorbents and filter materials	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland		
Within the Country	19 01 12	No	0.012	Bottom ash and slag	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland		
Within the Country	07 05 01	Yes	21.2	Solvent waste	D10	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2,Corrin,.,Fermoy,County Cork,Ireland	Corrin,.,Fermoy,County Cork,Ireland
Within the Country	07 05 01	Yes	474.47	Solvent waste	D13	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2,Corrin,.,Fermoy,County Cork,Ireland	Corrin,.,Fermoy,County Cork,Ireland
Within the Country	07 05 01	Yes	493.56	Solvent waste	R13	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2,Corrin,.,Fermoy,County Cork,Ireland	Corrin,.,Fermoy,County Cork,Ireland
To Other Countries	07 05 01	Yes	70.42	Solvent waste	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen GmbH,A51G00508,Osterweute 1,.,25541 Brunsbuttel,.,Germany	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	07 05 01	Yes	23.16	Solvent waste	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Veolia ES Clenaway (UK) Limited,BS51931E,Bridges Road,Ellesmere Port,South Wirral,Cheshire CH65 4EQ,United Kingdom	Bridges Road,Ellesmere Port,South Wirral,Cheshire CH65 4EQ,United Kingdom

Transfer Destination	European Waste Code	Hazardous	Quantity (Tonnes per Year)	Description of Waste	Waste Treatment Operation	Method Used M/C/E	Method Used 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)
To Other Countries	07 05 04	Yes	77.34	Solvent waste	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen GmbH,A51G00508,Osterweute 1,.,25541 Brunsbuttel,.,Germany	Osterweute 1,.,25541 Brunsbuttel,.,Germany
Within the Country	07 05 04	Yes	332.58	Solvent waste	D13	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2,Corrin,.,Fermoy,County Cork,Ireland	Corrin,.,Fermoy,County Cork,Ireland
Within the Country	07 05 04	Yes	5686.29	Solvent waste	R13	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2,Corrin,.,Fermoy,County Cork,Ireland	Corrin,.,Fermoy,County Cork,Ireland
To Other Countries	07 05 04	Yes	139.42	Solvent waste	R2	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Veolia ES Garston,BS54101G,King Street,Garston,Liverpool,L19 8EG,United Kingdom	King Street,Garston,Liverpool,L19 8EG,United Kingdom
To Other Countries	07 05 04	Yes	427.29	Solvent waste	R13	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Scoribel NV,38.152.BP,Rue de Courriere 49,Z.I.B. De Feluy,Seneffe,B-7181,Belgium	Rue de Courriere 49,Z.I.B. De Feluy,Seneffe,B-7181,Belgium
To Other Countries	07 05 04	Yes	0.805	Mix of waste solvent and lubricating oil	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen GmbH,A51G00508,Osterweute 1,.,25541 Brunsbuttel,.,Germany	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	07 05 13	Yes	2.043	Solid wastes containing dangerous substances	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen GmbH,A51G00508,Osterweute 1,.,25541 Brunsbuttel,.,Germany	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	07 05 01	Yes	0.604	Aqueous waste	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen GmbH,A51G00508,Osterweute 1,.,25541 Brunsbuttel,.,Germany	Osterweute 1,.,25541 Brunsbuttel,.,Germany
Within the Country	07 05 04	Yes	7.221	Solvent waste	R13	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Veolia Environmental Services Technical Solutions Ltd.,Licence Number W0050-2,Corrin,.,Fermoy,County Cork,Ireland	Corrin,.,Fermoy,County Cork,Ireland
To Other Countries	07 05 04	Yes	6.374	Solvent waste	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Sava GmbH & Co,A51G00508,Osterweute 1,25541 Brunsbuttel,.,.,Germany	Osterweute 1,25541 Brunsbuttel,.,.,Germany

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	7.549	Solid wastes containing dangerous substances	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Sava GmbH & Co,A51G00508,Osterweute 1,25541 Brunsbuttel,.,.,Germany	Osterweute 1,25541 Brunsbuttel,.,.,Germany
Within the Country	15 01 02	No	5.753	Plastic packaging	D15	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland		
To Other Countries	15 01 10	Yes	33.956	Contaminated packaging	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen GmbH,A51G00508,Osterweute 1,.,25541 Brunsbuttel,.,Germany	Osterweute 1,.,25541 Brunsbuttel,.,Germany
Within the Country	15 01 10	Yes	1.779	Contaminated packaging	D15	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2,Corrin,.,Fermoy,County Cork,Ireland	Corrin,.,Fermoy,County Cork,Ireland
To Other Countries	15 02 02	Yes	40.477	Contaminated absorbents and filter materials	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen GmbH,A51G00508,Osterweute 1,.,25541 Brunsbuttel,.,Germany	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	16 05 04	Yes	0.077	Empty camping gas cylinders	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen GmbH,A51G00508,Osterweute 1,.,25541 Brunsbuttel,.,Germany	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	16 05 06	Yes	7.967	Laboratory waste	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen GmbH,A51G00508,Osterweute 1,.,25541 Brunsbuttel,.,Germany	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	16 05 07	Yes	1.152	Waste inorganic chemicals	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen GmbH,A51G00508,Osterweute 1,.,25541 Brunsbuttel,.,Germany	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	16 05 08	Yes	0.278	Waste organic chemicals	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen GmbH,A51G00508,Osterweute 1,.,25541 Brunsbuttel,.,Germany	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	20 01 14	Yes	3.792	Waste acids	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen GmbH,A51G00508,Osterweute 1,.,25541 Brunsbuttel,.,Germany	Osterweute 1,.,25541 Brunsbuttel,.,Germany

Transfer Destination	European Waste Code	Hazardous	Quantity (Tonnes per Year) --	Description of Waste	Waste Treatment Operation	Method Used M/C/E	Method Used 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)
Within the Country	07 05 12	No	977.2	Non-contaminated wastewater treatment plant sludge	R13	M	Weighed	Offsite in Ireland	ERAS ECO Limited,W0211-01	Foxhole,Youghal,County Cork,.,Ireland		
To Other Countries	19 01 13	Yes	25.41	Spent lime and activated carbon (fly ash)	R13	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Revatech S.A.,DDT35/MJ/MV,Zoning Industriel,Ehein,Engis,B-4480,Belgium	Zoning Industriel,Ehein,Engis,B-4480,Belgium
Within the Country	16 02 13	Yes	5.69	Discarded electrical equipment	R13	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	TechRec Ireland Limited,Dublin City Council Wsate Permit Number WP 98099,Unit 51,Park West Business Park,Nangor Road,Dublin 12,Ireland	Unit 51,Park West Business Park,Nangor Road,Dublin 12,Ireland
Within the Country	19 01 12	No	42.92	Bottom ash and slag	D1	M	Weighed	Offsite in Ireland	Veolia Environmental Services,CK/WMC/10-01	Forge Hill,Kinsale Road,Cork,.,Ireland		
Within the Country	20 01 02	No	22.5	Glass for recycling	R5	M	Weighed	Onsite in Ireland	Veolia Environmental Services,CK/WMC/10-01	Forge Hill,Kinsale Road,Cork,.,Ireland		
Within the Country	15 01 04	No	122.42	Metallic packaging for recycling	R4	M	Weighed	Offsite in Ireland	Cork Metal Company Limited,CK(S) 204/05	Dublin Hill,.,Cork Metal Company Limited,.,Ireland		
Within the Country	15 01 03	No	62.64	Wooden packaging	R3	M	Weighed	Offsite in Ireland	Keohane Pallets,Not Applicable	Kilnap,Old Mallow Road,Cork,.,Ireland		
Within the Country	15 01 03	No	19.74	Wooden packaging	R3	M	Weighed	Offsite in Ireland	Veolia Environmental Services,CK/WMC/10-01	Forge Hill,Kinsale Road,Cork,.,Ireland		
Within the Country	15 01 03	No	41.44	Wooden packaging	R3	M	Weighed	Offsite in Ireland	Waste Recovery Services (Fermoy) Limited,W0107-1	Cullenagh,Fermoy,County Cork,.,Ireland		
Within the Country	20 01 21	Yes	0.248	Fluorescent tubes	R4	M	Weighed	Offsite in Ireland	Irish Lamp Recycling Company Limited,Kildare County Council Permit Number 02/2000B	Woodstock Industrial Estate,Kilkenny Road,Athy,County Kildare,Ireland	Irish Lamp Recycling Compnay,Kildare County Council permit Number 02/2000B,Woodstock Industrial Estate,Kilkenny Road,Athy,County Kildare,Ireland	Woodstock Industrial Estate,Kilkenny Road,Athy,County Kildare,Ireland
Within the Country	20 01 40	No	13.5	Scrap metal	R4	M	Weighed	Offsite in Ireland	Greenstar,CK WMC 20/01	Sarsfield Court Industrial Estate,Glanmire,County Cork,.,Ireland		
Within the Country	**17 01 07**	**No**	24.78	Concrete, bricks, tiles and ceramics	D1	M	Weighed	Offsite in Ireland	Ashgrove Recycling and Waste Management,W0147-01	Churchfield Industrial Estate,John F. Connolly Road,Cork,.,Ireland		
Within the Country	17 09 04	No	7.52	Mixed C + D waste	D1	M	Weighed	Offsite in Ireland	Ashgrove Recycling and Waste Management,W0147-01	Churchfield Industrial Estate,John F. Connolly Road,Cork,.,Ireland		
Within the Country	16 11 06	No	0.78	Refractory material	D1	M	Weighed	Offsite in Ireland	Waste Recovery Services (Fermoy) Limited,W0107-1	Cullenagh,Fermoy,County Cork,.,Ireland		
Within the Country	15 01 01	No	40.14	Paper and cardboard packaging	R3	M	Weighed	Offsite in Ireland	Veolia Environmental Services,CK/WMC/10-01	Forge Hill,Kinsale Road,Cork,.,Ireland		
Within the Country	15 01 02	No	0.14	Plastic packaging	R3	M	Weighed	Offsite in Ireland	Veolia Environmental Services,CK/WMC/10-01	Forge Hill,Kinsale Road,Cork,.,Ireland		
Within the Country	20 01 02	No	10.05	Glass for recycling	R5	M	Weighed	Offsite in Ireland	Rehab Enterprises Limited,Cork County Council Waste permit Number 08/04	Monaghan Road,.,Cork.,.,Ireland		
Within the Country	15 01 04	No	0.12	Metallic packaging for recycling	R4	M	Weighed	Offsite in Ireland	Rehab Enterprises Limited,Cork County Council Waste permit Number 08/04	Monaghan Road,.,Cork.,.,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					
Within the Country	15 02 03	No	426.06	Inert adsorbent for reuse	R4	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland		
To Other Countries	16 05 06	Yes	1.092	Laboratory waste	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Sava GmbH & Co,A51G00508,Osterweute 1,25541 Brunsbuttel,.,.,Germany	Osterweute 1,25541 Brunsbuttel,.,.,Germany
To Other Countries	16 08 07	Yes	38.1	Spent catalysts	R4	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number W0050-2	Corrin,.,Fermoy,County Cork,Ireland	Johnson Matthey,Not Applicable,Orchard Road,Royston,Hertfordshire, SG8 5HE,United Kingdom	Orchard Road,Royston,Hertfordshire, SG8 5HE,United Kingdom
Within the Country	20 03 01	No	100.1	Mixed municipal waste	D1	M	Weighed	Offsite in Ireland	Veolia Environmental Services,CK/WMC/10-01	Forge Hill,Kinsale Road,Cork,.,Ireland		

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

Attachment Number 2

Transfer Destination	European Waste Code	Hazardous	Quantity T/Year	Description of Waste	Waste Treatment Operation	Method Used		Location of Treatment	Name and Licence / Permit No. of Recoverer / Disposer / Broker	Address of Recoverer / Disposer / Broker	Name and Address of Final Destination i.e. Final Recovery / Disposal Site (HAZARDOUS WASTE ONLY)	Licence / Permit No. of Final Destination i.e. Final Recovery / Disposal Site (HAZARDOUS WASTE ONLY)
						M/C/E	Method Used					
Within the Country	16 11 06	No	0.780	Refractory material	D1	M	Weighed	Offsite in Ireland	Waste Recovery Services (Fermoy) Limited,W0107-1	Cullenagh,Fermoy,County Cork,,,Ireland	Not Applicable.	Not Applicable.
Within the Country	17 01 07	No	24.780	Concrete, bricks, tiles and ceramics	D1	M	Weighed	Offsite in Ireland	Ashgrove Recycling and Waste Management,W0147-01	Churchfield Industrial Estate,John F. Connolly Road,Cork,,,Ireland	Not Applicable.	Not Applicable.
Within the Country	17 09 04	No	7.520	Mixed C + D waste	D1	M	Weighed	Offsite in Ireland	Ashgrove Recycling and Waste Management,W0147-01	Churchfield Industrial Estate,John F. Connolly Road,Cork,,,Ireland	Not Applicable.	Not Applicable.
Within the Country	19 01 12	No	42.920	Bottom ash and slag	D1	M	Weighed	Offsite in Ireland	Veolia Environmental Services,CK/WMC/10-01	Forge Hill,Kinsale Road,Cork,,,Ireland	Not Applicable.	Not Applicable.
Within the Country	20 03 01	No	100.100	Mixed municipal waste	D1	M	Weighed	Offsite in Ireland	Veolia Environmental Services,CK/WMC/10-01	Forge Hill,Kinsale Road,Cork,,,Ireland	Not Applicable.	Not Applicable.
Within the Country	15 01 01	No	0.129	Paper and cardboard packaging	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	15 01 02	No	0.224	Plastic packaging	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	15 01 03	No	0.368	Wooden packaging	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	15 01 06	No	0.014	Mixed packaging	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	15 02 03	No	0.507	Non-contaminated absorbents and filter materials	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	19 01 12	No	0.012	Bottom ash and slag	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	15 01 02	No	5.753	Plastic packaging	D15	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Not Applicable.	Not Applicable.
Sub-total non-hazardous waste disposed:			**183.106**									

Transfer Destination	European Waste Code	Hazardous	Quantity T/Year	Description of Waste	Waste Treatment Operation	Method Used		Location of Treatment	Name and Licence / Permit No. of Recoverer / Disposer / Broker	Address of Recoverer / Disposer / Broker	Name and Address of Final Destination i.e. Final Recovery / Disposal Site (HAZARDOUS WASTE ONLY)	Licence / Permit No. of Final Destination i.e. Final Recovery / Disposal Site (HAZARDOUS WASTE ONLY)
						M/C/E	Method Used					
Within the Country	07 05 12	No	977.200	Non-contaminated wastewater treatment plant sludge	R13	M	Weighed	Offsite in Ireland	ERAS ECO Limited,W0211-01	Foxhole,Youghal,County Cork,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	15 01 01	No	40.140	Paper and cardboard packaging	R3	M	Weighed	Offsite in Ireland	Veolia Environmental Services,CK/WMC/10-01	Forge Hill,Kinsale Road,Cork,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	15 01 02	No	0.140	Plastic packaging	R3	M	Weighed	Offsite in Ireland	Veolia Environmental Services,CK/WMC/10-01	Forge Hill,Kinsale Road,Cork,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	15 01 03	No	62.640	Wooden packaging	R3	M	Weighed	Offsite in Ireland	Keohane Pallets,Not Applicable	Kilnap,Old Mallow Road,Cork,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	15 01 03	No	19.740	Wooden packaging	R3	M	Weighed	Offsite in Ireland	Veolia Environmental Services,CK/WMC/10-01	Forge Hill,Kinsale Road,Cork,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	15 01 03	No	41.440	Wooden packaging	R3	M	Weighed	Offsite in Ireland	Waste Recovery Services (Fermoy) Limited,W0107-1	Cullenagh,Fermoy,County Cork,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	15 01 04	No	122.420	Metallic packaging for recycling	R4	M	Weighed	Offsite in Ireland	Cork Metal Company Limited,CK(S) 204/05	Dublin Hill,.,Cork Metal Company Limited,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	15 01 04	No	0.120	Metallic packaging for recycling	R4	M	Weighed	Offsite in Ireland	Rehab Enterprises Limited,Cork County Council Waste permit Number 08/04	Monaghan Road,.,Cork.,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	15 02 03	No	426.060	Inert adsorbent for reuse	R4	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Not Applicable.	Not Applicable.
Within the Country	20 01 40	No	13.500	Scrap metal	R4	M	Weighed	Offsite in Ireland	Greenstar,CK WMC 20/01	Sarsfield Court Industrial Estate,Glanmire,County Cork,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	20 01 02	No	22.500	Glass for recycling	R5	M	Weighed	Onsite in Ireland	Veolia Environmental Services,CK/WMC/10-01	Forge Hill,Kinsale Road,Cork,.,Ireland	Not Applicable.	Not Applicable.
Within the Country	20 01 02	No	10.050	Glass for recycling	R5	M	Weighed	Offsite in Ireland	Rehab Enterprises Limited,Cork County Council Waste permit Number 08/04	Monaghan Road,.,Cork.,.,Ireland	Not Applicable.	Not Applicable.
Sub-total non-hazardous waste recovered:			**1,735.950**									

Transfer Destination	European Waste Code	Hazardous	Quantity T/Year	Description of Waste	Waste Treatment Operation	Method Used		Location of Treatment	Name and Licence / Permit No. of Recoverer / Disposer / Broker	Address of Recoverer / Disposer / Broker	Name and Address of Final Destination i.e. Final Recovery / Disposal Site (HAZARDOUS WASTE ONLY)	Licence / Permit No. of Final Destination i.e. Final Recovery / Disposal Site (HAZARDOUS WASTE ONLY)
						M/C/E	Method Used					
Within the Country	07 05 01	Yes	342.696	Solvent waste	D10	M	Volume Calculation	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	07 05 01	Yes	21.200	Solvent waste	D10	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland
To Other Countries	07 05 01	Yes	70.420	Solvent waste	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	07 05 01	Yes	23.160	Solvent waste	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Veolia ES Clenaway (UK) Limited,BS51931E,Bridges Road,Ellesmere Port,South	Bridges Road,Ellesmere Port,South Wirral,Cheshire CH65 4EQ,United Kingdom
To Other Countries	07 05 01	Yes	0.604	Aqueous waste	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen	Osterweute 1,.,25541 Brunsbuttel,.,Germany
Within the Country	07 05 04	Yes	0.180	Solvent waste	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-	Ringaskiddy, ,County Cork, ,Ireland
To Other Countries	07 05 04	Yes	77.340	Solvent waste	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	07 05 04	Yes	0.805	Mix of waste solvent and lubricating oil	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	07 05 04	Yes	6.374	Solvent waste	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Sava GmbH & Co,A51G00508,Osterweute 1,25541	Osterweute 1,25541 Brunsbuttel,.,.,Germany
Within the Country	07 05 10	Yes	6.328	Other filter cakes and spent absorbents	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	07 05 13	Yes	1.542	Solid wastes containing dangerous substances	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-	Ringaskiddy, ,County Cork, ,Ireland
To Other Countries	07 05 13	Yes	2.043	Solid wastes containing dangerous substances	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	07 05 13	Yes	7.549	Solid wastes containing dangerous substances	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Sava GmbH & Co,A51G00508,Osterweute 1,25541	Osterweute 1,25541 Brunsbuttel,.,.,Germany
Within the Country	13 02 05	Yes	0.033	Non-chlorinated lubricating oil	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	15 01 10	Yes	40.330	Contaminated packaging	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-	Ringaskiddy, ,County Cork, ,Ireland
To Other Countries	15 01 10	Yes	33.956	Contaminated packaging	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen	Osterweute 1,.,25541 Brunsbuttel,.,Germany
Within the Country	15 02 02	Yes	20.312	Contaminated absorbents and filter materials	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-	Ringaskiddy, ,County Cork, ,Ireland
To Other Countries	15 02 02	Yes	40.477	Contaminated absorbents and filter materials	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	16 05 04	Yes	0.077	Empty camping gas cylinders	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen	Osterweute 1,.,25541 Brunsbuttel,.,Germany
Within the Country	16 05 06	Yes	7.932	Laboratory waste	D10	M	Weighed	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-	Ringaskiddy, ,County Cork, ,Ireland

To Other Countries	16 05 06	Yes	7.967	Laboratory waste	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	16 05 06	Yes	1.092	Laboratory waste	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Sava GmbH & Co,A51G00508,Osterweute 1,25541	Osterweute 1,25541 Brunsbuttel,.,.,Germany
To Other Countries	16 05 07	Yes	1.152	Waste inorganic chemicals	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	16 05 08	Yes	0.278	Waste organic chemicals	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen	Osterweute 1,.,25541 Brunsbuttel,.,Germany
To Other Countries	20 01 14	Yes	3.792	Waste acids	D10	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Sava Sonderabfallverbrennungsanlagen	Osterweute 1,.,25541 Brunsbuttel,.,Germany
Within the Country	07 05 01	Yes	474.470	Solvent waste	D13	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland
Within the Country	07 05 04	Yes	332.580	Solvent waste	D13	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland
Within the Country	15 01 10	Yes	1.779	Contaminated packaging	D15	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland
Within the Country	07 05 01	Yes	5.369	Solvent waste	D8	M	Volume Calculation	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	07 05 04	Yes	442.651	Solvent waste	D8	C	Volume Calculation	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-	Ringaskiddy, ,County Cork, ,Ireland
Sub-total hazardous waste disposed:			**1,974.487**									

Transfer Destination	European Waste Code	Hazardous	Quantity T/Year	Description of Waste	Waste Treatment Operation	Method Used		Location of Treatment	Name and Licence / Permit No. of Recoverer / Disposer / Broker	Address of Recoverer / Disposer / Broker	Name and Address of Final Destination i.e. Final Recovery / Disposal Site	Licence / Permit No. of Final Destination i.e. Final Recovery / Disposal Site
						M/C/E	Method Used					
Within the Country	07 05 04	Yes	318.747	Solvent vapours	R1	E	Volume Calculation	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	07 05 04	Yes	1,534.934	Solvent waste	R1	M	Volume Calculation	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-	Ringaskiddy, ,County Cork, ,Ireland
Within the Country	07 05 01	Yes	493.560	Solvent waste	R13	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland
Within the Country	07 05 04	Yes	5,686.290	Solvent waste	R13	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland
To Other Countries	07 05 04	Yes	427.290	Solvent waste	R13	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Scoribel NV,38.152.BP,Rue de Courriere 49,Z.I.B. De Feluy,Seneffe,B-	Rue de Courriere 49,Z.I.B. De Feluy,Seneffe,B-7181,Belgium
Within the Country	07 05 04	Yes	7.221	Solvent waste	R13	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Veolia Environmental Services Technical Solutions Ltd.,Licence Number W0050-	Corrin,.,Fermoy,County Cork,Ireland
Within the Country	16 02 13	Yes	5.690	Discarded electrical equipment	R13	M	Weighed	Offsite in Ireland	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	TechRec Ireland Limited,Dublin City Council Wsate Permit Number WP	Unit 51,Park West Business Park,Nangor Road,Dublin 12,Ireland
To Other Countries	19 01 13	Yes	25.410	Spent lime and activated carbon (fly ash)	R13	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Revatech S.A.,DDT35/MJ/MV,Zoning Industriel,Ehein,Engis,B-	Zoning Industriel,Ehein,Engis,B-4480,Belgium
Within the Country	07 05 04	Yes	6,222.178	Solvent waste	R2	M	Volume Calculation	Onsite in Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-03	Ringaskiddy,.,County Cork,.,Ireland	Novartis Ringaskiddy Limited,IPPC Licence Register Number P0006-	Ringaskiddy, ,County Cork, ,Ireland
To Other Countries	07 05 04	Yes	139.420	Solvent waste	R2	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Veolia ES Garston,BS54101G,King Street,Garston,Liverpool,L19	King Street,Garston,Liverpool,L19 8EG,United Kingdom
To Other Countries	16 08 07	Yes	38.100	Spent catalysts	R4	M	Weighed	Abroad	Veolia Environmental Services Technical Solutions Limited,Licence Number	Corrin,.,Fermoy,County Cork,Ireland	Johnson Matthey,Not Applicable,Orchard Road,Royston,Hertfordshire,	Orchard Road,Royston,Hertfordshire, SG8 5HE,United Kingdom
Within the Country	20 01 21	Yes	0.248	Fluorescent tubes	R4	M	Weighed	Offsite in Ireland	Irish Lamp Recycling Company Limited,Kildare County Council Permit	Woodstock Industrial Estate,Kilkenny Road,Athy,County	Irish Lamp Recycling Compnay,Kildare County Council permit Number	Woodstock Industrial Estate,Kilkenny Road,Athy,County
Sub-total hazardous waste recovered:			**14,899.088**									

Attachment Number 3

Environmental and Industrial Hygiene Laboratory.
Novartis Ringaskiddy Limited,
Ringaskiddy, Co. Cork.

Telephone: 021/4862324.
Fax: 021/4862355.

REPORT: DEWATERED AEROBICALLY DIGESTED SLUDGE LEACHATE ANALYSIS

EMISSION POINT REFERENCE NUMBER 100 (WASTEWATER TREATMENT PLANT)

SCHEDULE C.4; INTEGRATED POLLUTION PREVENTION AND CONTROL LICENCE REGISTER NUMBER P0006-03

REPORTING PERIOD: March, 2009

Schedule C.4 of Integrated Pollution Prevention and Control Licence (IPPCL) Register Number P0006-03 requires that a leachate test be carried out on dewatered aerobically digested sludge produced as a by-product of effluent treatment. An analysis for heavy metals (individual), organic matter and water content is required a quarterly basis; and an analysis for organic compounds is required on an annual basis.

Novartis Ringaskiddy Limited engaged the services of Environmental Laboratory Services, Acorn Business Campus, Mahon Industrial Park, Blackrock, Cork, to carry out a distilled water leachate test on a sample this material. The leachate method reference method was to the German Standard DIN 38414-S4 (October, 1984).

The following table summarises the analytical results of the eluate from the leachate procedure (single leaching):

PARAMETER	RESULT
Sampling Date: 11-Mar-2009	
Total Organic Carbon:	517 mg/L TOC
Zinc:	0.5 mg/L Zn
Copper:	0.1 mg/L Cu
Dry Matter:	18 %

NOTE: Neither Copper nor Zinc has been used at Novartis Ringaskiddy Limited up to this point in time.

A subsample of the leachate was analysed by Environmental Laboratory Services for organic compounds. The results of this analysis are reproduced on the test certificate on the following page.

Signed VBoyton : Vincent Boyton.

Dated 17-Apr-2009 : 17-Apr-2009.

ENVIRONMENTAL LABORATORY SERVICES
Acorn Business Campus,
Mahon Industrial Park,
Blackrock,
CorkTel: 021-4536141
Fax: 021-4536149

Analysis Report

Attention:		**Report No:**	13267
Vincent Boyton			
Novartis Ringaskiddy Limited		**Date of receipt:**	31/03/2009
IDA Estate,		**Date Started:**	01/04/2009
Ringaskiddy,			
Co. Cork			
Fax No:		**Issue Date:**	17/04/2009
Tel No:	021- 4862324	**Page**	1 of 3
PO Number:	OP-95758	**Delivery Mode**	Pick-Up
Sample Type	Sludge	**No. of Samples**	1
Condition on receipt	Satisfactory	**Client Ref:**	089100006412 Sludge Cake

Parameter	Test Method
SAMPLE PREPARATION	
Leachability Test	ISEN12457-4 2002- 10/1 Leaching
Solids Content	EM113 Evaporation/gravimetric
DRIED SLUDGE TESTS	
Metals	EM130 ICP-MS
TKN	APHA4500 -Norg,C- Semi-Micro-Kjeldahl
Total Phosphorous	H8190: Acid Persulphate Digestion./Phos ver3
WET SLUDGE TESTS	
Organic Solvents	Pre-concentration & GC-FID
Volatile Organic Compounds	EO 025 Purge and Trap/GC/MS
LEACHATE TESTS (Filter through 0.45um filter-blank correct all results)	
Organic Solvents	Pre-concentration & GC-FID
Metals	EM130 ICP-MS
Dissolved Organic Carbon	EW123 by Combustion Oxidation
Volatile Organic Compounds	EO 025 Purge and Trap/GC/MS

Technical Manager (or Deputy) Brendan Murray 17/04/2009

Leachate,Wet and Dried Sludge

Parameter	Leachate from Sludge			Wet Sludge			Dried Sludge		
	Units	Detection Limit	Result	Units	Detection Limit	Result	Units	Detection Limit	Result
Methanol.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1	Not required to be tested		
Ethanol.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Isopropyl Alcohol.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
n-Hexane.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
sec-Butyl Alcohol.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Acetic Acid.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Isopropyl Ether.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Ethyl Acetate.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Isopropyl Acetate.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Heptane.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
n-Butyl Alcohol.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Acetonitrile	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Cyclohexane.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Triethylamine.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
N,N-Dimethylformamide.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Copper	mg/l	0.003	0.098	Not required to be tested			mg/kg	5	29.4
Zinc	mg/l	0.001	0.469				mg/kg	5	390.8
TOC	mg/l	0.025	517				Not required		
% Matter	Not required to be tested						%	-	13.7
Tc Nitrogen (TKN)							mg/kg N	10	7000
Total Phosphorus							mg/kg P	1	465
Total Potassium							mg/kg	1000	1825
Nickel							mg/kg	2.5	16.2
Cadmium							mg/kg	0.5	<0.5
Lead							mg/kg	1.5	6.3
Mercury							mg/kg	0.5	<0.5
Chromium							mg/kg	5	<5

Appendix A

VOC

No.	Analyte	Leachate			Wet Sludge		
		Units	Detection Limit	Result	Units	Detection Limit	Result
2	Dichlorodifluoromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
3	Chloromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
4	Ethyl Chloride/Chloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
5	Vinyl Chloride/Chloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
6	Bromomethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
8	Trichloromonofluoromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
9	Ethyl Ether/Diethyl Ether	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
10	11 Dichloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
11	Acetone	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
12	Iodomethane/Methyl Iodide	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
13	Carbon Disulphide	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
14	Allyl Chloride	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
15	Methylene Chloride/DCM	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
16	2-Propenenitrile/Acrylonitrile	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
17	Chlormethyl Cyanide/Chloroacetonitrile	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
18	Nitrobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
19	Propanenitrile	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
20	Hexachlorobutadiene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
21	Trans-1,2 Dichloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
22	MtBE	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
23	11 Dichloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
24	22 Dichloropropane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
25	cis-12 Dichloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
26	2-Butanone	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
27	Methyl Acrylate	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
28	Bromochloromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
29	Methacrylonitrile	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
30	Tetrahydrofuran	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
31	Trichloromethane/ Chloroform	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
32	111 Trichloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
33	1-Chlorobutane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
34	Carbon Tetrachloride	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
35	11 Dichloropropene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
36	Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
37	12 Dichloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
39	Trichloroethylene/ Trichloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
40	12 Dichloropropane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
41	Dibromomethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
42	Methyl Methacrylate	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
43	Bromodichloromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
44	13 Dichloropropene,cis	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
45	MIBK/4 Methyl 2 Pentanone	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
46	Toluene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
47	13 Dichloropropene,trans	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
48	Ethyl Methacrylate	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
49	112 Trichloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
50	Tetrachloroethylene/ Tetrachloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
51	13 Dichloropropane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
52	2-Hexanone	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
53	Dibromochloromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
54	12 Dibromoethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
55	Chlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
56	1112 Tetrachloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
57	Ethyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
58	m & p Xylene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
59	o Xylene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
60	Styrene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
61	Bromoform	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
62	Isopropyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
63	Bromobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
64	1122 Tetrachloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
65	123 Trichloropropane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
66	Trans 14 Dichloro 2 Butene, tran	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
67	Propyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
68	2-Chlorotoluene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
69	4 Chlorotoluene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
70	135 Trimethylbenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
71	Tert Butyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
72	124 Trimethylbenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
73	Sec Butyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
74	13 Dichlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
75	P Isopropyltoluene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
76	14 Dichlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
77	12 Dichlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
78	N Butyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
79	Hexachloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
80	12 Dibromo 3 Chloropropane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
81	124 Trichlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
82	Napththalene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
83	123 Trichlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1

Environmental and Industrial Hygiene Laboratory.
Novartis Ringaskiddy Limited,
Ringaskiddy, Co. Cork.

Telephone: 021/4862324.
Fax: 021/4862355.

REPORT: DEWATERED AEROBICALLY DIGESTED SLUDGE LEACHATE ANALYSIS

EMISSION POINT REFERENCE NUMBER 100 (WASTEWATER TREATMENT PLANT)

SCHEDULE C.4; INTEGRATED POLLUTION PREVENTION AND CONTROL LICENCE REGISTER NUMBER P0006-03

REPORTING PERIOD: June, 2009

Schedule C.4 of Integrated Pollution Prevention and Control Licence (IPPCL) Register Number P0006-03 requires that a leachate test be carried out on dewatered aerobically digested sludge produced as a by-product of effluent treatment. An analysis for heavy metals (individual), organic matter and water content is required a quarterly basis; and an analysis for organic compounds is required on an annual basis.

Novartis Ringaskiddy Limited engaged the services of Environmental Laboratory Services, Acorn Business Campus, Mahon Industrial Park, Blackrock, Cork, to carry out a distilled water leachate test on a sample this material. The leachate method reference method was to the German Standard DIN 38414-S4 (October, 1984).

The following table summarises the analytical results of the eluate from the leachate procedure (single leaching):

PARAMETER	RESULT
Sampling Date: 30-Jun-2009	
Total Organic Carbon:	91 mg/L TOC
Zinc:	11,130 mg/L Zn (*)
Copper:	< 0.1 mg/L Cu
Dry Matter:	14 %

NOTE: Neither Copper nor Zinc has been used at Novartis Ringaskiddy Limited up to this point in time.

A subsample of the leachate was analysed by Environmental Laboratory Services for organic compounds. The results of this analysis are reproduced on the test certificate on the following page.

(*) Note that Zinc is not used in production processes at Novartis Ringaskiddy Limited

Signed Vincent Boyton : Vincent Boyton.

Dated 17-Jul-2009 : 17-Jul-2009.

ENVIRONMENTAL LABORATORY SERVICES
Acorn Business Campus,
Mahon Industrial Park,
Blackrock,
CorkTel: 021-4536141
Fax: 021-4536149

Analysis Report

Attention:		**Report No:**	14108
Vincent Boyton			
Novartis Ringaskiddy Limited		**Date of receipt:**	30/06/2009
IDA Estate,		**Date Started:**	01/07/2009
Ringaskiddy,			
Co. Cork			
Fax No:		**Issue Date:**	17/07/2009
Tel No:	021- 4862324	**Page**	1 **of** 3
PO Number:	OP-95758	**Delivery Mode**	Pick-Up
Sample Type	Sludge	**No. of Samples**	1
Condition on receipt	Satisfactory	**Client Ref:**	089100009520

Parameter	Test Method
SAMPLE PREPARATION	
Leachability Test	ISEN12457-4 2002- 10/1 Leaching
Solids Content	EM113 Evaporation/gravimetric
DRIED SLUDGE TESTS	
Metals	EM130 ICP-MS
TKN	APHA4500 -Norg,C- Semi-Micro-Kjeldahl
Total Phosphorous	H8190: Acid Persulphate Digestion./Phos ver3
WET SLUDGE TESTS	
Organic Solvents	Pre-concentration & GC-FID
Volatile Organic Compounds	EO 025 Purge and Trap/GC/MS
LEACHATE TESTS (Filter through 0.45um filter-blank correct all results)	
Organic Solvents	Pre-concentration & GC-FID
Metals	EM130 ICP-MS
Dissolved Organic Carbon	EW123 by Combustion Oxidation
Volatile Organic Compounds	EO 025 Purge and Trap/GC/MS

Technical Manager (or Deputy) _____ 17/07/2009

Brendan Murray

Leachate,Wet and Dried Sludge

Parameter	Leachate from Sludge			Wet Sludge			Dried Sludge		
	Units	Detection Limit	Result	Units	Detection Limit	Result	Units	Detection Limit	Result
Methanol.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1	Not required to be tested		
Ethanol.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Isopropyl Alcohol.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
n-Hexane.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
sec-Butyl Alcohol.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Acetic Acid.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Isopropyl Ether.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Ethyl Acetate.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Isopropyl Acetate.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Heptane.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
n-Butyl Alcohol.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Acetonitrile	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Cyclohexane.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Triethylamine.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
N,N-Dimethylformamide.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Copper	mg/l	0.003	<0.03	Not required to be tested			mg/kg	5	834
Zinc	mg/l	0.001	11130				mg/kg	5	2358
TOC	mg/l	0.025	91				Not required		
% Dry Matter	Not required to be tested						%	-	14
Total Nitrogen (TKN)							mg/kg N	10	96000
Total Phosphorus							mg/kg P	1	2175
Total Potassium							mg/kg	1000	4163
Nickel							mg/kg	2.5	176
Cadmium							mg/kg	0.5	<0.5
Lead							mg/kg	1.5	69.1
Mercury							mg/kg	0.5	<0.5
Chromium							mg/kg	5	125

NOTES

1. Leachate reporting limit changed as sample needed to be diluted during leaching step

Appendix A

VOC

No.	Analyte	Leachate			Wet Sludge		
		Units	Detection Limit	Result	Units	Detection Limit	Result
2	Dichlorodifluoromethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
3	Chloromethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
4	Ethyl Chloride/Chloroethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
5	Vinyl Chloride/Chloroethene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
6	Bromomethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
8	Trichloromonofluoromethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
9	Ethyl Ether/Diethyl Ether	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
10	11 Dichloroethene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
11	Acetone	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
12	Iodomethane/Methyl Iodide	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
13	Carbon Disulphide	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
14	Allyl Chloride	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
15	Methylene Chloride/DCM	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
16	2-Propenenitrile/Acrylonitrile	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
17	Chlormethyl Cyanide/Chloroacetonitrile	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
18	Nitrobenzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
19	Propanenitrile	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
20	Hexachlorobutadiene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
21	Trans-1,2 Dichloroethene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
22	MtBE	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
23	11 Dichloroethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
24	22 Dichloropropane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
25	cis-12 Dichloroethene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
26	2-Butanone	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
27	Methyl Acrylate	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
28	Bromochloromethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
29	Methacrylonitrile	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
30	Tetrahydrofuran	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
31	Trichloromethane/ Chloroform	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
32	111 Trichloroethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
33	1-Chlorobutane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
34	Carbon Tetrachloride	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
35	11 Dichloropropene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
36	Benzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
37	12 Dichloroethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
39	Trichloroethylene/ Trichloroethene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
40	12 Dichloropropane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
41	Dibromomethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
42	Methyl Methacrylate	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
43	Bromodichloromethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
44	13 Dichloropropene,cis	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
45	MIBK/4 Methyl 2 Pentanone	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
46	Toluene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
47	13 Dichloropropene,trans	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
48	Ethyl Methacrylate	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
49	112 Trichloroethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
50	Tetrachloroethylene/ Tetrachloroethene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
51	13 Dichloropropane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
52	2-Hexanone	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
53	Dibromochloromethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
54	12 Dibromoethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
55	Chlorobenzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
56	1112 Tetrachloroethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
57	Ethyl Benzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
58	m & p Xylene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
59	o Xylene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
60	Styrene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
61	Bromoform	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
62	Isopropyl Benzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
63	Bromobenzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
64	1122 Tetrachloroethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
65	123 Trichloropropane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
66	Trans 14 Dichloro 2 Butene, tran	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
67	Propyl Benzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
68	2-Chlorotoluene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
69	4 Chlorotoluene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
70	135 Trimethylbenzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
71	Tert Butyl Benzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
72	124 Trimethylbenzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
73	Sec Butyl Benzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
74	13 Dichlorobenzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
75	P Isopropyltoluene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
76	14 Dichlorobenzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
77	12 Dichlorobenzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
78	N Butyl Benzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
79	Hexachloroethane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
80	12 Dibromo 3 Chloropropane	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
81	124 Trichlorobenzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
82	Napththalene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1
83	123 Trichlorobenzene	mg/l	0.1	<1.0	mg/kg	0.1	<0.1

NOTES

1. Leachate reporting limit changed as sample needed to be diluted during leaching step

Environmental and Industrial Hygiene Laboratory.
Novartis Ringaskiddy Limited,
Ringaskiddy, Co. Cork.

Telephone: 021/4862324.
Fax: 021/4862355.

REPORT: DEWATERED AEROBICALLY DIGESTED SLUDGE LEACHATE ANALYSIS

EMISSION POINT REFERENCE NUMBER 100 (WASTEWATER TREATMENT PLANT)

SCHEDULE C.4; INTEGRATED POLLUTION PREVENTION AND CONTROL LICENCE REGISTER NUMBER P0006-03

REPORTING PERIOD: September, 2009

Schedule C.4 of Integrated Pollution Prevention and Control Licence (IPPCL) Register Number P0006-03 requires that a leachate test be carried out on dewatered aerobically digested sludge produced as a by-product of effluent treatment. An analysis for heavy metals (individual), organic matter and water content is required a quarterly basis; and an analysis for organic compounds is required on an annual basis.

Novartis Ringaskiddy Limited engaged the services of Environmental Laboratory Services, Acorn Business Campus, Mahon Industrial Park, Blackrock, Cork, to carry out a distilled water leachate test on a sample this material. The leachate method reference method was to the German Standard DIN 38414-S4 (October, 1984).

The following table summarises the analytical results of the eluate from the leachate procedure (single leaching):

PARAMETER	RESULT
Sampling Date: 17-Sep-2009	
Total Organic Carbon:	75 mg/L TOC
Zinc:	< 0.1 mg/L Zn
Copper:	< 0.1 mg/L Cu
Dry Matter:	12 %

NOTE: Neither Copper nor Zinc has been used at Novartis Ringaskiddy Limited up to this point in time.

A subsample of the leachate was analysed by Environmental Laboratory Services for organic compounds. The results of this analysis are reproduced on the test certificate on the following page.

Signed V Boyton : Vincent Boyton.

Dated 15-OCT-2009 : 15-Oct-2009.

ENVIRONMENTAL LABORATORY SERVICES
Acorn Business Campus,
Mahon Industrial Park,
Blackrock,
CorkTel: 021-4536141
Fax: 021-4536149

Analysis Report

Attention:		**Report No:**	14844
Vincent Boyton			
Novartis Ringaskiddy Limited		**Date of receipt:**	18/09/2009
IDA Estate,		**Date Started:**	21/09/2009
Ringaskiddy,			
Co. Cork			
Fax No:		**Issue Date:**	15/10/2009
Tel No:	021- 4862324	**Page**	1 **of** 3
PO Number:	OP-95758	**Delivery Mode**	Pick-Up
Sample Type	Sludge	**No. of Samples**	1
Condition on receipt	Satisfactory	**Client Ref:**	089100012147

Parameter	Test Method
SAMPLE PREPARATION	
Leachability Test	ISEN12457-4 2002- 10/1 Leaching
Solids Content	EM113 Evaporation/gravimetric
DRIED SLUDGE TESTS	
Metals	EM130 ICP-MS
TKN	APHA4500 -Norg,C- Semi-Micro-Kjeldahl
Total Phosphorous	EW146 Total P by Ganimede method
WET SLUDGE TESTS	
Organic Solvents	Pre-concentration & GC-FID
Volatile Organic Compounds	EO 025 Purge and Trap/GC/MS
LEACHATE TESTS (Filter through 0.45um filter-blank correct all results)	
Organic Solvents	Pre-concentration & GC-FID
Metals	EM130 ICP-MS
Dissolved Organic Carbon	EW123 by Combustion Oxidation
Volatile Organic Compounds	EO 025 Purge and Trap/GC/MS

SIGNED **(15/10/2009)**

Technical Manager (or Deputy)
Brendan Murray

Leachate,Wet and Dried Sludge

Parameter	Leachate from Sludge			Wet Sludge			Dried Sludge		
	Units	Detection Limit	Result	Units	Detection Limit	Result	Units	Detection Limit	Result
Methanol.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1	Not required to be tested		
Ethanol.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Isopropyl Alcohol.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
n-Hexane.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
sec-Butyl Alcohol.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Acetic Acid.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Isopropyl Ether.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Ethyl Acetate.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Isopropyl Acetate.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Heptane.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
n-Butyl Alcohol.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Acetonitrile	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Cyclohexane.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
Triethylamine.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
N,N-Dimethylformamide.	mg/l	0.1	<0.1	mg/kg	0.1	<0.1			
[illegible]per	mg/l	0.003	<0.03	Not required to be tested			mg/kg	5	874.50
[illegible]	mg/l	0.001	0.02				mg/kg	5	129
TOC	mg/l	0.025	74.99				Not required		
% Dry Matter	Not required to be tested						%	-	12.2
Total Nitrogen (TKN)							mg/kg N	10	94254
Total Phosphorus							mg/kg P	1	4187
Total Potassium							mg/kg	1000	30882
Nickel							mg/kg	2.5	15.2
Cadmium							mg/kg	0.5	<0.5
Lead							mg/kg	1.5	3.6
Mercury							mg/kg	0.5	1
Chromium							mg/kg	5	9

NOTES

1. Leachate reporting limit changed as sample needed to be diluted during leaching step

Environmental Laboratory Services Ltd	Report Number	14844-1
	Page	3 of 3

Appendix A

VOC

No.	Analyte	Leachate			Wet Sludge		
		Units	Detection Limit	Result	Units	Detection Limit	Result
2	Dichlorodifluoromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
3	Chloromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
4	Ethyl Chloride/Chloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
5	Vinyl Chloride/Chloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
6	Bromomethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
8	Trichloromonofluoromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
9	Ethyl Ether/Diethyl Ether	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
10	11 Dichloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
11	Acetone	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
12	Iodomethane/Methyl Iodide	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
13	Carbon Disulphide	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
14	Allyl Chloride	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
15	Methylene Chloride/DCM	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
16	2-Propenenitrile/Acrylonitrile	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
17	Chlormethyl Cyanide/Chloroacetonitrile	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
18	Nitrobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
19	Propanenitrile	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
20	Hexachlorobutadiene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
21	Trans-1,2 Dichloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
22	MtBE	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
23	11 Dichloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
24	22 Dichloropropane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
25	cis-12 Dichloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
26	2-Butanone	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
27	Methyl Acrylate	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
28	Bromochloromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
29	Methacrylonitrile	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
30	Tetrahydrofuran	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
31	Trichloromethane/ Chloroform	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
32	111 Trichloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
33	1-Chlorobutane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
34	Carbon Tetrachloride	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
35	11 Dichloropropene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
36	Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
37	12 Dichloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
39	Trichloroethylene/ Trichloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
40	12 Dichloropropane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
41	Dibromomethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
42	Methyl Methacrylate	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
43	Bromodichloromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
44	13 Dichloropropene,cis	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
45	MIBK/4 Methyl 2 Pentanone	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
46	Toluene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
47	13 Dichloropropene,trans	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
48	Ethyl Methacrylate	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
49	112 Trichloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
50	Tetrachloroethylene/ Tetrachloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
51	13 Dichloropropane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
52	2-Hexanone	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
53	Dibromochloromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
54	12 Dibromoethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
55	Chlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
56	1112 Tetrachloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
57	Ethyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
58	m & p Xylene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
59	o Xylene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
60	Styrene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
61	Bromoform	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
62	Isopropyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
63	Bromobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
64	1122 Tetrachloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
65	123 Trichloropropane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
66	Trans 14 Dichloro 2 Butene, tran	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
67	Propyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
68	2-Chlorotoluene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
69	4 Chlorotoluene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
70	135 Trimethylbenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
71	Tert Butyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
72	124 Trimethylbenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
73	Sec Butyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
74	13 Dichlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
75	P Isopropyltoluene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
76	14 Dichlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
77	12 Dichlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
78	N Butyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
79	Hexachloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
80	12 Dibromo 3 Chloropropane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
81	124 Trichlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
82	Napththalene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
83	123 Trichlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1

Environmental and Industrial Hygiene Laboratory.
Novartis Ringaskiddy Limited,
Ringaskiddy, Co. Cork.

Telephone: 021/4862324.
Fax: 021/4862355.

REPORT: DEWATERED AEROBICALLY DIGESTED SLUDGE LEACHATE ANALYSIS

EMISSION POINT REFERENCE NUMBER 100 (WASTEWATER TREATMENT PLANT)

SCHEDULE C.4; INTEGRATED POLLUTION PREVENTION AND CONTROL LICENCE REGISTER NUMBER P0006-03

REPORTING PERIOD: November, 2009

Schedule C.4 of Integrated Pollution Prevention and Control Licence (IPPCL) Register Number P0006-03 requires that a leachate test be carried out on dewatered aerobically digested sludge produced as a by-product of effluent treatment. An analysis for heavy metals (individual), organic matter and water content is required a quarterly basis; and an analysis for organic compounds is required on an annual basis.

Novartis Ringaskiddy Limited engaged the services of Environmental Laboratory Services, Acorn Business Campus, Mahon Industrial Park, Blackrock, Cork, to carry out a distilled water leachate test on a sample this material. The leachate method reference method was to the German Standard DIN 38414-S4 (October, 1984).

The following table summarises the analytical results of the eluate from the leachate procedure (single leaching):

PARAMETER	RESULT
Sampling Date: 26-Nov-2009	
Total Organic Carbon:	30 mg/L TOC
Zinc:	70 mg/L Zn
Copper:	< 0.1 mg/L Cu
Dry Matter:	13 %

NOTE: Neither Copper nor Zinc has been used at Novartis Ringaskiddy Limited up to this point in time.

A subsample of the leachate was analysed by Environmental Laboratory Services for organic compounds. The results of this analysis are reproduced on the test certificate on the following page.

Signed : Vincent Boyton.

Dated 23-DEC-2009 : 23-Dec-2009.

ENVIRONMENTAL LABORATORY SERVICES
Acorn Business Campus,
Mahon Industrial Park,
Blackrock,
CorkTel: 021-4536141
Fax: 021-4536149

Analysis Report

Attention:		**Report No:**	15875
Vincent Boyton			
Novartis Ringaskiddy Limited		**Date of receipt:**	11/12/2009
IDA Estate,		**Date Started:**	14/12/2009
Ringaskiddy,			
Co. Cork			
Fax No:		**Issue Date:**	23/12/2009
Tel No:	021- 4862324	**Page**	1 **of** 3
PO Number:	OP-95758	**Delivery Mode**	Pick-Up
Sample Type	Sludge	**No. of Samples**	1
Condition on receipt	Satisfactory	**Client Ref:**	089100014472

Parameter	Test Method
SAMPLE PREPARATION	
Leachability Test	ISEN12457-4 2002- 10/1 Leaching
Solids Content	EM113 Evaporation/gravimetric
DRIED SLUDGE TESTS	
Metals	EM130 ICP-MS
TKN	APHA4500 -Norg,C- Semi-Micro-Kjeldahl
Total Phosphorous	EW146 Total P by Ganimede method
WET SLUDGE TESTS	
Organic Solvents	Pre-concentration & GC-FID
Volatile Organic Compounds	EO 025 Purge and Trap/GC/MS
LEACHATE TESTS (Filter through 0.45um filter-blank correct all results)	
Organic Solvents	Pre-concentration & GC-FID
Metals	EM130 ICP-MS
Dissolved Organic Carbon	EW123 by Combustion Oxidation
Volatile Organic Compounds	EO 025 Purge and Trap/GC/MS

SIGNED **(23/12/2009)**

Technical Manager (or Deputy)
Brendan Murray

Leachate,Wet and Dried Sludge

Parameter	Leachate from Sludge			Wet Sludge			Dried Sludge		
	Units	Detection Limit	Result	Units	Detection Limit	Result	Units	Detection Limit	Result
Methanol.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1	Not required to be tested		
Ethanol.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Isopropyl Alcohol.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
n-Hexane.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
sec-Butyl Alcohol.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Acetic Acid.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Isopropyl Ether.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Ethyl Acetate.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Isopropyl Acetate.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Heptane.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
n-Butyl Alcohol.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Acetonitrile	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Cyclohexane.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
Triethylamine.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
N,N-Dimethylformamide.	mg/l	0.1	<1.0	mg/kg	0.1	<0.1			
[illegible]per	mg/l	0.003	<0.03	Not required to be tested			mg/kg	5	27.6
[illegible]	mg/l	0.001	70				mg/kg	5	110
TOC	mg/l	0.025	29.64				Not required		
% Dry Matter	Not required to be tested						%	-	12.8
Total Nitrogen (TKN)							mg/kg N	10	6195
Total Phosphorus							mg/kg P	1	370
Total Potassium							mg/kg	1000	1514
Nickel							mg/kg	2.5	13.2
Cadmium							mg/kg	0.5	<0.5
Lead							mg/kg	1.5	9.2
Mercury							mg/kg	0.5	<0.5
Chromium							mg/kg	5	<5.0

NOTES
LOD's raised to sample dilution at leaching step

Environmental Laboratory Services Ltd	Report Number	15875
	Page	3 of 3

Appendix A

VOC

No.	Analyte	Leachate			Wet Sludge		
		Units	Detection Limit	Result	Units	Detection Limit	Result
2	Dichlorodifluoromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
3	Chloromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
4	Ethyl Chloride/Chloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
5	Vinyl Chloride/Chloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
6	Bromomethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
8	Trichloromonofluoromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
9	Ethyl Ether/Diethyl Ether	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
10	11 Dichloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
11	Acetone	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
12	Iodomethane/Methyl Iodide	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
13	Carbon Disulphide	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
14	Allyl Chloride	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
15	Methylene Chloride/DCM	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
16	2-Propenenitrile/Acrylonitrile	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
17	Chlormethyl Cyanide/Chloroacetonitrile	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
18	Nitrobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
19	Propanenitrile	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
20	Hexachlorobutadiene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
21	Trans-1,2 Dichloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
22	MtBE	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
23	11 Dichloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
24	22 Dichloropropane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
25	cis-12 Dichloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
26	2-Butanone	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
27	Methyl Acrylate	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
28	Bromochloromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
29	Methacrylonitrile	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
30	Tetrahydrofuran	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
31	Trichloromethane/ Chloroform	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
32	111 Trichloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
33	1-Chlorobutane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
34	Carbon Tetrachloride	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
35	11 Dichloropropene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
36	Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
37	12 Dichloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
39	Trichloroethylene/ Trichloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
40	12 Dichloropropane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
41	Dibromomethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
42	Methyl Methacrylate	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
43	Bromodichloromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
44	13 Dichloropropene,cis	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
45	MIBK/4 Methyl 2 Pentanone	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
46	Toluene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
47	13 Dichloropropene,trans	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
48	Ethyl Methacrylate	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
49	112 Trichloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
50	Tetrachloroethylene/ Tetrachloroethene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
51	13 Dichloropropane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
52	2-Hexanone	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
53	Dibromochloromethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
54	12 Dibromoethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
55	Chlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
56	1112 Tetrachloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
57	Ethyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
58	m & p Xylene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
59	o Xylene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
60	Styrene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
61	Bromoform	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
62	Isopropyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
63	Bromobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
64	1122 Tetrachloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
65	123 Trichloropropane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
66	Trans 14 Dichloro 2 Butene; tran	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
67	Propyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
68	2-Chlorotoluene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
69	4 Chlorotoluene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
70	135 Trimethylbenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
71	Tert Butyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
72	124 Trimethylbenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
73	Sec Butyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
74	13 Dichlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
75	P Isopropyltoluene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
76	14 Dichlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
77	12 Dichlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
78	N Butyl Benzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
79	Hexachloroethane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
80	12 Dibromo 3 Chloropropane	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
81	124 Trichlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
82	Napththalene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1
83	123 Trichlorobenzene	mg/l	0.1	<0.1	mg/kg	0.1	<0.1

Novartis Ringaskiddy Limited

On-Site Incineration Record Summary 2009:

Emission Point Reference Number 3 (Solid Waste Incinerator)

IPPCL Register Number P0006-03

EWC Code	Waste Material Description	Quantity Incinerated (kgs)
07 05 04 (*)	Other organic solvents, washing liquids and mother liquors	179.74
07 05 10 (*)	Other filter cakes and spent absorbents	6,328.24
07 05 13 (*)	Solid wastes containing dangerous substances	1,541.95
13 02 05 (*)	Mineral based non-chlorinated engine, gear and lubricating oils	32.52
15 01 01	Paper and cardboard packaging	129.10
15 01 02	Plastic packaging	223.72
15 01 03	Wooden packaging	368.11
15 01 06	Mixed packaging	14.00
15 01 10 (*)	Packaging containing residues of or contaminated by dangerous substances	40,329.86
15 02 02 (*)	Absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by dangerous substances	20,312.48
15 02 03	Absorbents, filter materials, wiping cloths and protective clothing other than those mentioned in 15 02 02	506.52
16 05 06 (*)	Laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals	7,931.69
19 01 12	Bottom ash and slag other than those mentioned in 19 01 11	12.00
	Total Quantity Incinerated 2009 (tonnes):	77.910

Note that a total of 28,283 kgs of fibreboard drums were incinerated (primarily under the other codes as waste containers). The 2009 total also includes 233.63 kgs of plastic drums. Again, some of these were incinerated under EWC code 15 01 02 as empty drums but some were also incinerated under the other codes as waste containers. A total of 3,744 plastic bags were also incinerated (as waste containers)

Novartis Ringaskiddy Limited

On-Site Incineration Record Summary 2009:

Emission Point Reference Number 4 (Liquid Vapour Incinerator)

IPPCL Register Number P0006-03

EWC Code	Waste Material Description	Quantity Incinerated (Tonnes)
07 05 01	Aqueous washing liquids and other liquors	342.696
07 05 04	Other organic solvents, washing liquids and mother liquors (Liquid waste)	1,534.934
07 05 04	Gaseous wastes containing organic and inorganic gases (Vapour waste)	318.747
Total Quantity Incinerated 2009:		2,196.377

Novartis Ringaskiddy Limited

Resource Consumption Summary 2009: Water and Energy

IPPCL Register Number P0006-03

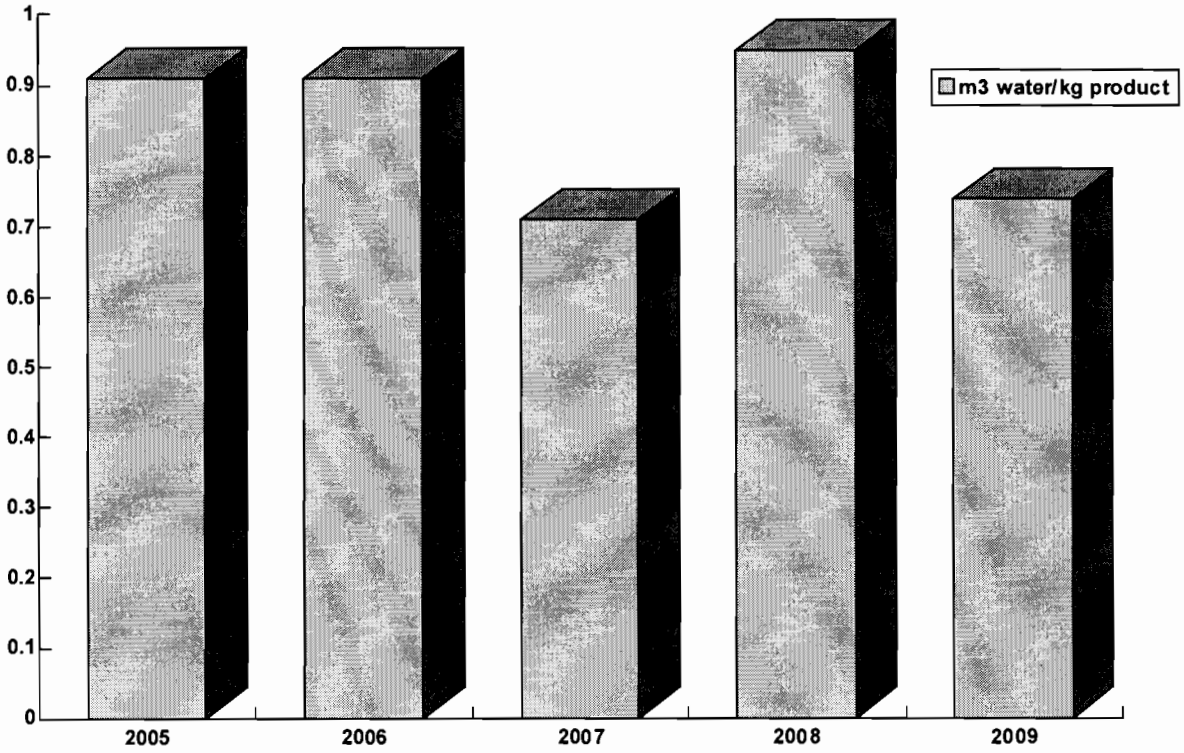
Water Source	Consumption (m^3)
Municipal Supply	275,778
Total	275,778

Fuel Type	Consumption (GigaJoule)
Marked Gas Oil	4,644
Natural Gas	283,170
Electricity	163,626
Solvent Incinerated On-Site	46,342
Total	497,783

Trend analyses for water, natural gas and electricity consumption/kg of product produced are included on the following pages. Data for the years 2005 to 2009 are included on the trends.

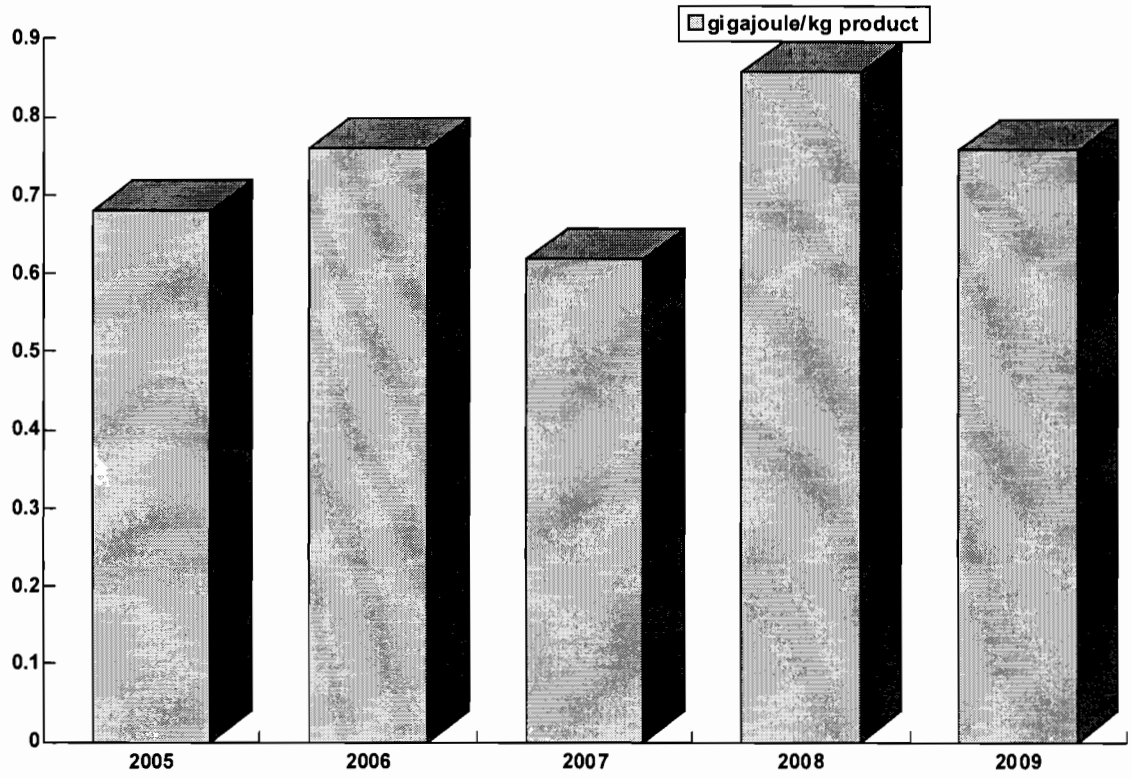
Water Consumption

Water consumption is expressed as m^3 consumed per kilogramme of product manufactured.



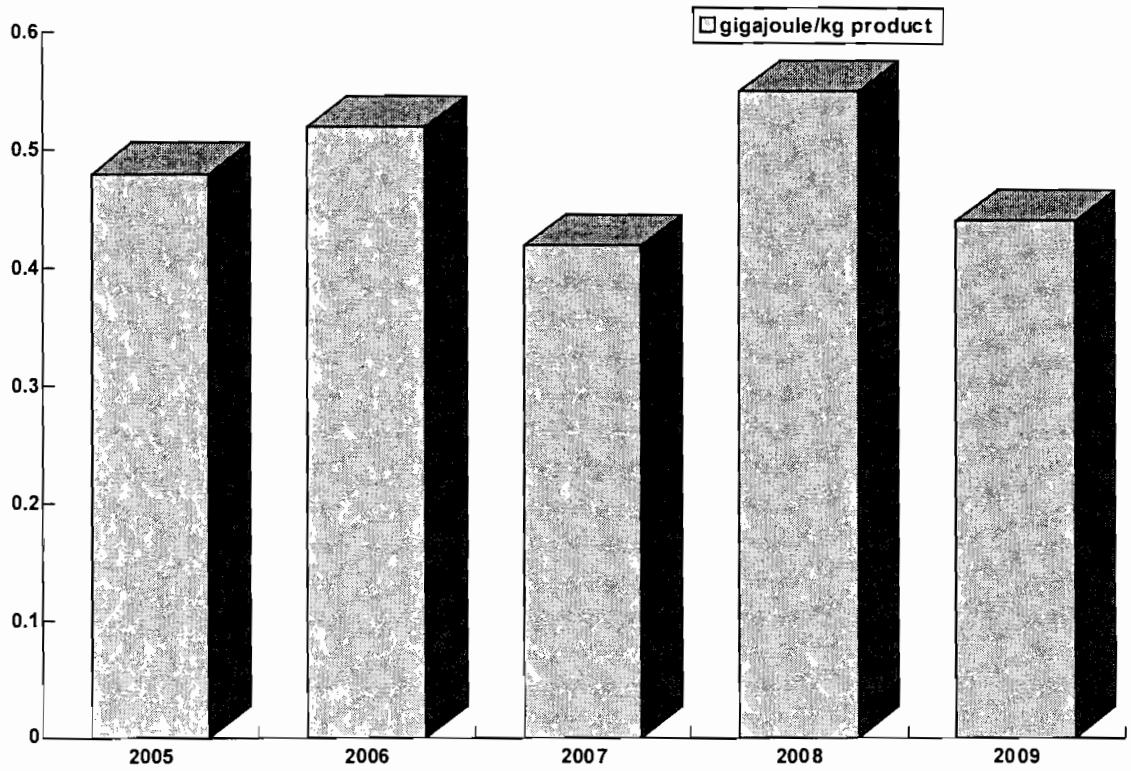
Natural Gas Consumption

Natural Gas consumption is expressed as GigaJoule consumed per kilogramme of product manufactured.



Electricity Consumption

Electricity consumption is expressed as GigaJoule consumed per kilogramme of product manufactured.



Novartis Ringaskiddy Limited

Complaints Summary 2009

IPPCL Register Number P0006-03

Complaint Class	Noise	Odour	Water	Dust	Procedural	Miscellaneous	Total
Month							
January	0	0	0	0	0	0	0
February	0	0	0	0	0	0	0
March	0	0	0	0	0	0	0
April	0	0	0	0	0	0	0
May	0	0	0	0	0	0	0
June	0	0	0	0	0	0	0
July	0	0	0	0	0	0	0
August	0	0	0	0	0	0	0
September	0	0	0	0	0	0	0
October	0	0	0	0	0	0	0
November	1	0	0	0	0	0	0
December	0	0	0	0	0	0	0
Totals	1	0	0	0	0	0	0

Novartis Ringaskiddy Limited received one complaint of an environmental nature during 2009 – details as follows:

The company received an unsigned letter of complaint (date of receipt 18-Nov-2009) alleging '*that noise levels from the plant have picked up sharply over the last couple of months, causing considerable local nuisance for the areas of Shanbally and Coolmore*'. At the time there had been no material change to the operation of the facility at Novartis Ringaskiddy Limited that would have account for this. The annual noise level survey was undertaken during July of 2009 and this confirmed no change in the sound levels compared to previous years and certainly nothing that would be audible from as far away as Shanbally.

However, it may be that the complainant was referring to noise originating from some civil work that was taking place in the area of the company's Stormwater Retention Pond at the time. This activity was located at the southwest part of the facility and was away from operational areas of the plant. This noise was confined to daytime and the area in question was also very close to Coolmore. However, without some details as to the location of the complainant's residence it was be very difficult to say if this is the source of the noise that they are complaining of.

The Head of Health, Safety and Environmental Protection (HSE) also took a call on Monday 16-Nov-2009 in respect of noise from the facility. While in this case the caller did leave their name they did not leave a contact number or an address to allow the company to follow up. It may be that the letter that was received on 18-Nov-2009 (written on 15-Nov-2009) was related to this call. The company was prepared to outline the facts as presented above should the caller

telephone again but no further communication was received. These were (in summary) that no changes had been made to plant and equipment on-site that would have affected boundary noise levels but that there was some small civil work taking place near the western perimeter of the site of a temporary nature that might explain the source of the complaint(s).

A full copy of the letter referred to above; and a copy of the company's most recently undertaken sound level survey was forwarded to the Environmental Protection Agency on 20-Nov-2009. A full copy of the 2009 sound level survey is also included elsewhere in this AER

Novartis Ringaskiddy Limited

Reported Incidents Summary 2009

IPPCL Register Number P0006-03

Novartis Ringaskiddy Limited did not report any major incident to the Agency during 2009. The overall environmental compliance of Novartis Ringaskiddy Limited in respect of the imposed licence conditions was greater than 99.99 % during the period from January 2009, to December, 2009 (inclusive). Nine readings out of a total of more than 211,000 were judged to be in non-compliance and were reported to the Environmental Protection Agency. All non-compliances were judged to be minor deviations and did not present the potential for having an adverse effect on the local environment. Note from the Emissions to Atmosphere Summary and the Emissions to Sewer Summary of this AER that the mass discharges of all licensed parameters were substantially below the regulated amounts and that the overall performance of key environmental control modules at the facility was excellent during 2009. It is also worthy noting that despite this performance that the regulatory requirement in respect of testing has grown significantly in recent years. A total of more than 133,000 test results were reported on during 2005 compared to more than 211,000 results in 2009.

Category of Notified Incidents: All nine deviations fell into Category 3

(Environmental incidents are categorised from 1 to 3 based on Agency Guidance)

Category 1: An environmental incident, which is causing, has caused or which could have caused *Significant* environmental damage or *Significant* environmental risk or hazard to the public or to the general environment. Incidents that fall into this category are those having any of the impacts listed below:

- Significant effects on water quality
- Significant effects on air quality
- Major damage to an ecosystem (e.g. Significant impact of fish population)
- Notification or closure of potable water extractors
- Reduction in amenity value of an area
- Damage to agriculture or commerce
- Impact on local residents or community
- Urgent remedial action necessary

Category 2: A minor environmental incident with typical impacts as listed below:

- Local limited impact to water or land.
- Public warnings not required.
- Effect on air quality as evidenced by Odour complaints.

Category 3: An environmental incident where there was never at any time any damage injury or significant risk or exposure to hazard to the public or the general environment. In general,

category three incidents are not notifiable to the agency unless required by the licence. Typical incidents that may fall into this category are:

- Environmental incidents with no impact on water or land
- No offsite environmental impact
- No onsite personnel health impact
- No effect on air quality as evidenced by offsite odour complaints

The following three pages briefly summarise the aforementioned nine non-compliances. This summary is then followed by a more detailed breakdown of the non-compliances.

Novartis Ringaskiddy Limited: Environmental Compliance Data: Summary: January 2009 to December 2009 (inclusive).

The overall environmental compliance of Novartis Ringaskiddy Limited in respect of the imposed licence conditions was greater than 99.99 % during the period from January 2009 to December 2009 (inclusive). Nine readings out of a total of more than 211,000 were judged to be in non-compliance and were reported to the Environmental Protection Agency. All non-compliances were judged to be minor deviations and did not present the potential for having an adverse effect on the local environment. More detailed information on compliance reporting to the Environmental Protection Agency is given on the following pages.

Novartis Ringaskiddy Limited: Environmental Compliance Data: Summary: January 2009 to December 2009 (inclusive).

Solid Waste Incinerator (Emission Point Reference Number 3)

Continuous Monitoring:	Carbon Monoxide:	>99% compliance (30 minute means)
	"	(Non-compliance – 2 out of 2,664 readings)
	"	100% compliance (24 hour means)
	Sulphur Dioxide:	100% compliance
	Hydrochloric Acid:	100% compliance
	Particulates:	100% compliance
	Total Organic Carbon:	100% compliance
	Nitrogen Oxides	100% compliance
	Flow:	100% compliance
Occasional Monitoring:	Hydrogen Fluoride:	100% compliance
	Hydrogen Bromide:	100% compliance
	Dioxins and Dibenzofurans:	100% compliance
	Metals:	100% compliance

Liquid Vapour Incinerator (Emission Point Reference Number 4)

Continuous Monitoring:	Carbon Monoxide:	100% compliance
	Sulphur Dioxide:	100% compliance
	Particulates:	100% compliance (30 minute means)
	"	>99% % compliance (24 hour means)
		(Non-compliance – 2 out of 365 readings)
	Hydrochloric Acid:	100% compliance
	Total Organic Carbon:	100% compliance
	Nitrogen Oxides	100% compliance
	Flow:	100% compliance
Occasional Monitoring:	Hydrogen Fluoride:	100% compliance
	Hydrogen Bromide:	100% compliance
	Dioxins and Dibenzofurans:	100% compliance
	Metals:	100% compliance

NOTE: Daily mass discharges of all parameters from Emission Point Reference Number 3 and 4 were in 100% compliance with the requirements of Integrated Pollution Prevention and Control Licence Register Number P0006-03

Parameters as required by Integrated Pollution Prevention and Control Licence (IPPCL) Register Number P0006-03.

Air Emissions were controlled under Air Pollution Register Number: A.P. 2/1993 (R) up to 16-May-1995 after which Integrated Pollution Control Licence (IPCL) Register Number 6, issued by the Environmental Protection Agency, came into force. IPCL Register Number 6 was superseded by IPCL Register Number 545 on 31-Oct-2000. This was superseded in turn by IPPCL Register Number P0006-03 on 02-Feb-2006.

Novartis Ringaskiddy Limited: Environmental Compliance Data: Summary: January 2009 to December 2009 (inclusive).

Treated Effluent (Wastewater Treatment Plant)(Emission Point Reference Number 100).

Daily Monitoring of Mass Discharges and Concentrations:

Total Suspended Solids:	>99% compliance (Non-compliance – 2 out of 364 readings)
Total Phosphorus:	100% compliance
Total Kjeldahl Nitrogen:	100% compliance
Total Ammonia:	100% compliance
Nitrate Nitrogen	100% compliance
Chemical Oxygen Demand:	>99% compliance (Non-compliance – 3 out of 364 readings)
Biochemical Oxygen Demand:	100% compliance
Copper:	100% compliance
Zinc:	100% compliance
Flow:	100% compliance

Continuous Monitoring of pH:

pH:	100% compliance

Daily Monitoring of Conductivity:

Conductivity:	100% compliance

Occasional Monitoring of Treated Effluent Toxicity:

Toxicity:	100% compliance

Sound Level Monitoring

Sound levels at the boundary of Novartis Ringaskiddy Limited were demonstrated to be compliant with the requirements of Integrated Pollution Prevention and Control Licence Register Number P0006-03 during the annual sound level surveys between 2004 and 2008.

Groundwater Quality

The quality of the groundwater beneath the facility has remained the same as that established prior to the commencement of the development at Novartis Ringaskiddy Limited.

Surface Water Quality

All surface water leaving the site was monitored, found to be of an acceptable quality for discharge and conformed to the requirements of Integrated Pollution Prevention and Control Licence Register Number P0006-03.

Parameters as required by Integrated Pollution Prevention and Control Licence (IPPCL) Register Number P0006-03.

Treated effluent emissions and the quality of groundwater under the facility were controlled under Licence Register Number: W.P. (S) 7/1993 (R) up to 16-May-1995 after which IPCL Register Number 6, issued by the Environmental Protection Agency, came into force. IPCL Register Number 6 was superseded by IPCL Register Number 545 on 31-Oct-2000. This was superseded in turn by IPPCL Register Number P0006-03 on 02-Feb-2006.

Sound levels at the boundary of the facility were controlled under Planning Register Reference Number: S/2989/89 up to 16-May-1995 after which IPCL Register Number 6, issued by the Environmental Protection Agency, came into force. IPCL Register Number 6 was superseded by IPCL Register Number 545 on 31-Oct-2000. This was superseded in turn by IPPCL Register Number P0006-03 on 02-Feb-2006.

Novartis Ringaskiddy Limited

Reported Incidents Summary 2009: Emission Point Reference Number 3

IPPCL Register Number P0006-03

Date:	19-Mar-2009: 16:30 to 17:00 29-Mar-2009: 06:30 to 07:00
Parameter:	Carbon Monoxide (CO).
Emission Point Reference Number:	Emission Point Reference Number 3 (Solid Waste Incinerator).
Number of Exceedences vs. Number of Samples:	2 out of 2,664 (> 99 % compliance)(thirty minute mean concentration levels). 0 out of 2,664 (100 % compliance)(thirty minute mean mass discharges).
Maximum Exceedence vs. Emission Limit Value:	120 mg/Nm^3 vs. 100 mg/Nm^3. (Corresponding mass discharge 0.27 kg vs. 0.50 kg).
Cause:	The reading of 19-Mar-2009 was recorded under a light loading regime on the Solid Waste Incinerator. The waste consisted of an empty fibre board drum and plastic liners; and some general floor waste packed in a fibre drum and plastic liner (total weight of 11.88 kgs between 16:30 and 17:00) The reading of 29-Mar-2009 was also recorded under a light loading regime on the Solid Waste Incinerator. The waste consisted of an empty fibre board drum and plastic liners; some general floor waste packed in a fibre drum and plastic liner; and one empty (bulk) fibre bag (total weight of 22.99 kgs between 06:30 and 07:00) In both cases the fundamental cause of the generation of CO was an insufficient supply of Oxygen (O_2) in the Solid Waste Incinerator's supply of combustion air and the corrective actions listed below were aimed at establishing the cause of this.

Novartis Ringaskiddy Limited

Reported Incidents Summary 2009: Emission Point Reference Number 3

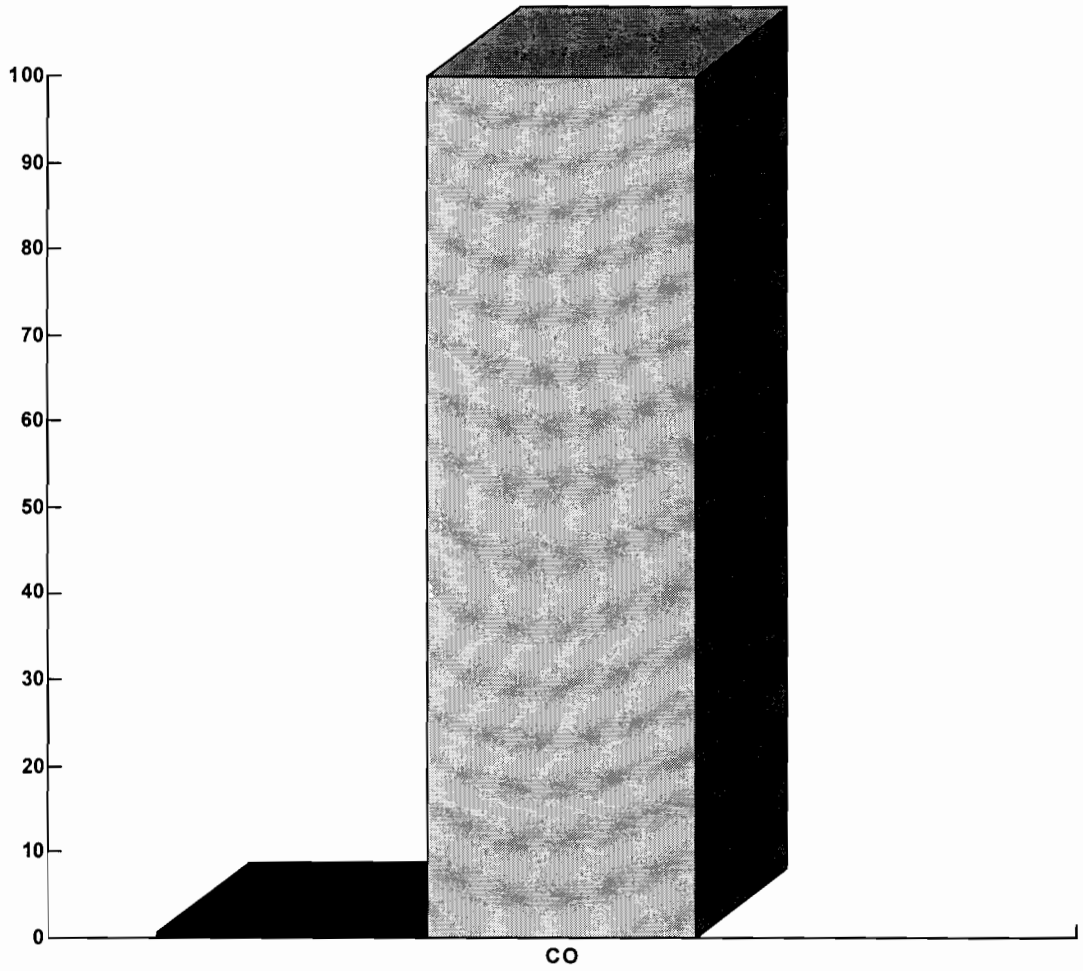
IPPCL Register Number P0006-03

Corrective Action:	A meeting was held Tuesday, 31-Mar-2009, to review a number of suggested corrective actions in light of the aforementioned deviations for CO. These are summarised here: (a). O_2 probe and analyser were checked - analyser/probe removed from Combustion Stage 3, found to be in perfect condition, calibration carried out and found to be in calibration. (b). Combustion Stage 2 & 3 blower air flows checked - all readings were higher than Solid Waste Incinerator upgrade design recommendations by manufacturers Basic International (note Low Flow and High Flow settings are normal operating ranges). (c). Reburn tunnel combustion air injection pipe blowbacks have been checked and are operational. (d). Rodding of pulse hearth combustion air injection pipes - completed by the Environmental Controls Department. Percentage compliance for thirty-minute (concentration) mean CO emissions from the Solid Waste Incinerator was > 99 % during 2009. Percentage compliance for ten-minute and twenty-four hour (concentration) mean CO emissions was 100%. All mass discharges of CO were within the controlled amounts.

Novartis Ringaskiddy Limited

Reported Incidents Summary 2009: Emission Point Reference Number 3

IPPCL Register Number P0006-03



Mass Discharge of Carbon Monoxide (CO) from Solid Waste Incinerator (first column) Expressed as a Percentage of the Discharge Regulated Under IPPCL Register Number P0006-03 (Second Column): 2009

Legend: CO: Carbon Monoxide

Novartis Ringaskiddy Limited

Reported Incidents Summary 2009: Emission Point Reference Number 4

IPPCL Register Number P0006-03

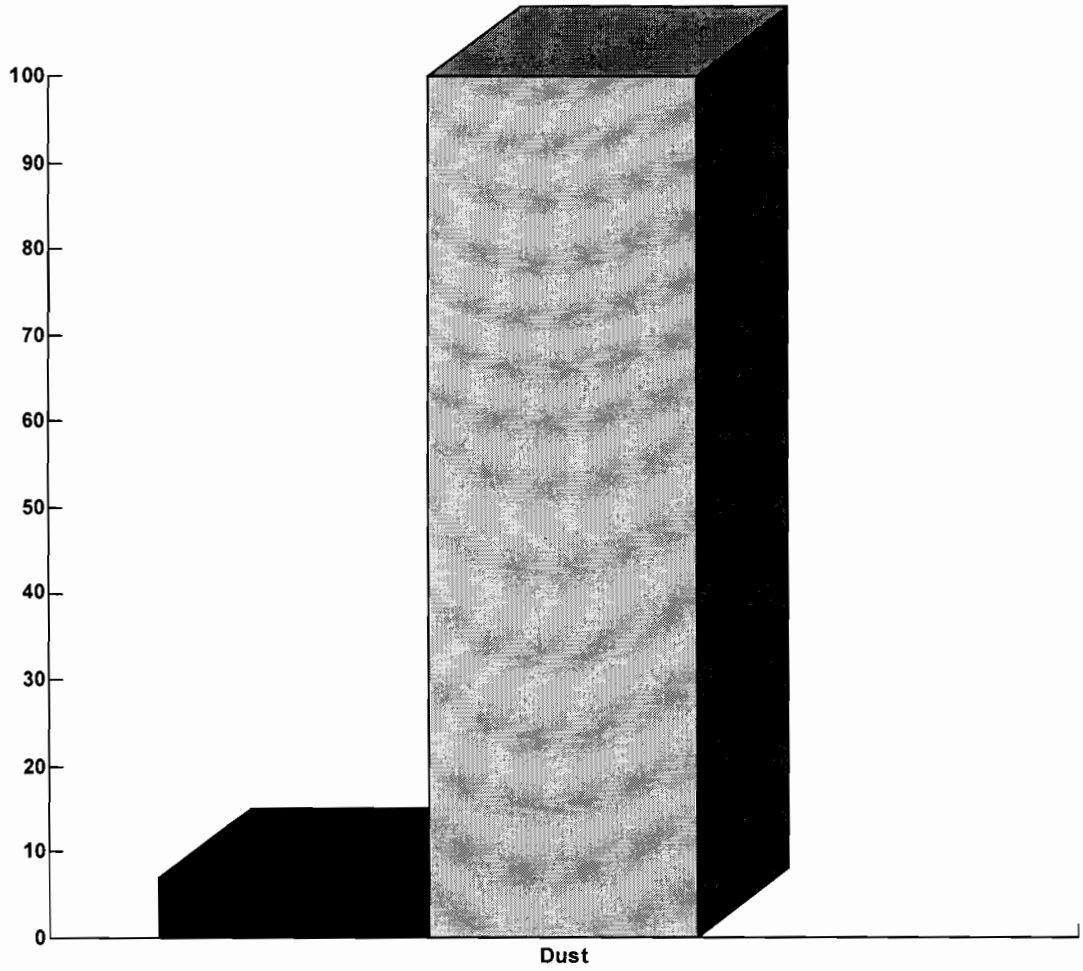
Date:	04-Nov-2009: 00:00 to 24:00 27-Nov-2009: 00:00 to 24:00
Parameter:	Particulates (Dust).
Emission Point Reference Number:	Emission Point Reference Number 4 (Liquid Vapour Incinerator).
Number of Exceedences vs. Number of Samples:	2 out of 365 (> 99 % compliance)(twenty-four hour mean concentration levels). 0 out of 365 (100 % compliance)(twenty-four hour mean mass discharges).
Maximum Exceedence vs. Emission Limit Value:	15 mg/Nm^3 vs. 10 mg/Nm^3. (Corresponding mass discharge 4.84 kgs vs. Controlled discharge of 10 kg).
Cause:	<u>Reading of 04-Nov-2009:</u> The main section of the Liquid Vapour Incinerator (LVI) was scheduled to be shutdown on Friday 13-Nov-2009 to permit cleaning of the heat recovery unit the following week. This work was necessary to physically remove a build-up of inorganic solids (salts) in the unit (primarily the boiler tubes). During this period it was proposed to run the Redundant Vapour Treatment (RVT) module of the LVI to treat vent gases and vapours only. The RVT module was started up on 04-Nov-2009 for a short duration to check its functionality in advance of the works outlined above. All liquid incineration was stopped in the main section of the LVI for this short functionality check. Elevated concentrations of Particulates were recorded during this time period (from 15:00 to 16:30) and these were directly responsible for the non-compliance with the 24-hour emission limit value for Particulates. The source of these Particulates was corrosion on the inside of the 28" duct that connects the induction fan of the RVT module to the main discharge stack. This can result in a deposit of rust on the inside of the duct over time and this is accompanied by further shedding of corroded material once the temperature rises following start-up. <u>Reading of 27-Nov-2009:</u> The main section of the LVI was shutdown on Friday 13-Nov-2009 to permit cleaning of the heat recovery unit. This work was necessary to physically remove a build-up of inorganic solids (salts) in the unit (primarily the boiler tubes). The work was completed by Friday 20-Nov-2009 and the unit returned to normal operation incinerating both liquid and vapour waste. This cleaning should have removed practically all of the deposited inorganic salts on the boiler tubes and even

	allowing for one week's normal operation the build-up of inorganic solids on the boiler tubes should not have been significant. An evaluation of this time period indicated that the bulk of the dust released on 30-Nov-2009 was between 11:30 and 12:00 when a calculated 2.54 kgs (or over half of the total reported for 30-Nov-2009) was measured. This coincided with routine on-line cleaning of the boiler tubes of the heat recovery system and should not have resulted in a non-compliant result having to be reported for the twenty-four hour mean for Particulates.
Corrective Action:	<u>Reading of 04-Nov-2009:</u> Prior start-up of the RVT module on 04-Nov-2009 the last time that the module was tested/run was in April of 2009. A more frequent test start-up schedule of the RVT module is to be implemented to avoid too big a build-up of extraneous dust and particulates in the ductwork of the module; and to maintain on-going compliance with the 24-hour emission limit value. <u>Reading of 27-Nov-2009:</u> The company had (separate to this incident) scheduled its final round of QAL2 testing on the continuous emission monitors monitoring the emissions from the LVI for Week 51 of 2009 (and also the early part of 2010). Part of this scope of work was/is to determine a validated correction factor for the on-line dust meter. This unit needs a correction factor for the output from its photometric cell based on gravimetric samples of particulates so that its reading can be evaluated in terms of mg/m^3. This work was just to focus on normal routine incineration of liquid and vapour waste. The work was subsequently expanded to include a number of periods of on-line cleaning of the boiler tubes of the heat recovery system. The preliminary results from this testing indicate that the photometer that is used to analyse particulate emissions has an inappropriate correction factor set for the high range, which would explain a high concentration reading in the absence of 'real' particulate matter. The QAL2 work was complete by the end of February of 2010.

Novartis Ringaskiddy Limited

Reported Incidents Summary 2009: Emission Point Reference Number 4

IPPCL Register Number P0006-03



Mass Discharge of Particulates (Dust) from Liquid Vapour Incinerator (first column) Expressed as a Percentage of the Discharge Regulated Under IPPCL Register Number P0006-03 (Second Column): 2009

Legend: Dust: Particulates

Novartis Ringaskiddy Limited

Reported Incidents Summary 2009: Emission Point Reference Number 100

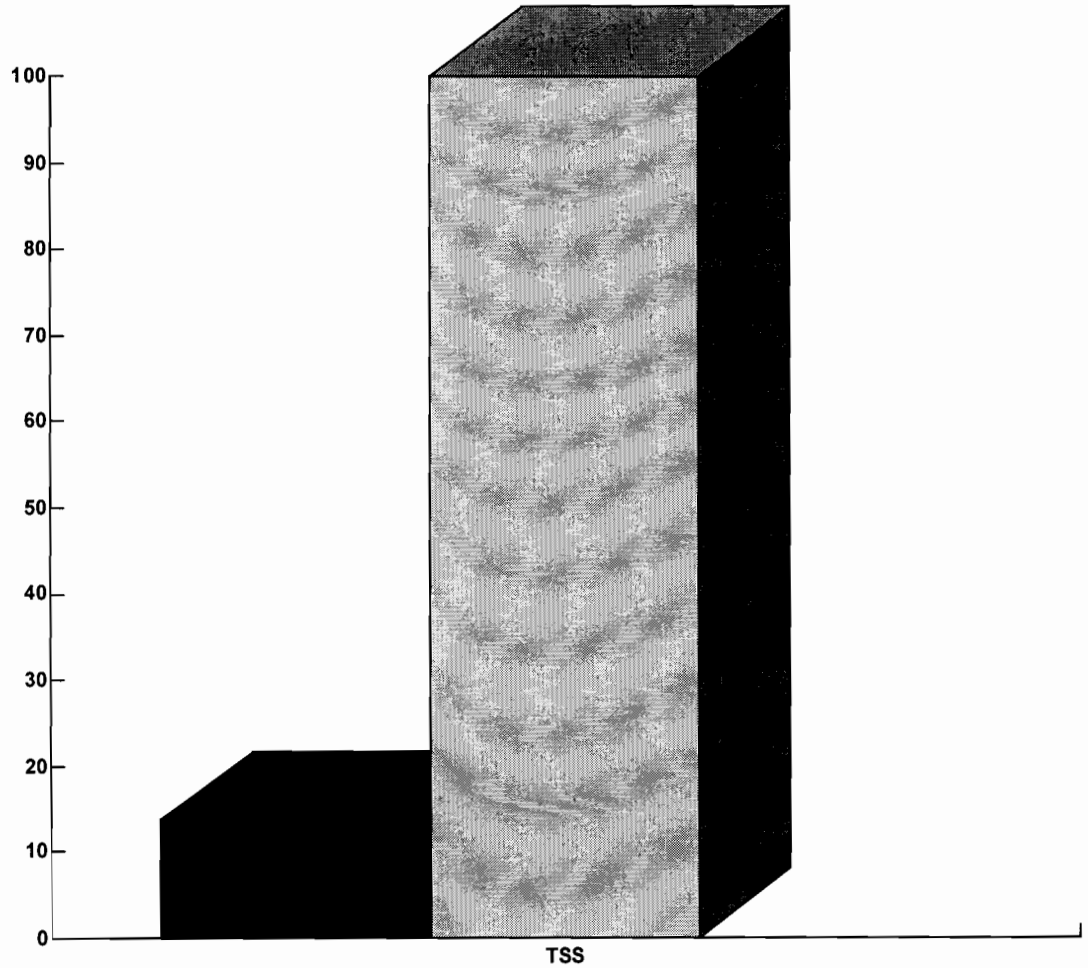
IPPCL Register Number P0006-03

Date:	01-Feb-2009: 00:00 to 24:00; and 02-Feb-2009: 00:00 to 24:00
Parameter:	Total Suspended Solids.
Emission Point Reference Number:	Emission Point Reference Number 100 (Wastewater Treatment Plant).
Number of Exceedences vs. Number of Samples:	2 out of 364 (> 99 % compliance).
Maximum Exceedence vs. Emission Limit Value:	578 mg/L vs. 500 mg/L. (Corresponding mass discharge 289 kgs vs. 225 kgs).
Cause:	Both readings were recorded during a period of poor settlement in the Clarifiers of the Wastewater Treatment Plant. This was primarily due to mechanical problems and the underlying biological treatment of influent wastewater streams to the Wastewater Treatment Plant was not affected during this time. Corrective actions included reducing the hydraulic loading on the Clarifiers to encourage better settlement of the sludge blanket in the Clarifiers; and reducing the amount of air used for aeration purposes in the associated Aeration Basins (where biological treatment takes place). This may have had the unintended effect of raising the sludge blanket. Additional polymer and inorganic nutrients were also introduced to aid the settling process. Towards the end of January a decision was also taken to stop the main aqueous waste streams form production processes discharging to the Wastewater Treatment Plant in an effort to further stabilise the treatment process. This continued until mid-February when the Wastewater Treatment Plant performance had returned consistently within the IPPCL specification. One other contributory factor may have been the effect of the relatively cold weather during January and February on the quality of the polymers that are used as part of the water treatment process. This is under evaluation by the suppliers of the company's water treatment chemicals.
Corrective Action:	As above. The readings were not of especial environmental significance. The deviations recorded for Total Suspended Solids and Chemical Oxygen Demand were associated with a loss of biomass (bacterial and fungal material) that is used to treat aqueous waste. As noted above the underlying treatment of aqueous waste was not affected during this period. The biomass that was lost would be co-mixed with untreated sanitary wastewater from the nearby town of Carrigaline and it would finally discharge (without further treatment) in deep water inside the mouth of Cork Harbour. No adverse environmental impact is anticipated given the biodegradable nature of the biosolids and the relatively small amounts involved.

Novartis Ringaskiddy Limited

Reported Incidents Summary 2009: Emission Point Reference Number 100

IPPCL Register Number P0006-03



Discharge of Total Suspended Solids from Wastewater Treatment Plant (first column) Expressed as a Percentage of the Discharge Regulated Under IPPCL Register Number P0006-03 (Second Column): 2009

Legend: TSS: Total Suspended Solids

Novartis Ringaskiddy Limited

Reported Incidents Summary 2009: Emission Point Reference Number 100

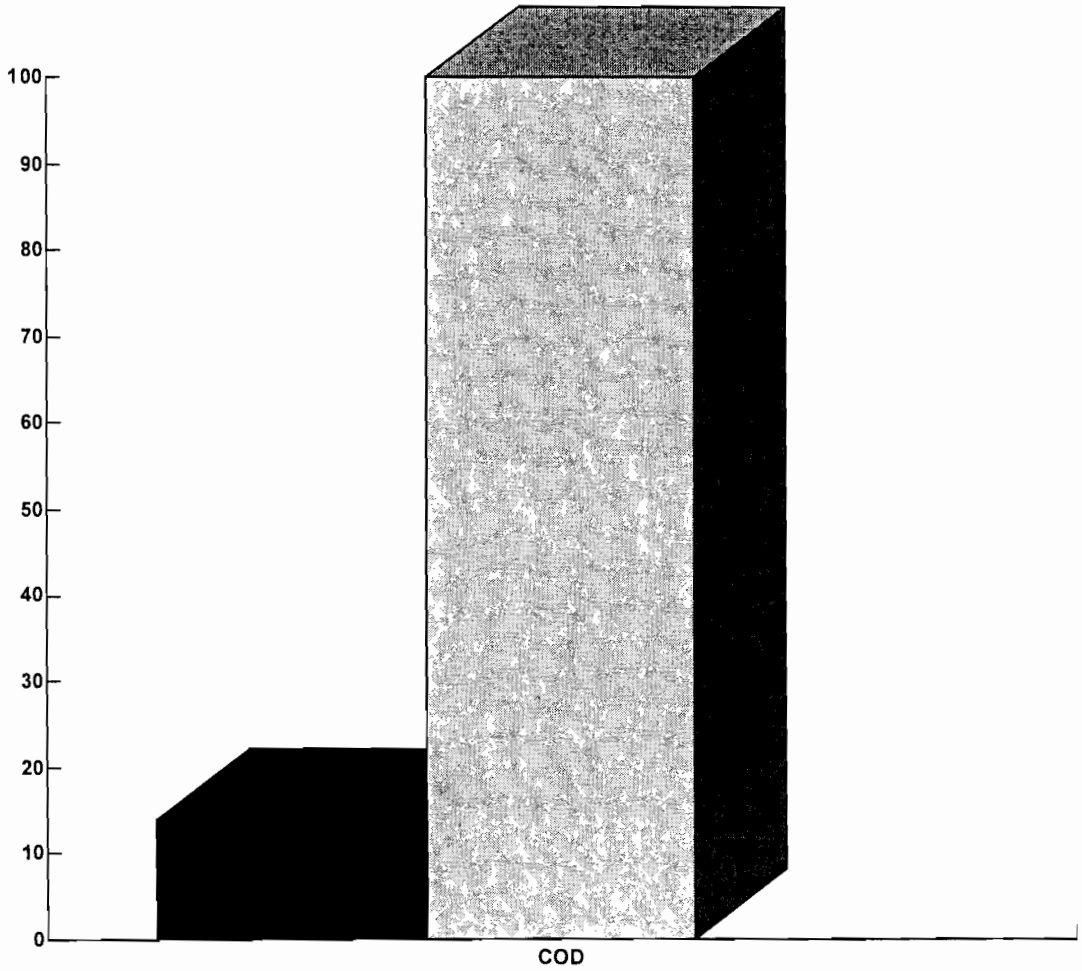
IPPCL Register Number P0006-03

Date:	20-Jan-2009: 00:00 to 24:00; 30-Jan-2009: 00:00 to 24:00; and 01-Feb-2009: 00:00 to 24:00
Parameter:	Chemical Oxygen Demand.
Emission Point Reference Number:	Emission Point Reference Number 100 (Wastewater Treatment Plant).
Number of Exceedences vs. Number of Samples:	1 out of 28 (96 % compliance).
Maximum Exceedence vs. Emission Limit Value:	919 mg/L vs. 700 mg/L. (Corresponding mass discharge 460 kgs vs. 630 kgs).
Cause:	All three readings were recorded during a period of poor settlement in the Clarifiers of the Wastewater Treatment Plant. This was primarily due to mechanical problems and the underlying biological treatment of influent wastewater streams to the Wastewater Treatment Plant was not affected during this time. Corrective actions included reducing the hydraulic loading on the Clarifiers to encourage better settlement of the sludge blanket in the Clarifiers; and reducing the amount of air used for aeration purposes in the associated Aeration Basins (where biological treatment takes place). This may have had the unintended effect of raising the sludge blanket. Additional polymer and inorganic nutrients were also introduced to aid the settling process. Towards the end of January a decision was also taken to stop the main aqueous waste streams form production processes discharging to the Wastewater Treatment Plant in an effort to further stabilise the treatment process. This continued until mid-February when the Wastewater Treatment Plant performance had returned consistently within the IPPCL specification. One other contributory factor may have been the effect of the relatively cold weather during January and February on the quality of the polymers that are used as part of the water treatment process. This is under evaluation by the suppliers of the company's water treatment chemicals.
Corrective Action:	As outlined above. The reading was not of especial environmental significance. The deviation recorded for Chemical Oxygen Demand was associated with a loss of biomass (bacterial and fungal material) that is used to treat aqueous waste. As noted above the underlying treatment of aqueous waste was not affected during this period. The biomass that was lost would be co-mixed with untreated sanitary wastewater from the nearby town of Carrigaline and it would finally discharge (without further treatment) in deep water inside the mouth of Cork Harbour. No adverse environmental impact is anticipated given the biodegradable nature of the biosolids and the relatively small amounts involved.

Novartis Ringaskiddy Limited

Reported Incidents Summary 2009: Emission Point Reference Number 100

IPPCL Register Number P0006-03



Discharge of Chemical Oxygen Demand from Wastewater Treatment Plant (first column) Expressed as a Percentage of the Discharge Regulated Under IPPCL Register Number P0006-03 (Second Column): 2009

Legend: COD: Chemical Oxygen Demand

Novartis Ringaskiddy Limited

Annual Environmental Report 2009

IPPCL Register Number P0006-03

Section 3: Management of the Activity:

Environmental Expenditure Summary: Capital and Current

European Pollutant Release and Transfer Register (PRTR) – Report for 2009

Schedule of Environmental Objectives and Targets - 2009 (Update)

Schedule of Environmental Objectives and Targets - 2010

Environmental Management Programme - Proposal

Environmental Management Programme - Report

Novartis Ringaskiddy Limited

Environmental Expenditure Summary: Capital and Current Expenditure 2009

IPPCL Register Number P0006-03

Capital expenditure for environmental protection 2009: € 1,880,926

Current expenditure for environmental protection 2009: € 11,728,040

Fulltime employees for environmental protection 2009: 20

Novartis Ringaskiddy Limited

European Pollutant Release and Transfer Register (PRTR) - Report for 2009

IPPCL Register Number P0006-03

The requirement to prepare a Pollutant Release and Transfer Register (PRTR) arises from the requirements of Schedule D of IPPCL Register Number P0006-03; and the Agency's correspondence on the subject dated 18-Jan-2007, which was included in Attachment Number 1 of the corresponding section of the AER for 2006. At the time the company proposed to include, where appropriate, the following pollutants from Annex II of the E-PRTR Regulation (EC) No 166/2009 concerning the establishment of a European Pollutant Release and Transfer Register in its 2009 E-PRTR and will do likewise for the 2010 E-PRTR:

Annex II Number	Pollutant
2	Carbon monoxide
3	Carbon dioxide
7	Non-methane volatile organic compounds
8	Nitrogen oxides
11	Sulphur oxides
12	Total Nitrogen
13	Total Phosphorus
14	Hydrochlorofluorocarbons
20	Copper
24	Zinc
35	Dichloromethane
47	PCDD + PCDF (dioxins and furans)
73	Toluene
76	Total organic carbon
79	Chlorides
83	Fluorides

The E-PRTR data for 2009 was submitted to the Agency in electronic format (as required). Attachment Number 1 contains a hard copy summary of the aforementioned data.

Attachment Number 1

| PRTR# : P0006 | Facility Name : Novartis Ringaskiddy Limited | Filename : P0006_2009.xls | Return Year : 2009 |

Environmental Protection Agency

AER Returns Worksheet

Version 1.1.10

REFERENCE YEAR	2009

1. FACILITY IDENTIFICATION

Parent Company Name	Novartis Ringaskiddy Limited
Facility Name	Novartis Ringaskiddy Limited
PRTR Identification Number	P0006
Licence Number	P0006-03

Waste or IPPC Classes of Activity

No.	class_name
5.16	The use of a chemical or biological process for the production of basic pharmaceutical products.
11.1	##

Address 1	Ringaskiddy
Address 2	County Cork
Address 3	
Address 4	
Country	Ireland
Coordinates of Location	-8.34273 51.825
River Basin District	IESW
NACE Code	2110
Main Economic Activity	Manufacture of basic pharmaceutical products
AER Returns Contact Name	Vincent Boyton
AER Returns Contact Email Address	vincent.boyton@novartis.com
AER Returns Contact Position	Environmental and Industrial Hygiene Services Manager
AER Returns Contact Telephone Number	021-4860000
AER Returns Contact Mobile Phone Number	
AER Returns Contact Fax Number	021-4862358
Production Volume	375.25795
Production Volume Units	tonnes
Number of Installations	3
Number of Operating Hours in Year	8424
Number of Employees	437
User Feedback/Comments	
Web Address	

2. PRTR CLASS ACTIVITIES

Activity Number	Activity Name
4(e)	Installations using a chemical or biological process for the production on an industrial scale of basic pharmaceutical products
50.1	General

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) ?	No
Is the reduction scheme compliance route being used ?	No

4.1 RELEASES TO AIR

| PRTR# : P0006 | Facility Name : Novartis Ringaskiddy Limited | Filename : P0006_2009.xls | Return Year : 2009 | 18/05/2010 08:48

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SECTION A : SECTOR SPECIFIC PRTR POLLUTANTS

RELEASES TO AIR

POLLUTANT		METHOD										QUANTITY		
			Method Used		Emission Point Reference Number 03 (Solid Waste Incinerator)	Emission Point Reference Number 04 (Liquid Vapour Incinerator)	Emission Point Reference Number 01 (Utility Boiler Number 1)	Emission Point Reference Number 02 (Utility Boiler Number 2)	Emission Point Reference Number 05 (Emergency Generator)	Emission Point Reference Number 06 (Firewater Pump 1)	Emission Point Reference Number 08 (Firewater Pump 2)			
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	Emission Point 7	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
11	Sulphur oxides (SOx/SO2)	M	ALT	10/23-8.11 EN	6.0	34.0	0.0	0.0	0.0	0.0	0.0	40.0	0.0	0.0
08	Nitrogen oxides (NOx/NO2)	M	ALT	10/23-8.11 EN	236.0	9929.0	2085.0	3319.0	0.0	0.0	0.0	15571.0	0.0	0.0
07	Non-methane volatile organic compounds (NMVOC)	M	ALT	10/23-8.11 EN	21.0	113.0	0.0	0.0	0.0	0.0	0.0	134.0	0.0	0.0
47	PCDD + PCDF (dioxins + furans)(as Teq)	M	PER	BS EN 1948-1: 2006 and BS EN 1948-2: 1997	0.000000023	0.000001013	0.0	0.0	0.0	0.0	0.0	########	0.0	0.0
18	Cadmium and compounds (as Cd)	M	ALT	BS EN 14385 and BS EN 13211	0.008	0.28	0.0	0.0	0.0	0.0	0.0	0.288	0.0	0.0
21	Mercury and compounds (as Hg)	M	ALT	BS EN 14385 and BS EN 13211	0.005	0.043	0.0	0.0	0.0	0.0	0.0	0.048	0.0	0.0
03	Carbon dioxide (CO2)	C	ETS	To meet the requirements of the EU Emissions Trading Scheme (ETS)	973676.0	8373089.0	3507030.0	641822.0	330024.0	5197.0	5197.0	########	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 AIR

POLLUTANT		METHOD											QUANTITY			
			Method Used		Emission Point Reference Number 03 (Solid Waste Incinerator)	Emission Point Reference Number 04 (Liquid Vapour Incinerator)	Emission Point Reference Number 01 (Utility Boiler Number 1)	Emission Point Reference Number 02 (Utility Boiler Number 2)	Emission Point Reference Number 05 (Emergency Generator)	Emission Point Reference Number 06 (Firewater Pump 1)	Emission Point Reference Number 08 (Firewater Pump 2)	Site refrigerant on and freeze drying equipment				
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	Emission Point 7	Emission Point 8	Emission Point 9	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
02	Carbon monoxide (CO)	M	ALT	10/23-8.11 EN	26.0	135.0	26.0	49.0	0.0	0.0	0.0	0.0	0.0	236.0	0.0	0.0
84	Fluorine and inorganic compounds (as HF)	M	OTH	Off-site contract laboratory test - isokinetic sampling to impinger - followed by determination by in chromatography	1.01	19.238	0.0	0.0	0.0	0.0	0.0	0.0	0.0	20.248	0.0	0.0
14	Hydrochlorofluorocarbons (HCFCs)	E	OTH	Estimation of losses based on HCFC replacement requirements during 2009	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.335	0.0	0.335	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		Emission Point Reference Number 03 (Solid Waste Incinerator)	Emission Point Reference Number 04 (Liquid Vapour Incinerator)	Production Building Number 1	Production Building Number 1A	Production Building Number 2				
Pollutant No.	Name	M/C/E	Method Code	Designation or Description	Emission Point 1	Emission Point 2	Emission Point 3	Emission Point 4	Emission Point 5	T (Total) KG/Year	A (Accidental) KG/Year	F (Fugitive) KG/Year
244	Total Particulates	M	ALT	Isokinetic sampling followed by continuous photometric determination	27.0	257.0	0.0	0.0	0.0	284.0	0.0	0.0
214	Hydrogen bromide	M	OTH	Off-site contract laboratory test - isokinetic sampling to impinger - followed by determination by in chromatography	1.684	12.741	0.0	0.0	0.0	14.425	0.0	0.0
237	Volatile organic compounds (as TOC)	E	OTH	Estimation of fugitive emissions of non-chlorinated solvents to atmosphere from diffuse sources - based on PID measurements	0.0	0.0	865.0	268.0	2111.0	3244.0	0.0	0.0

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

Additional Data Requested from Landfill operators

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

Landfill: Novartis Ringaskiddy Limited

Please enter summary data on the quantities of methane flared and / or utilised

T (Total) kg/Year	M/C/E	Method Used: Method Code	Method Used: Designation or Description	Facility Total Capacity m3 per hour

Total estimated methane generation (as per site model)	0.0				N/A	
Methane flared	0.0				0.0	(Total Flaring Capacity)
Methane utilised in engine/s	0.0				0.0	(Total Utilising Capacity)
Net methane emission (as reported in Section A above)	0.0				N/A	

4.3 RELEASES TO WASTEWATER OR SEWER

[PRTR# : P0006 | Facility Name : Novartis Ringaskiddy Limited | Filename : P0006_2009.xls] Return 18/05/2010 08:49

SECTION A : PRTR POLLUTANTS

OFFSITE TRANSFER OF POLLUTANTS DESTINED FOR WASTE-WATER TREATMENT OR SEWER

POLLUTANT		METHOD			QUANTITY			
			Method Used		Emission Point Reference Number 100			
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
73	Toluene	M	CRM	EO 025 - Off-site contract laboratory test - Purge and Trap/GC/MS	0.103	0.103	0.0	0.0
20	Copper and compounds (as Cu)	M	CRM	EM 130 ICP-MS - Off-site contract laboratory test.	1.1	1.1	0.0	0.0
24	Zinc and compounds (as Zn)	M	CRM	EM 130 ICP-MS - Off-site contract laboratory test.	19.85	19.85	0.0	0.0
13	Total phosphorus	M	OTH	Internal test procedure 000.9933.0666 (Modification of ascorbic acid method approved by US EPA)	519.0	519.0	0.0	0.0
12	Total nitrogen	M	OTH	Internal test procedure 000.933.0667	899.0	899.0	0.0	0.0
76	Total organic carbon (TOC) [as total C or COD/3]	C	OTH	Based on the determination of Chemical Oxygen Demand (Internal test procedure 000.933.0662)	10837.0	10837.0	0.0	0.0
47	PCDD + PCDF (dioxins + furans)(as Teq)	M	CRM	AES Organics Laboratory Method O-36 (accredited under the UKAS accreditation scheme)	0.0	0.0	0.0	0.0
06	Ammonia (NH3)	M	OTH	Internal test procedure 000.933.0669 (Determination by ion-selective electrode)	21.0	21.0	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		Emission Point Reference Number 100			
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
306	COD	M	OTH	Internal test procedure 000.933.0662	32510.0	32510.0	0.0	0.0
303	BOD	M	OTH	Internal test procedure 000.933.0689 (5 day determination of BOD by closed bottle test procedure)	4792.0	4792.0	0.0	0.0
240	Suspended Solids	M	OTH	Internal test procedure 000.933.7177 (gravimetric determination following drying at 104 oC)	11283.0	11283.0	0.0	0.0

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

Novartis Ringaskiddy Limited

Schedule of Objectives and Targets – 2009 (Update)

Note that these Objectives are not a Requirement of IPPCL Register Number P0006-03

The schedule of environmental objectives and targets listed here are not a requirement of Schedule D of IPPCL Register Number P0006-03. Further information on the objectives and suggested benefits are described in Sections 4.0 and 5.0 of the 2009 Environmental Management Programme (Rev 13)(which forms part of 2008 Annual Environmental Report).

1. **Diovan Process Unit.** Maximise Batch Still throughput to reduce fresh solvent consumption and the amount of hazardous waste requiring final treatment.

   (To support the objective of reusing/recycling more of the hazardous waste that is generated on-site (optimisation of the use of natural resources); and the objective of striving for continual improvement in our HSE performance)

   Status: Complete: The amount of hazardous waste generated in 2009 was 28.7 kg/kg of product shipped, which is a 24 % reduction on the 2007 figure (note that 2007 was set as the baseline year).

2. **Ciclo/Peptides/SSF Process Unit.** Review management of waste streams from the Ciclosporin Process purification process and update the process mass balance in the MMP.

   (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

   Status: On-going. The process mass balance has been established; and optimization of A-column blowdown is progressing.

3. **Ciclo/Peptides/SSF Process Unit.** Improve off-loading procedures and/or upgrade the exit area from the used AUXSP off-loading area to avoid potential losses to the surface water system.

   (To support the objective of minimising the environmental impact of our activities; and to support the objective of measuring progress and verifying compliance with National regulatory requirements)

   Status: Complete. Newly regarded exit ramp was installed.

4. **Production Building 2.** Reduce the amount of fugitive emissions of organic carbon from Production Building 2 by 5% using the 2008 discharge of 1,373 kgs as the baseline.

(To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

Status: Complete. Overall site fugitive emissions were reduced by 497 kgs – representing a 13.3% decrease on 2008.

5. **Production Building 2.** Reduce electricity consumption by 2.5% relative to production (intermediates and products) to actively contribute to the site energy conservation target; and achieve an absolute reduction of 1.25 % based on implementation of specific projects.

(To support the objective of minimising the environmental impact of our activities; the objective of conducting our business in as sustainable a manner as is possible; and the objective of striving for continual improvement in our HSE performance)

Status: Complete. The cumulative site energy consumption (natural gas and electricity) for 2009 was 1.184 GJ/kg of product shipped and the target figure was also 1.184 GJ/kg of product shipped (based on a 7.5% relative reduction on the 2006 figure).

6. **Production Building 2**. Maintain a schedule of potential and realised improvements in increasing the efficiency of use of raw materials (for example through the implementation of Lean and IQP projects).

(To support the objective of conducting our business in as sustainable a manner as is possible; the objective of optimising the use of natural resources; and the objective of striving for continual improvement in our HSE performance)

Status: Not complete. More focus will be given to maintaining this schedule during 2010 as much good work is going unrecognised.

7. **Lescol/Glivec Process Unit.** Facilitate the optimal treatment of aqueous wastes from the Fluvastatin pipeline. Minimise the discharge of TBME to the wastewater treatment plant.

(To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

Status: Complete. Aqueous waste from the second and third production campaigns during 2009 was well managed and treatment plant performance was optimized.

8. **Production Buildings 1 and 1A.** Reduce the amount of fugitive emissions of organic carbon from Production Buildings 1 and 1A by 5% using the 2008 discharge of 2,362 kgs as the baseline.

(To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

Status: Complete. Overall site fugitive emissions were reduced by 497 kgs – representing a 13.3% decrease on 2008.

9. **Production Buildings 1 and 1A.** Reduce electricity consumption by 2.5% relative to production (intermediates and products) to actively contribute to the site energy conservation target; and achieve an absolute reduction of 1.25 % based on implementation of specific projects.

(To support the objective of minimising the environmental impact of our activities; the objective of conducting our business in as sustainable a manner as is possible; and the objective of striving for continual improvement in our HSE performance)

Status: Complete. The cumulative site energy consumption (natural gas and electricity) for 2009 was 1.184 GJ/kg of product shipped and the target figure was also 1.184 GJ/kg of product shipped (based on a 7.5% relative reduction on the 2006 figure).

10. **Production Buildings 1 and 1A.** Maintain a schedule of potential and realised improvements in increasing the efficiency of use of raw materials (for example through the implementation of Lean and IQP projects).

(To support the objective of conducting our business in as sustainable a manner as is possible; the objective of optimising the use of natural resources; and the objective of striving for continual improvement in our HSE performance)

Status: Complete. However, more focus will be given to maintaining this schedule during 2010 as much good work is going unrecognised.

11. **Technical Services.** Optimise management of the surface water protection system in line with the findings of the 2006 Environmental Liability Risk Assessment (ELRA) (to be in place before the end of June).

(To support the objective of minimising the environmental impact of our activities)

Status: Complete. Significant upgrade to Storm Water Retention Pond undertaken with some minor works to be complete in 2010.

12. **Technical Services.** Reduce the amount of fugitive emissions of organic carbon arising from vent disconnections and/or unavailability by 5% using the 2008 figure of 1,621 kgs as the baseline.

(To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

Status: Not complete.

13. **Technical Services.** Maintain a schedule of potential and realised improvements in increasing the throughput of solvent recovery operations.

(To support the objective of reusing/recycling more of the hazardous waste that is generated on-site (optimisation of the use of natural resources); and the objective of striving for continual improvement in our HSE performance)

Status: Complete. Significant increase in throughput in Solvent Recovery during 2009.

14. **Technical Services.** Achieve a 20% reduction in the number of OOE results for operation of environmental controls modules. Note that these are not IPPCL non-compliant results.

(To support the objective of measuring progress and verifying compliance with National regulatory requirements)

Status: Not Complete. Note, however, that a total of 9 deviations required reporting to the EPA during 2009 (out of more than 200,000 reported results) and none of these were of environmental significance.

15. **HSE.** Introduce an aqueous waste management system (in collaboration with Production Building 1 and Production Building 2 Process Units and Technical Services) to optimise on-site treatment and facilitate ease of 'trouble shooting' at times of sub-optimal wastewater treatment plant performance.

(To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

Status: Complete. Technical Services have now allocated additional engineering resources to help better manage the organic loading on the wastewater treatment plant, which also considers the varying loads arising from changing production activities.

16. **HSE.** Coordinate the implementation of the EPA's protocol for bypass of air emissions abatement equipment.

(To support the objective of measuring progress and verifying compliance with National regulatory requirements)

Status: Complete. The elements that are required to implement the protocol are now in place.

Novartis Ringaskiddy Limited

Schedule of Objectives and Targets – 2010

Note that these Objectives are not a Requirement of IPPCL Register Number P0006-03

The schedule of environmental objectives and targets listed here are not a requirement of Schedule D of IPPCL Register Number P0006-03. Further information on the objectives and suggested benefits are described in Sections 4.0 and 5.0 of the 2010 Environmental Management Programme (Rev 14)(which forms part of this Annual Environmental Report).

Technical Services Support Unit. Maximise Batch Still throughput to reduce fresh solvent consumption and the amount of hazardous waste requiring final treatment. Contribute to achieving overall site hazardous waste reduction target of 5% based on the 2009 relative rate of hazardous waste generation.

(To support the objective of reusing/recycling more of the hazardous waste that is generated on-site (optimisation of the use of natural resources); and the objective of striving for continual improvement in our HSE performance)

Technical Services Support Unit. Coordinate site projects and activities to meet the overall site energy target of a 10% reduction on 2006 baseline relative energy consumption figure (equates to 2.5% for each year 2007, 2008, 2009 and 2010).

(To support the objective of conducting our business in as sustainable a manner as is possible; the objective of optimising the use of natural resources; and the objective of striving for continual improvement in our HSE performance)

Technical Services Support Unit. Install and commission a Low Flow Transfer Station at the Strom Water Retention Pond to further optimise the facility's firewater retention capacity (in line with the Environmental Liability Risk Assessment).

(To support the objective of minimising the environmental impact of our activities)

Technical Services Support Unit. Reduce the amount of fugitive emissions of organic carbon arising from vent disconnections and/or unavailability by 10% using the 2008 figure of 1,621 kgs as the baseline (note that the 2009 target was not achieved).

(To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

Technical Services Support Unit. Develop an implementation plan for the possible use of a Wet Electrostatic Precipitator at the Liquid Vapour Incinerator to facilitate more on-site treatment of waste with heat recovery; and further reduce emissions of inorganic particulate material.

(To support the objective of reusing/recycling more of the hazardous waste that is generated on-site (optimisation of the use of natural resources); and the objective of striving for continual improvement in our HSE performance)

Technical Services Support Unit. Achieve an internal compliance rate of 99.98% (or greater) in respect of the number of OOE results reported for operation of environmental controls modules. Note that these are not IPPCL non-compliant results.

(To support the objective of measuring progress and verifying compliance with National regulatory requirements)

Ciclo/Peptides/SSF Process Unit. Eliminate the discharge of residual amounts of Ciclosporin to the wastewater treatment plant; and minimise the discharge of aqueous solvent to the wastewater treatment plant from washing of the A-column.

(To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

Production Building 2. Reduce the amount of fugitive emissions of organic carbon from Production Building 2 by 10% using the 2008 discharge of 1,373 kgs as the baseline.

(To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

Production Building 2. Reduce electricity consumption by 2.5% relative to production (intermediates and products) to actively contribute to the site energy conservation target; and achieve an absolute reduction of 1.25 % based on implementation of specific projects.

(To support the objective of minimising the environmental impact of our activities; the objective of conducting our business in as sustainable a manner as is possible; and the objective of striving for continual improvement in our HSE performance)

Production Building 2. Maintain a schedule of potential and realised improvements in increasing the efficiency of use of raw materials (for example through the implementation of Lean and IQP projects).

(To support the objective of conducting our business in as sustainable a manner as is possible; the objective of optimising the use of natural resources; and the objective of striving for continual improvement in our HSE performance) (To support the objective of measuring progress and verifying compliance with National regulatory requirements)

Production Buildings 1 and 1A. Stabilise the amount of fugitive emissions of organic carbon from Production Buildings 1 and 1A at the 2009 discharge level of 1,133 kgs.

(To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

Production Buildings 1 and 1A. Reduce electricity consumption by 2.5% relative to production (intermediates and products) to actively contribute to the site energy conservation target; and achieve an absolute reduction of 1.25 % based on implementation of specific projects.

(To support the objective of minimising the environmental impact of our activities; the objective of conducting our business in as sustainable a manner as is possible; and the objective of striving for continual improvement in our HSE performance)

Production Buildings 1 and 1A. Maintain a schedule of potential and realised improvements in increasing the efficiency of use of raw materials (for example through the implementation of Lean and IQP projects).

(To support the objective of conducting our business in as sustainable a manner as is possible; the objective of optimising the use of natural resources; and the objective of striving for continual improvement in our HSE performance) (To support the objective of measuring progress and verifying compliance with National regulatory requirements)

HSE. Coordinate the implementation of the EPA's requirements in respect of the quality of self-monitoring compliance data (as per the Agency's letter of 18-Nov-2009).

(To support the objective of measuring progress and verifying compliance with National regulatory requirements)

Novartis Ringaskiddy Limited

Environmental Management Programme

(Fourteenth Revision)

01-Apr-2010

EMAS

This site has an Environmental Management System and its environmental performance is reported on to the public in accordance with the Community Eco-Management and Audit Scheme.

(Registration Number IE - 002)

Novartis Ringaskiddy Limited and Responsible Care

As a member of the PharmaChemical Ireland group Novartis Ringaskiddy Limited strongly supports the unique initiative developed by the international chemical industry, called **RESPONSIBLE CARE**, and is fully committed to the set of health, safety and environment Guiding Principles drawn up under Responsible Care by PCI.

Accordingly, Novartis Ringaskiddy Limited is committed to "managing its activities so that they present an acceptably high level of protection for health and safety of employees, customers, the public and the environment", and in doing so will "work closely with public and statutory bodies".

But more than this, since the underlying philosophy of Responsible Care is very much focused on continuous improvement of the performance of the chemical industry in every aspect, Novartis Ringaskiddy Limited is already voluntarily committed to the principle of environmental improvement on a continuous planned basis.

List of Abbreviations Used Frequently in the Text of this Document:

%	Percent
AER	Annual Environmental Report
BOM	Bill of Material
CEM	Continuous Emission Monitor
CIP	Cleaning In Place
DCS	Distributed Control System
EC	European Community
EEC	European Economic Community
EIS	Environmental Impact Statement
ELV	Emission Limit Value
EMAS	Eco-Management and Audit Scheme
EMP	Environmental Management Programme
EPA	Environmental Protection Agency
E-PRTR	European Pollutant Release and Transfer Register
ESB	Electricity Supply Board
HSA	Health and Safety Authority
HSE	Health, Safety and Environmental Protection
HVAC	Heating, Vacuum and Air Conditioning
IDA	Industrial Development Authority
IPCL	Integrated Pollution Control Licence
IPPCL	Integrated Pollution Prevention and Control Licence
kg	Kilogramme
LVI	Liquid Vapour Incinerator
m^3	Cubic metre
PB1	Production Building 1
PB1A	Production Building 1A
PB2	Production Building 2
SEI	Sustainable Energy Ireland
SOP	Standard Operating Procedure
SWI	Solid Waste Incinerator
TALAS	T.A. Luft Analytical System
TOC	Total Organic Carbon

1.0 INTRODUCTION

Novartis AG provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group's continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in Research and Development activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 full-time-equivalent associates and operate in more than 140 countries around the world.

Further Group information is available at http://www.novartis.com.

Novartis in Ireland is involved in the distribution of medications and the manufacture of drug substances for pharmaceuticals. Novartis Ringaskiddy Limited, the company's pharmaceutical production plant at Ringaskiddy, County Cork, currently employs approximately 437 people and manufactures a wide range of speciality drug substances used in the treatment of immunologic, dermatologic, cardiovascular, oncological and central nervous system diseases. The company has currently developed about 30 ha of what is now a 53 ha site for the manufacture and purification of a range of drug substances. The end products are exported worldwide to formulation and packaging plants, for incorporation into forms suitable for the end user (tablet, phial, etc.).

Novartis Ringaskiddy Limited is located on the western side of a large industrially zoned area in Ringaskiddy, County Cork. Areas of mixed agriculture and a number of small villages including Ringaskiddy itself border the industrial zone. Ringaskiddy has been developed over the past twenty years into the deep-water berth for the Port of Cork; and further significant development of the port area is planned in the coming years.

The design and construction of the facility at Ringaskiddy provided for the most up to date environmental concepts. The ever improving approach over the course of the last century to environmental concepts applied to chemical factories has reached a point with Novartis Ringaskiddy Limited where the factory has central treatment for all process related activities and only one wastewater discharge point. This permits accurate, and in many cases continuous, monitoring of emissions from the facility to the environment.

Of further special note in this context is the fact that the wastewater treatment plant is fully enclosed and that the air used in the treatment of wastewater is subsequently used as the combustion air for the incinerator. This concept dramatically reduces emissions and avoids odours and also makes it possible to measure accurately all emissions and discharges so that the highest standards of environmental responsibility are set and maintained.

Resources such as solvents (liquids used for dissolving solids), paper, metal and glass are recycled wherever economically practicable and solvent recovery units have been installed to ensure that a high proportion of solvents can be recycled on-site.

Protection of surface water and groundwater has also been catered for in the design of the facility. All surface water, for example, rain water or fire water, which falls on the site is guided to a retention pond. Water from this pond can only be released after testing has proved that it is not contaminated. If any contamination is found, the water is pumped to the wastewater treatment plant for treatment prior to discharge.

Novartis' manufacturing facility in Ringaskiddy is comprised of three main production buildings, which are known as Production Buildings 1, 1A and 2. At this moment in time an extension is being added to Production Building 1A; and a dedicated Small Scale Facility (SSF) has also been developed. The SSF plant is located north of Production Building 1A. Both developments have the necessary planning permissions in place and are not of such a magnitude that would require a revision to the company's Integrated Pollution Prevention and Control Licence (IPPCL). The SSF, which was commissioned during 2008, was first used for the manufacture of certain 'low volume high value' products during 2009. No immediate use for the extension to Production Building 1A is foreseen during 2010.

All production buildings are supported by a Technical Services Function which supplies raw materials, utility services and waste management services. The latter scope of work includes solvent recovery; wastewater treatment; and air emission control. The facility also has a dedicated Health, Safety and Environmental Protection (HSE) Support Unit, which is dedicated to maintaining full regulatory compliance in all aspects of HSE.

The company shipped 375.258 tonnes of active drug substances in 2009, which was a significant increase on the 316.899 tonnes shipped in 2008 (an increase of some 18%). It is anticipated that production volumes will be of the same order of magnitude during 2009.

The Environmental Protection Agency (EPA) regulates aspects of Novartis Ringaskiddy Limited's operations that might impact on the environment. The company has been issued with an IPPCL by the Agency – Register Number P0006-03 dated 02-Feb-2006. This IPPCL superseded Integrated Pollution Control Licence (IPCL) Register Number 545, which had been in force since 31-Oct-2000. The latter IPCL superseded the company's original IPCL (Register Number 6), which was issued to the company by the EPA on 16-May-1995. IPPCL Register Number P0006-03 has introduced a number of new requirements for the company - some of which are addressed in Section 4 of this document.

The Agency also issued Novartis Ringaskiddy Limited with a Greenhouse Gas Emissions Permit (Permit Register Number GHG078-1) on 29-Mar-2004. This permit was subsequently updated by the Agency on 23-Sep-2005 when Greenhouse Gas Emissions Permit (Permit Register Number IE-GHG078-2) was issued; and 12-Aug-2008 when Greenhouse Gas Emissions Permit (Permit Register Number IE-GHG078-3) was issued.

Novartis Ringaskiddy Limited's site is also host to another Novartis company. Novartis International Pharmaceutical Branch Ireland is part of a Novartis owned technology and proprietary company and is responsible for controlling chemical production of bulk raw material on a global basis by Novartis Pharma AG. It is comprised of quality control, logistics and quality assurance departments. Another of the company's principal functions is the provision of assistance to Novartis' various manufacturing sites in the procurement of raw materials. This operation currently employs approximately 100 people. These employees are housed in a single storey building that is comprised of an administration block and a quality assurance/quality control service laboratory block.

Full details of the Novartis International Pharmaceutical Branch Ireland development have already been forwarded to the EPA (correspondence of 24-Sep-1998, ref.: IPC10159.doc).

2.0 FOURTEENTH REVISION TO SITE ENVIRONMENTAL MANAGEMENT PROGRAMME

Novartis Ringaskiddy Limited was required, under Conditions 2.1 and 2.3; and Schedule 6 (i) of IPCL Register Number 6, to submit its first Environmental Management Programme (EMP) to the EPA on 16-Nov-1995. The EPA subsequently approved the aforementioned EMP on 19-Jan-1996 without any changes. A report on the implementation of this EMP was forwarded to the EPA on 03-Feb-1997 in accordance with the provisions of Schedule 6 (i) of the company's IPCL. This report was approved by the Agency on 18-Feb-1997.

The company submitted its first annual revision to the site EMP, required under Schedule 6(i) of IPCL Register Number 6, on 21-Nov-1996. This revision was approved by the Agency on 02-Dec-1996 without any changes. A report on the implementation of the first revision was forwarded to the EPA on 11-Feb-1998 in accordance with the provisions of Schedule 6 (i) of the company's IPCL.

Novartis Ringaskiddy Limited submitted its second annual revision to the site EMP, required under Schedule 6(i) of IPCL Register Number 6, on 21-Nov-1997. This revision was approved by the Agency on 30-Dec-1997 without any changes. A report on the implementation of the second revision of the EMP (covering the calendar year 1998) was forwarded to the EPA on 23-Feb-1999 in accordance with the provisions of Schedule 6 (i) of the company's IPCL.

The company submitted its third annual revision to the site EMP, required under Schedule 6(i) of IPCL Register Number 6, on 07-Dec-1998. A report on the implementation of the third revision of the EMP (covering the calendar year 1999) was forwarded to the EPA on 10-Feb-2000 in accordance with the provisions of Schedule 6 (i) of the company's IPCL.

The company submitted its fourth annual revision to the site EMP, required under Schedule 6(i) of IPCL Register Number 6, on 15-Dec-1999. A report on the implementation of the fourth revision of the EMP (covering the calendar year 2000) was submitted to the EPA as part of the company's Annual Environmental Report (AER) for 2000.

In the intervening period IPCL Register Number 6, which was issued on 16-May-1995, was superseded by IPCL Register Number 545 on 31-Oct-2000.

The company submitted its fifth annual revision to the site EMP, required under Schedule 5(i) of IPCL Register Number 545, on 01-Feb-2001. A report on the implementation of the fifth revision of the EMP (covering the calendar year 2001) was submitted to the EPA as part of the company's AER for 2001 (dated 01-Feb-2002).

The company submitted its sixth annual revision to the site EMP, required under Schedule 5(i) of IPCL Register Number 545, on 01-Feb-2002. A report on the implementation of the sixth revision of the EMP (covering the calendar year 2002) was submitted to the EPA as part of the company's AER for 2002 (dated 01-Apr-2003).

The company submitted its seventh annual revision to the site EMP, required under Schedule 5(i) of IPCL Register Number 545, on 31-Mar-2003. A report on the implementation of the seventh revision of the

EMP (covering the calendar year 2003) was submitted to the EPA as part of the company's AER for 2003 (dated 31-Mar-2004).

The company submitted its eight annual revision to the site EMP, required under Schedule 5(i) of IPCL Register Number 545, on 01-Apr-2004. A report on the implementation of the eight revision of the EMP (covering the calendar year 2004) was submitted to the EPA as part of the company's AER for 2004.

The company submitted its Ninth annual revision to the site EMP, required under Schedule 5(i) of IPCL Register Number 545, on 01-Apr-2005. A report on the implementation of the ninth revision of the EMP (covering the calendar year 2005) was submitted to the EPA as part of the company's AER for 2005.

In the intervening period IPCL Register Number 545, which was issued on 31-Oct-2000, was superseded by IPPCL Register Number P0006-03 on 02-Feb-2006.

The company submitted its Tenth annual revision to the site EMP, required under Condition 2.2.2.3 and Schedule D of IPPCL Register Number P0006-03, on 01-Apr-2006. A report on the implementation of the tenth revision of the EMP (covering the calendar year 2006) was submitted to the EPA as part of the company's AER for 2006.

The company submitted its Eleventh annual revision to the site EMP, required under Condition 2.2.2.3 and Schedule D of IPPCL Register Number P0006-03, on 01-Apr-2007. A report on the implementation of the eleventh revision of the EMP (covering the calendar year 2007) was submitted to the EPA as part of the company's AER for 2008.

The company submitted its Twelfth annual revision to the site EMP, required under Condition 2.2.2.3 and Schedule D of IPPCL Register Number P0006-03, on 01-Apr-2008. A report on the implementation of the twelfth revision of the EMP (covering the calendar year 2008) was submitted to the EPA as part of the company's AER for 2008.

The company submitted its Thirteenth annual revision to the site EMP, required under Condition 2.2.2.3 and Schedule D of IPPCL Register Number P0006-03, on 01-Apr-2009. A report on the implementation of the thirteenth revision of the EMP (covering the calendar year 2009) is currently being submitted to the EPA as part of the company's AER for 2009.

This document is the fourteenth annual revision to the site EMP required under Condition 2.2.2.3 and Schedule D of IPPCL Register Number P0006-03. By default it is a more concise document than the original and subsequent revisions. The structure of this fourteenth revision follows that of thirteen preceding documents. Consequently, cross-reference is made to the preceding documents where there have been no significant changes. Subject to approval by the Agency, a report on the implementation of this fourteenth revision of the EMP (covering the calendar year 2010) will be forwarded to the EPA as part of the company's AER for 2010 (due 31-Mar-2011) in accordance with the provisions of Condition 2.2.2.3 and Schedule D of IPPCL Register Number P0006-03.

Section 3.0 of this document presents the company's Interim Environmental Statement for the year 2008. This document was produced to meet the requirements of the European Community's Eco-Management

and Audit Scheme (EMAS) Regulation. With the publication of this independently verified document Novartis Ringaskiddy Limited completed fourteen years of continuous participation in EMAS. Now into its sixth cycle of EMAS participation the company intends to publish an independently verified Environmental Statement (for the calendar years 2007, 2008 and 2009) during the first half of 2010. Novartis Ringaskiddy Limited was the first Irish company in the Chemical/Pharmaceutical sector to register under the scheme. The new Environmental Statement will be the company's first under the recently revised EMAS Regulation 1221/2009 (also known as EMAS III)

The objective of EMAS is to

"promote continual improvements in the environmental performance organisations by:

(a) the establishment and implementation of environmental policies, programmes and management systems by organisations;

(b) the systematic, objective and periodic evaluation of the performance of such systems;

(c) the provision of information of environmental performance and an open dialogue with the public and other interested parties;

(and)

(d) the active involvement of employees in the organisation and appropriate initial and advanced training that makes participation in the tasks referred to under (a) possible."

Participation in EMAS is voluntary and the Irish Government actively supports such participation.

To assist in the provision of information concerning environmental performance to the public, EMAS requires participating companies to prepare an Environmental Statement. The contents of this Statement have to be validated by an independent and nationally accredited verifying organisation. In Novartis Ringaskiddy Limited's case this is SGS United Kingdom Limited. Environmental Statements are normally produced every three years. However, EMAS participation also requires companies to produce annual interim Environmental Statements during years when a full Environmental Statement is not being prepared. The contents of such interim statements also have to be independently verified. The document reproduced in Section 3.0 is Novartis Ringaskiddy Limited's Interim Environmental Statement covering the calendar year 2008.

The contents of the Interim Environmental Statement underline Novartis Ringaskiddy Limited's on-going commitment to environmental protection. The document complements the company's first Environmental Statement of 1996 (covering the years 1994 and 1995); second Environmental Statement of 1998 (covering the years 1996 and 1997); third Environmental Statement of 2001 (covering the years 1998, 1999 and 2000); fourth Environmental Statement of 2004 (covering the years 2001, 2002 and 2003); fifth Environmental Statement of 2007 (covering the years 2004, 2005 and 2006); and Interim Environmental Statement of 2007; meetings with the local community and the records of the approximately 200,000

analyses that are carried out on an annual basis to check the company's environmental performance and which are also available to the public.

It is noteworthy that despite this transparent decade long commitment to improving environmental performance that implementation of IPPCL Register Number P0006-03 necessitated an approximate 50% increase in environmental analyses (from approximately 133,000 analyses per annum in 2005 to approximately 200,000 analyses per annum in 2009); together with additional regulatory requirements.

As noted above the next Environmental Statement will be issued during the first half of this year and will outline the company's efforts in respect of environmental protection for the calendar years 2007, 2008 and 2009.

Section 4.0 of this proposal outlines any changes to the Management of the Activity (more correctly referred to as aspects of the Environmental Management System (EMS) at Novartis Ringaskiddy Limited). Some of the changes/modifications outlined in this section will not be completed during the lifetime of this proposed revision to the EMP. This is because of the detailed nature of the work involved. However, subsequent revisions to this document will present an update on the proposals described in this document.

Section 5.0 outlines the 2010 EMP and associated targets. This section is slightly modified in that it now takes cognisance of the requirements of Condition 2.2.2.3 of IPPCL Register Number P0006-03.

3.0 INTERIM ENVIRONMENTAL STATEMENT 2008

One of the requirements of Novartis Ringaskiddy Limited's participation in the EMAS scheme is that the company makes key data in relation to its environmental performance freely available to the general public. The primary vehicle for doing this is an Environmental Statement. The contents of this statement are subject to independent verification on an audit cycle of not longer than three years. During intervening years key environmental data is made available in a more concise annual report whose contents are also independently audited.

Of special note during this period is the fact that the Interim Environmental Statement of 2001; the full Environmental Statement of 2001 to 2003; and the Interim Environmental Statement of 2004 were recipients of commendations under the Annual Environmental Reporting Awards Scheme run by ACCA Ireland. The awards aim to:

Give recognition to those organisations which report and disclose environmental, social or full sustainability information;

Encourage the uptake of environmental, social and sustainability reporting; and

Raise the awareness of corporate transparency issues

ACCA is very active worldwide in the promotion and benchmarking of environmental, social and sustainability reporting.

The Environmental Statement and the Interim Environmental Statements provide information on:

- The company's direct environmental aspects:
  - general progress in the area of environmental protection;
  - production volumes;
  - water and energy consumption;
  - emissions to water and air;
  - noise;
  - groundwater quality; and
  - waste.

- The company's indirect environmental aspects:
  - Participation in Novartis Corporate Citizenship programmes;
  - supporting Novartis in the Global Reporting Imitative;
  - supporting the Novartis global Community Partnership Day; and
  - enhancing local biodiversity; and provision of local amenity walkways.

These documents are available to the public.

To-date Novartis Ringaskiddy Limited has produced five Environmental Statements as part of the company's registration under the EMAS scheme. The most recent Environmental Statement issued by the company covered the calendar years 2004 to 2006 and was included in the AER for 2007 as an inset to the twelfth revision to the EMP. A copy of the Interim Environmental Statement for the calendar year 2008 is included as an inset on the page after next.

Taken on an annual basis the key environmental data in the company's Environmental Statements and interim Environmental Statements should serve to demonstrate how consumption of resources and emissions to the environment, expressed per tonne of product, are progressively decreasing at the Ringaskiddy facility. The data set for the year 2008 confirms that this generally continues to be the case at Novartis Ringaskiddy Limited. These data can be compared with data for the years from 1994 (when manufacturing commenced at the facility) to 2007 and which have been included in the company's original EMP and subsequent revisions.

Novartis Ringaskiddy Limited considers that the information contained in the following pages compares favourably with preceding reports and the company anticipates presenting an equally satisfactory set of results for 2009 when the next Environmental Statement is published.

Insert: Interim Environmental Statement 2008

NOVARTIS

Novartis Ringaskiddy Limited
Ringaskiddy, County Cork, Ireland

INTERIM ENVIRONMENTAL STATEMENT 2008

(Prepared to Meet the Requirements of the European Community's EMAS Regulation)

This site has an Environmental Management System and its environmental performance is reported on to the public in accordance with the Community Eco-Management and Audit Scheme.

EMAS (Registration Number IE-002)

FOREWORD

I have pleasure in presenting Novartis Ringaskiddy Limited's Interim Environmental Statement for 2008. It summarises the company's environmental performance during the year 2008; identifies the company's environmental targets for 2009; and describes the means by which the facility's impact on the environment is minimised.

Novartis Ringaskiddy Limited underwent a significant decrease in production from 426 tonnes in 2007 to 317 tonnes in 2008. This approximate 26% decrease in manufacturing output required significant focus and effort on minimising the associated energy inputs and waste outputs during 2008 and in many cases it was not possible to report as good a relative environmental performance as was reported in the 2007 Interim Environmental Statement.

Two key areas where there will be greater focus and effort during 2009 will be in the area of energy conservation and hazardous waste minimisation – where I will be taking an active interest in the implementation of the various programmes that have been established.

In respect of energy a suite of energy saving initiatives is to be undertaken by the various Process Units and Support Units on site. This bundle of projects will involve much greater participation from the end users of energy at the facility and its implementation will be closely monitored by the company's main management group. It is noteworthy that this initiative is also attracting significant attention at a parent company level, which should add to our focus in meeting the targets set.

There is also much greater scope to reduce the volumes of hazardous waste that are generated at Novartis Ringaskiddy Limited. Although the ratio of hazardous waste generated compared to the amount of product manufactured has remained relatively stable over the past five years the total amount is still too high and carries a high environmental and financial cost.

Therefore many of the Process Units on-site are now working on yield improvement projects and projects to reduce material inputs to processes, which should help in this regard. I also note that additional focus was given to solvent recovery on the Diovan® process during 2008 in an effort to further optimise hazardous waste management associated with the product.

There were of course a number of very positive developments during 2008 and two in particular come to mind as I read the contents of this Interim Statement. Fugitive emissions (of solvent material), which arise from a large number of small sources, showed a continuing reduction during 2008: Down approximately 49% from 7,396 kgs in 2007 to 3,740 kgs in 2008. I also note that the amount of non-hazardous waste recycled increased from 2.4 kg/kg of product shipped in 2007 to 5.4 kg/kg of product shipped during 2008; while the amount of non-hazardous waste requiring disposal and treatment decreased from 2.9 kg/kg of product shipped in 2007 to 0.7 kg/kg of product shipped in 2008, which was an excellent achievement.

Finally I would like to thank everyone for their contribution to minimising the company's environmental impact during 2008 and once again encourage everyone on the Ringaskiddy Campus to contribute with the same degree of commitment and enthusiasm during 2009.

John Alexander
Managing Director

1 – INTRODUCTION

ECO-MANAGEMENT AND AUDIT SCHEME

This Interim Environmental Statement has been prepared in accordance with the provisions of the European Community's Eco-Management and Audit Scheme - more commonly known as EMAS.

The objective of EMAS is to "promote continual improvements in the environmental performance of organisations by:

(a) the establishment and implementation of environmental management systems by organisations;

(b) the systematic, objective and periodic evaluation of the performance of such systems;

(c) the provision of information on environmental performance and an open dialogue with the public and other interested parties; and

(d) the active involvement of employees in the organisation and appropriate initial and advanced training that makes active participation in the tasks referred to under (a) possible."

Participation in EMAS is voluntary and the Irish Government actively supports such participation.

To assist in the provision of information concerning environmental performance to the public, EMAS requires participating companies to prepare an Environmental Statement on a cycle of not more than three years and Interim Environmental Statements during the intervening years. The purpose of the Interim Environmental Statement is to provide for an annual update to the information contained in the most recent Environmental Statement. The contents of both types of Statement have to be validated by an independent and nationally accredited verifying organisation. In Novartis Ringaskiddy Limited's case this is SGS United Kingdom Limited.

This Interim Environmental Statement for the year 2008 updates the information presented in the 2004 to 2006 Environmental Statement, which was published two years ago; and the information presented in the 2007 Interim Environmental Statement, which was published one year ago. It also compliments the information presented in the company's previous Environmental Statements, which cover the years 1995 to 2003.

The document updates the company's product portfolio and highlights progress in the area of environmental protection. The company's Health, Safety and Environment (HSE) Policy is also included. Detailed environmental performance data is included as an appendix to this document. This data provides for a year by year comparison of key data over a six year period.

The next externally verified Environmental Statement (covering the calendar years 2007 to 2009) will be issued in June of 2010.

PRODUCT PORTFOLIO 2008

Novartis Ringaskiddy Limited is designed to produce the drug substances for what are often life saving treatments for people around the world. The company does this while being keenly aware of society's other demands for cost-effectiveness and environmental excellence.

The drug substances produced at the facility are shipped ultimately to Novartis formulation plants around the world, where these substances, which are responsible for the therapeutic effect in a medicine, are formulated into tablets, capsules, ointment and other dosage forms. To manufacture the medically active component of such medications it is necessary to go through many production cycles to ensure the purity and potency of the active substance.

Novartis Ringaskiddy Limited manufactures a variety of pharmaceutical compounds by standard chemical synthesis routes. Such synthesis and the related separation and purification steps are carried out in standard chemical process equipment. The company also manufactures active substances through application of purification procedures (rather than chemical synthesis). Fermentation processes in existing facilities outside Ireland produce the raw materials for the active substances falling into this category. Crude materials, which are isolated from the fermentation slurry, are sent to the facility at Ringaskiddy for final purification.

Novartis Ringaskiddy Limited exported 317 tonnes of pharmaceutical drug substances in 2008, which represented a significant decrease in manufacturing volumes at the facility when compared to the previous years. The corresponding data for the previous three years was as follows: 365 tonnes shipped in 2005; 344 tonnes shipped in 2006; and 426 tonnes shipped in 2007. Some of the additional output in 2007 was to help to build up safety stocks of certain 'life-saving' drug substances – to cater for the (then thought likely) possibility of a flu pandemic. Consequently the same relatively high level of production was not required during 2008 and this had a consequential impact on many of the environmental performance indicators reported on in this Interim Environmental Statement. It is anticipated that production volumes will be similar to those of 2008 during the current year.

The 2008 portfolio consisted of the following ten products, five of which are among Novartis Pharma's top 10 products based on global sales during 2008. Further information on Novartis products is available from the company's website, which is located at

http://www.novartis.com

Asmex 03 is an immediate precursor for the product Elidel® (Pimecrolimus), a non-steroid cream developed for treating atopic eczema. It is one of the first new eczema treatments to have been introduced since the 1950s, when topical corticosteroids – the mainstay of therapy until now – became available. Atopic eczema is a common skin condition in which the patient's skin is typically dry and from time to time becomes inflamed, itchy and may crack, become infected, weep and form crusts. Elidel® cream 1% is indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable. A total of 1,077 kgs of Asmex 03 were manufactured at Novartis Ringaskiddy Limited during 2008.

PRODUCT PORTFOLIO 2008 (Continued)

Calcitonin, sold as Miacalcic®, is a peptide that regulates calcium metabolism and is mainly used in the treatment of osteoporosis. Osteoporosis is a disease that develops with age and is characterised by a progressive and symptomless loss of bone mass, leading to fragility of bones and an increased risk of fracture, notably in the spine, hip and forearm. Calcitonin is a thyroid hormone that regulates the calcium content of the blood. Available as a daily nasal spray, which is particularly easy and safe to use, Miacalcic® prevents further loss of bone mass and promotes healthy normal bone formation. Miacalcic® is effective, safe and well tolerated. As a peptide Calcitonin is one of the company's 'low volume, high value products' and a total of 4 kgs of Calcitonin were manufactured at Novartis Ringaskiddy Limited during 2008.

Cyclosporine is the active ingredient of Neoral® (capsules and oral solution) an immunosuppressant used to prevent organ rejection following a kidney, liver or heart transplant. Neoral® is one of the world's most commonly used primary immunosuppressants, largely replacing its predecessor Sandimmun®, which revolutionized organ transplantation when it was introduced by Novartis in 1982. First launched in 1995, Neoral® is also used in treating select autoimmune disorders such as psoriasis and rheumatoid arthritis. Sandimmun®/Neoral® is one of Novartis Pharma's top ten global products (based on 2008 sales). Cyclosporine accounted for approximately 9% of all drug substances shipped from Novartis Ringaskiddy Limited during 2008 – representing some 27,406 kgs.

Darifenacin is the active drug substance in Emselex® (also known as Enablex® in the United States) a once-daily oral treatment for overactive bladder. This product was approved in the European Union and the United States in 2004 and has been shown to reduce the number of weekly "urge" urinary incontinence episodes by up to 83% versus placebo. A total of 3,007 kgs of Darifenacin were shipped from Novartis Ringaskiddy Limited during 2008.

PRODUCT PORTFOLIO 2008 (Continued)

Diovan® (Valsartan) and Co-Diovan/Diovan HCT® (Valsartan and Hydrochlorothiazide) are leaders in the angiotensin-II receptor blocker (ARB) class of high-blood pressure agents and together comprise the world's best-selling brand of high blood pressure medicines. Diovan® is the only agent in its class approved to treat all of the following: Patients with high blood pressure, high-risk heart attack survivors and patients with heart failure. The efficacy and safety profile of Diovan® has been well-established by a large body of evidence. Diovan® inhibits a hormone, angiotensin II, from binding to a receptor that causes arteries to tighten and narrow, an action that can cause high blood pressure. The single-pill combination product Co-Diovan® includes the diuretic hydrochlorothiazide and provides additional efficacy for patients needing a greater reduction in blood pressure. In July 2008, the US Food and Drug Administration (FDA) approved Diovan HCT as a first-line therapy. First launched in 1996, Diovan® is available in more than 100 countries.

Diovan® is currently one of Novartis Pharma's flagship products accounting for approximately 27% of the Group's worldwide sales in 2008. It also accounted for approximately 55% of all drug substances shipped from Novartis Ringaskiddy Limited during 2008 – representing some 174,219 kgs – and is one of the company's great achievements of recent years.

Fluvastatin, sold as Lescol® and as Lescol XL® in an extended release formulation, is a drug that is used in the treatment of high cholesterol levels. The drug affects a broad range of lipid parameters, including high-density lipoprotein (HDL) cholesterol. In 70 percent of all patients with coronary heart disease, HDL cholesterol levels are too low. Lescol XL® raises HDL cholesterol (the "good" cholesterol) by up to 20 percent and has also been shown in trials to provide effective and comprehensive lipid management. It reduces low-density lipoprotein (LDL) ("bad") cholesterol levels by up to 38 percent and lowers triglycerides (TG) by up to 25 percent. Lescol® is one of Novartis Pharma's top ten global products based on sales. Fluvastatin accounted for approximately 15% of all drug substances shipped from Novartis Ringaskiddy Limited during 2008 – representing some 46,933 kgs.

Glivec® (also known as **Gleevec**® in the United States) (Imatinib Mesylate/Imatinib) is a signal transduction inhibitor approved to treat certain forms of chronic myeloid leukemia (CML) and gastrointestinal stromal tumours (GIST). First launched in 2001, Glivec® is available in more than 80 countries. It is one of the first oncology drugs that validates rational drug design based on an understanding of how some cancer cells work. A signal transduction inhibitor interferes with the pathways that stimulate the growth of tumour cells. In the United States, Gleevec®/Glivec® is used to treat newly diagnosed adult and pediatric patients with a form of CML. This condition is a rare form of cancer but one of the most common adult leukemias, and it usually tests positive for the presence of the Philadelphia (Ph) chromosome.

Gleevec®/Glivec® is also indicated for the treatment of patients with certain forms of GIST and, in the United States, Gleevec®/Glivec® is also approved for aggressive systemic mastocytosis. In 2008 Gleevec®/Glivec® received US regulatory approval for an adjuvant treatment of patients with GIST and is awaiting approval in Europe. Gleevec®/Glivec® is also approved in the United States and Europe for the treatment of Philadelphia-positive acute lymphoblastic leukemia (ALL) and in certain markets for use in various rare cancers.

Novartis Ringaskiddy Limited takes particular pride in its role in making this treatment available to patients as it was the manufacturing launch site for the active drug substance. A total of 24,964 kgs of Glivec® were manufactured at Novartis Ringaskiddy Limited during 2008 and it is one of Novartis Pharma's top ten products based on 2008 global sales.

PRODUCT PORTFOLIO 2008 (Continued)

Ketotifen Hydrogen Fumarate is the active ingredient of Zaditen®, an oral asthma prophylactic and anti-allergic that is used in the treatment and prevention of paediatric asthma, allergic skin diseases (atopic dermatitis and urtiaria) and allergic rhinitis (hay fever). It is a non-bronchodialator anti-asthmatic drug with marked anti-anaphylactic properties and a specific antihistaminic effect. A total of 556 kgs Ketotifen Hydrogen Fumarate were shipped from Novartis Ringaskiddy Limited during 2008.

Octreotide Acetate is the active ingredient of Sandostatin LAR®/Sandostatin SC®, which is used for the treatment of patients with acromegaly, a chronic disease in adults caused by over-secretion of pituitary growth hormone. It is also approved for use to treat certain symptoms associated with carcinoid tumours and other types of gastrointestinal neuroendocrine and pancreatic tumours. Sandostatin® is a synthetic protein that mimics the action of somatostatin, a naturally occurring hormone.

New technology has enabled patients to be treated once a month with injections of Sandostatin LAR® Depot (long-acting release), allowing them greater freedom. Two variants of Octreotide Acetate are produced at Novartis Ringaskiddy Limited, one of which uses state-of-the-art technology to assemble the Octreotide Acetate molecule. As a peptide Octreotide Acetate is one of the company's 'low volume, high value products' and a total of 33 kgs of Octreotide Acetate were manufactured at Novartis Ringaskiddy Limited during 2008. Sandostatin LAR®/Sandostatin SC® is one of Novartis Pharma's top ten products (based on worldwide sales in 2008).

Terbinafine is the active ingredient in Lamisil®. In fungal nail infections (onychomycosis), nails can become discoloured or thickened and even splinter as dermatophyte fungi attack the nail plate, nail bed or nail matrix. Such fungal nail infections are highly prevalent throughout the world, and an estimated 20% of the population aged between 40 and 60 suffers from this condition. Popular public areas such as swimming pools, fitness rooms and even hotel carpets offer ideal conditions for the continuing spread of fungal infections. Treatment with Lamisil® tablets is innovative in that it actually eradicates the fungus causing the infection from the inside. Other antifungals merely prevent the fungus from reproducing. Lamisil® is well-tolerated and has a well-established safety profile and over 22 million patients have been treated with Lamisil® tablets, which are available in more than 50 countries. Terbinafine accounted for approximately 12% of all drug substances shipped from Novartis Ringaskiddy Limited during 2008 – representing a total volume of 38,700 kgs.

Novartis Ringaskiddy Limited Health, Safety and Environment Policy

As a member of the Novartis Group of companies Novartis Ringaskiddy Limited wants to be known for being a responsible corporate citizen. This means that we do everything that we can to operate in a manner that is sustainable: Economically, socially and environmentally – in the best interest of long-term success for our enterprise. We expect all our employees to implement this policy and the Group policy on Corporate Citizenship.

We integrate Health, Safety and Environmental Protection into our business strategies to add value to the enterprise, to manage risk and to enhance the reputation of the company.

- The health and safety of our employees, neighbours, customers and consumers, and the protection of the environment are company priorities consistently pursued at all levels in the organisation.
- We take HSE into account in all business decisions and activities. All departments establish proper structures and allocate sufficient resources in order to live up to this policy.
- Each employee shall comply with the HSE guidelines and the laws applicable to their area of operational responsibility.

We want to be a leader in Health, Safety and Environmental Protection by managing these disciplines actively, consistently and efficiently.

- We strive for continual improvement in our HSE performance. We measure progress and verify compliance with Novartis Corporate HSE guidelines and National regulatory requirements through audits and management reviews. To this end we set clear annual objectives and targets, which are assessed on an on-going basis.
- We foster awareness and a sense of responsibility for HSE among our employees; to this end we provide appropriate information and training and develop their HSE skills.
- We optimise the use of natural resources and minimise the environmental impact of our activities so as to conduct our business in as sustainable a manner as is possible.
- We assess HSE implications to ensure that the benefits of manufacturing new products and introducing new technologies and processes outweigh remaining risks.

We care about the expectations and concerns of our stakeholders.

- We provide our employees with safe workplaces. We promote programmes to maintain or improve the health of our employees.
- We cooperate with our suppliers and contractors and offer assistance to enable them to achieve an HSE performance matching our own.
- We recognise the interest of our employees, neighbours, customers, the authorities and the public at large in our societal behaviour; and the HSE impacts of our business. We provide relevant information and actively listen to stakeholders. We openly communicate and provide the information necessary to understand the risks and effects of our operations on health, safety and the environment.

J. B. Alexander

J. Alexander, 10-Mar-2006

Managing Director, Novartis Ringaskiddy Limited

4 · ENVIRONMENTAL IMPACTS AND CONTINUOUS IMPROVEMENT IN THE AREA OF ENVIRONMENTAL PROTECTION

4.1 – TOTAL PRODUCTION

Production volumes underwent a significant decrease from 426 tonnes during 2007 to 317 tonnes during 2008. The product portfolio remained largely the same in 2008 as in 2007. Some of the additional manufacturing activity undertaken at the facility during 2007 was to build up safety stocks of some critical life-saving drug substances to cater for a then anticipated influenza pandemic. When this did not materialise during the influenza season of the winter of 2007/2008 it became necessary to adjust the company's inventory, which had a direct impact on manufacturing volumes at Novartis Ringaskiddy Limited. This reduction in activity had a consequential impact on many of the environmental performance indicators reported on in this Interim Environmental Statement. It is anticipated that output during 2009 will be of the same order of magnitude as 2008.

The largest volume product during 2008 was Diovan®, which accounted for 55% of the company's output during 2008. Additional focus was given to solvent recovery on the Diovan® process during 2008 in an effort to further optimise hazardous waste management associated with the product. However, this work will only come to full realisation during 2009. Terbinafine and Fluvastatin were also relatively high volume products and accounted for 12% and 15% respectively of shipped material during 2008. It is thought that volumes of Terbinafine will decrease in the coming years following the entry of US generic competition in July of 2007; and likewise for Fluvastatin, which has been impacted by the 2007 launch in the US of a generic version of simvastatin, another medicine in this class.

The approximate 26% decrease in manufacturing output in 2008 required significant focus and effort on minimising the energy and waste outputs associated and in many cases it was not possible to report as good a relative environmental performance as was reported in the 2007 Interim Environmental Statement. Details of the various initiatives that were undertaken can be found in the section providing an update on the 2008 environmental targets. Some of these initiatives will only be fully realised during the coming year and their outcome will be documented in the next full Environmental Statement that is due to be published in June of 2010.

Production output was down 26% - from 426 tonnes in 2007 to 317 tonnes in 2008 – this impacted adversely on some of the reported environmental performance criteria

4.2 – WATER AND ENERGY CONSUMPTION

As noted in the 2004 to 2006 Environmental Statement significant progress was made in the area of water and energy conservation over the years 2004 to 2006. Water consumption was reduced from 1.11 m^3/kg of drug substance shipped in 2004 to 0.91 m^3/kg of drug substance shipped by the end of 2006. A similarly positive trend was recorded for total energy consumption during the same period: It decreased from 1.68 GJ/kg of drug substance shipped to 1.43 GJ/kg of drug substance shipped.

Against the backdrop of decreased production volumes it was not possible to maintain this trend during 2008. Water consumption was 0.95 m^3/kg of drug substance shipped and energy consumption was 1.57 GJ/kg of drug substance shipped. The company is confident that the positive trend established up to the time of the last Environmental Statement (refer to the graphs in Appendix 2 and Appendix 3 of this Interim Environmental Statement) can be re-established and to this end has again included very specific energy targets as part of the overall site environmental targets for 2009.

In 2008, the Site Energy Management Group oversaw a number of projects that helped mitigate the impact that the reduction in manufacturing volumes had in respect of energy consumption at Novartis Ringaskiddy Limited. Some of the projects included:

- Reducing chilled water flow rate, which was identified in the 2005 water usage report. This project, which was initiated in 2006 and which is still on-going, has a projected saving of 651 GJ. (Electricity)
- Development of a proposal for a new energy efficient replacement option for the company's existing use of glycol as a chiller refrigerant, which would have a projected saving of 4,982 GJ (Note that actual implementation of this project did not take place during 2008 – the preparatory work that commenced during 2007/2008 will continue into 2009). (Electricity)
- Installation of energy efficient lighting in the Tank Farm area, which has a projected saving of 456 GJ. This item is currently being actioned on a replacement basis. (Electricity)
- Installation of near infra-red (NIR) detectors on Diovan® and Fluvastatin driers, which has a projected annual GJ saving of 468. Novartis Ringaskiddy Limited is currently installing instrumentation on the Diovan® and Fluvastatin production trains that use NIR spectroscopy to determine when an intermediate/product has been dried to specification. This information will be used to optimise dryer run time. In other words the dryer will only be active until such time as the end point for drying is reached. Previously this would have been done based on a sample and laboratory analysis, which meant that the dryer would have been maintained in an active setting until the laboratory result was received. It is anticipated that in addition to removing a number of production bottlenecks that this initiative will also generate significant energy savings. (Electricity)

During 2008 the company continued to optimise its use of the facility's Energy Monitoring System; and fostered employee awareness, for example by participating in the Electricity Supply Board's (ESB) Winter Demand Reduction Incentive.

Relative water consumption was up 32% from 0.72 m^3/kg of product in 2007 to 0.95 m^3/kg of product in 2008

Process Improvements Can Yield Big Energy Savings

The drug substance for Glivec® is manufactured in Novartis Ringaskiddy Limited in five distinct intermediate steps. The LEAN Glivec® project was initiated with the aim of reducing the total throughput time across the pipeline. In doing this, LEAN methodology was used to identify areas where the throughput time could be reduced on each intermediate step of the pipeline. There were numerous areas identified using this methodology, eight of which had a direct positive impact on energy use.

The main achievements delivered from this project were in throughput time reduction for the Glivec® pipeline. There were energy savings achieved as a result of these throughput time reductions. The calculated energy savings directly resulting from this project for 2008 is a reduction of 540 GJ which is equivalent to 0.3% of the site's total annual electricity consumption.

Solar Panels 'Go Live' On The Administration Building

During the course of 2008 the Technical Services group coordinated the replacement the of the water heating unit that supplies domestic hot water to the canteen in the Administration Building. The design of the replaced unit resulted in the over usage of energy as the unit was steam heated and uncontrollable during low/zero usage periods, for example, during the night.

The Technical Services Group decided that the best approach was the installation of an industrial solar panel system on the Administration Building roof. This was put into operation at the start of September 2008 and now supplies a minimum of 60% of the canteen hot water use. The common conception is that Ireland with its seemingly perpetual cloud cover and endless winter nights makes an unsuitable location for harvesting solar energy. The company choose a system suitable to counter these factors to gain the required results: Vacuum Tube Collectors.

Vacuum tubes are made up of a number of glass tubes. The glass tubes have all the air vacuumed out to create an excellent insulating barrier, like a thermos bottle. The energy of the sun's rays passes through the glass and heats up the inner copper tube, but the heat can't get back out. This is the key advantage in cooler climates such as Ireland. So the vacuum tube allows the inner liquid to be heated to a relatively high temperature even when the outdoor temperature is cold. In addition the sun's rays deliver the most energy when they shine directly onto the surface, not at an angle. Due to the shape of the glass tubes, sunlight is able to strike the inner heating element from many directions, thus allowing it to work well in summer and winter.

4.2 – WATER AND ENERGY CONSUMPTION (Continued)

A number of energy saving initiatives is now planned for 2009 (some of which continue work that was started during 2008). These include:

– Installation of additional on-site electricity meters. A capital allocation of the order of €50,000 has been made to provide additional on-site electricity meters that will facilitate better end use of electricity by some of the main Process Units at the facility. The new meters will be fully integrated into the site's energy monitoring system and will allow real time analysis and retrospective analysis of patterns of electricity consumption with a view to identifying possibilities for minimisation of consumption.

– Installation of new on-site gas meters. A capital allocation of the order of €30,000 has been made to replace and upgrade the on-site gas meters that service the Solid Waste Incinerator, the Liquid Vapour Incinerator, the two Utility Boilers and the Cafeteria with meters that correct for both temperature and pressure. The new meters will be fully integrated into the site's energy monitoring system and will allow real time analysis and retrospective analysis of patterns of natural gas consumption with a view to identifying possibilities for minimisation of consumption.

A suite of energy saving initiatives is also to be undertaken by the various Process Units and Support Units on site. These include:

- Installation of a utility boiler stand-by heating coil
- Reducing the use of cooling water in production buildings
- Increasing the supply temperature of cold glycol to – 15°C
- Implementation of a compressed air leak management programme
- Installation of a variable speed drive on the primary glycol distribution pump

This bundle of projects will involve much greater participation from the end users of energy at the facility and its implementation will be closely monitored by the company's main management group.

Relative energy consumption was up 29% from 1.22 GJ/kg of product in 2007 to 1.57 GJ/kg of product in 2008 – A total of approximately 500,000 GJ of energy was used at the facility during 2008

4.3 – DISCHARGES TO WATER/ GROUNDWATER AND SURFACE WATER PROTECTION

Novartis Ringaskiddy Limited operates an enclosed wastewater treatment plant, which is used to treat lightly contaminated water that is used in processing activities, in addition to sanitary wastewater. The effluent is treated by a mixture of physical and biological treatment before being discharged to the Local Authority's (Cork County Council) marine outfall pipeline. This pipeline services a number of local towns and industries and discharges in deep water in the outer section of Cork Harbour.

The overall performance of the wastewater treatment plant was not quite as good when compared to the previous year with some (relatively minor) increases in the discharges of Total Suspended Solids (TSS) and associated Chemical Oxygen Demand (COD). Nevertheless the discharges, which are controlled under the company's Integrated Pollution Prevention and Control Licence (IPPCL) issued by the Environmental Protection Agency (EPA), were significantly below the regulated discharges permitted.

In overall terms the discharge of COD and Biochemical Oxygen Demand (BOD), which are two of the parameters used to measure the potential for oxygen depletion of the discharge (and which can adversely affect fish) continued to remain at relatively low levels (38 tonnes and 6 tonnes respectively); and the loss of nutrients, which can act inappropriately as fertilizers in the aquatic environment also remained very low.

A very significant upgrade was made to the company's wastewater treatment plant during 2008. The project involved the installation of additional containment around two critical parts of the wastewater treatment plant – the process lift station where aqueous waste is introduced into the wastewater treatment plant and the neutralisation basin where the wastewater's pH is adjusted. This containment is an additional safeguard to prevent any inadvertent contamination of soil or groundwater arising from wastewater treatment activities at the company. The capital spend for this project was of the order of €500,000.

The quality of the groundwater under the site is checked twice per annum and surface water (primarily rainfall) running off the site is continuously monitored. The quality of the groundwater under the site did not change during 2008 when compared to the time when manufacturing activities commenced at the facility. All surface water discharges were suitable for direct discharge to the local Owenabwee estuary during 2008.

Discharge of Chemical Oxygen Demand was 38 tonnes and the discharge of Biochemical Oxygen Demand was 6 tonnes in 2008

4.4 – EMISSIONS TO AIR/AMBIENT AIR QUALITY/NOISE

There were some very positive trends to be noted in the profile of the company's emissions to air during 2008. These emissions, which are also controlled under the company's IPPCL issued by the EPA, were significantly below the regulated emissions permitted. Such emissions arose primarily from the company's two natural gas fired boilers and two incinerators.

Of especial note is that fugitive emissions (of organic carbon), which arise from a large number of small sources, showed a continuing reduction during 2008: Down from a total of 0.017 kg/kg of drug substance shipped in 2007 to a total of 0.012 kg/kg of drug substance shipped in 2008. This was effected by continuing to set more stringent environmental targets during 2008 aimed at reducing such emissions. Additional environmental targets have been put in place for 2009 to further minimise fugitive emissions.

The company also continues to actively contribute to the local animal health surveillance scheme that is run by the Veterinary Department of the Local Authority on behalf of the EPA. This scheme, which has been running since 1993, has not identified any animal health issues in the Cork area that can be associated with air emissions arising from industrial activity. The most recent report was issued during December 2005, covers the years 2001 to 2004 and is available from the Agency.

Sound levels at the boundary of the facility have remained in compliance with the terms of the company's planning permission and the relevant EPA Guidelines based on the results of annual sound level monitoring that have been submitted to the Agency and which are publicly available.

During 2008 Novartis Ringaskiddy Limited completed its participation in the first year of the second round of the European Union Emissions Trading Scheme (EU ETS). This round involves the years 2008 to 2012 and is referred to as NAP II – NAP referring to Ireland's National Allocation Plan for emissions trading. The overall purpose of the scheme is to move the European Union to a position where it can stabilise its emissions of Carbon Dioxide at 1990 levels – in line with the Kyoto protocol. This has special resonance for the world of Novartis and top level management has committed the company worldwide to meeting the principles of the Kyoto protocol.

> *"Climate change, one of the most pressing global issues, not only challenges our generation, but will influence the lifestyle of all future generations as well. Novartis is seriously committed to contributing to sustainable approaches, fostering acceptance of the Kyoto protocol as a first step. Looking ahead, I am convinced that even stronger efforts to fight climate change will be needed. Therefore, we are committed to leadership in this area, supporting and initiating actions, saving energy and reducing greenhouse gas emissions worldwide."*
>
> Thomas Wellauer, Head of Corporate Affairs

In Ireland the EU ETS is administered by the EPA and the Agency has issued the company with a Greenhouse Gas (GHG) permit (permit number GHG078-3) which is available on the Agency's webpage www.epa.ie The permit came into full force at the beginning of 2005. The final Carbon Dioxide emission figure of 8,395 tonnes for 2008 for the purposes of the Emissions Trading Scheme (ETS) was determined before the end of March 2009 and was verified by SGS Ireland Limited. The figures were subsequently updated on the Emissions Trading Registry. The company ended the first year of the NAP II period with a slight excess of Carbon Dioxide credits, which will be subsequently surrendered. Note that not all sources of Carbon Dioxide that are generated on-site are included in the EU-ETS, which mainly covers the company's natural gas fired boilers and gas oil operated generators and pumps.

Fugitive emissions (of organic carbon) were down approximately 49% from 7,396 kgs in 2007 to 3,740 kgs in 2008

4.5 – NON-HAZARDOUS WASTE

Non-hazardous waste generated during 2008 at Novartis Ringaskiddy Limited included office, cafeteria, non-contaminated glass, metal and inert absorbent wastes, wastewater treatment plant sludge and bottom ash and slag.

The company has made very significant steps in the area of management of non-hazardous waste over the past number of years. The total amount of non-hazardous waste that is generated at the facility has been systematically reduced over the course of the last two Environmental Statements. However, the relative amount of non-hazardous waste generated did increase somewhat during 2008 when compared to 2007: Up from 5.3 kg/kg of product shipped during 2007 to 6.1 kg/kg of product shipped during 2008.

Two waste streams account for approximately 70% of all non-hazardous waste generated at the facility (based on 2008 data): Dewatered wastewater treatment plant sludge (953 tonnes) and used inert absorbent (383 tonnes). Although all of the used inert absorbent material is reused only 9% of the dewatered wastewater treatment plant sludge was shipped from the facility under a 'reuse/recovery' code during 2007. This challenge was taken up in 2008 and by year end a total of 96% of the dewatered sludge was shipped under a 'reuse/recovery' code.

It is interesting to note that the water content of the non-hazardous wastewater treatment plant sludge stream described above accounts for approximately 40% of the figure of 1,930 tonnes of all non-hazardous waste generated at Novartis Ringaskiddy Limited during 2008.

Note that an additional 1,272 tonnes of non-hazardous construction and demolition waste was consigned off-site during 2008. This waste, which was not process related, was primarily generated during excavation works over a number of years. This type of waste material was not reported in previous Environmental Statements or Interim Environmental Statements but will be going forward as the company's waste tracking system now effectively captures all off-site shipments of waste whether hazardous or (as in this case) not.

The amount of non-hazardous waste recycled increased from 2.4 kg/kg of product shipped in 2007 to 5.4 kg/kg of product shipped during 2008; while the amount of non-hazardous waste requiring disposal and treatment decreased from 2.9 kg/kg of product shipped in 2007 to 0.7 kg/kg of product shipped in 2008

4.6 – HAZARDOUS WASTE

Hazardous waste generated during 2008 comprised mainly solvents, but also included smaller quantities of acids, alkalis and other chemical wastes. A significant effort is made at the facility to reuse/recycle as much of this material as possible. In common with its approach to non-hazardous waste the company actively applies the hierarchical approach to waste management of:

- Avoiding waste generation (including substitution of hazardous compounds)
- Reducing waste generation (through upgrading of manufacturing processes)
- Reusing waste that is generated (preferably on site)
- Recycling waste that is generated (preferably on site)
- Recycling waste with heat recovery (preferably on site)
- Treatment of waste (preferably on site)

The total amount of hazardous waste generated during 2008 was 16,729 tonnes representing a relative amount of hazardous waste of 52.8 kg/kg drug substance. The reason that this figure is larger than the corresponding non-hazardous waste figure is that a significant amount of solvent material is used in production, which does not form part of the final product – but without which the final product cannot be manufactured. Approximately 80% of this figure of 52.8 kg/kg drug substance was either reused or recovered during 2008 – broadly in line with the reuse/recovery rate of previous years.

The corresponding relative amount of hazardous waste generated during 2007 was 50.3 kg/kg of drug substance giving a small overall relative increase in hazardous waste generation of the order of 5%. Towards the end of 2008 the operation of the batch still, which is used as part of solvent recovery in the Diovan® production train, was taken over by the Technical Services Support Unit. This group intends to increase the number of batches processed for solvent recovery on a weekly basis from approximately eight to twelve. It is anticipated that this will have a significant impact on the total amount of hazardous waste generated at the facility given that Diovan® accounted for approximately 55% of the site's production output during 2008. Additional work is to be undertaken on the Fluvastatin production train in respect of reducing solvent usage, which should also effect a reduction in overall hazardous waste volumes. Fluvastatin accounted for approximately 15% of the site's production output during 2008.

The relative amount of hazardous waste generated was up 5% from 50.3 kg/kg of product in 2007 to 52.8 kg/kg of product in 2008

5 – SOCIAL PERFORMANCE and CORPORATE CITIZENSHIP

5.1 – CORPORATE CITIZENSHIP POLICY

As a pharmaceutical company and a member of the Novartis Group of companies, Novartis Ringaskiddy Limited is fully committed to Corporate Citizenship. Corporate Citizenship at Novartis is an integral part of how we operate and a key to our success. We believe Corporate Citizenship is the right thing to do and essential to maintaining our license to operate, innovate and grow. Through responsible business, we endeavour to create value for society.

Corporate Citizenship commitment at Novartis rests on four pillars: patients, business conduct, people and communities, and environmental care.

Patients

Novartis is committed to creating value for all patients — including those who cannot afford treatment. In 2008, our access-to-medicines programs, valued at US$ 1.26 billion, reached 74 million patients around the world. Through multilateral institutions and public-private partnerships, we provide free leprosy and tuberculosis treatment and our antimalarial drug Coartem® without profit to patients in the developing world.

Novartis provides discounts and assistance programs to low-income patients in the developed world, including a patient assistance program for the cancer therapy Gleevec/Glivec® — one of the most far-reaching patient-assistance programs ever implemented on a global scale — ensuring access for all patients who cannot afford it.

Ethical business conduct

Novartis is committed to sustainable performance built on a solid foundation of ethical values at all levels of our business. We have received recognition from key indices and rankings because we work to make this commitment a reality. In 2008, Novartis was:

- Named "healthcare supersector leader" in the Dow Jones Sustainability Index
- Ranked among the top 20 most respected companies in the world by Barron's magazine
- Listed as one of the world's most ethical companies by the Ethisphere Institute

Integrity and compliance involve all Novartis Group company associates. In 2008, Novartis Group company associates completed 178,655 training courses in integrity and compliance topics.

People and communities

Novartis strives to provide our associates with the safest possible workplace and to promote their health and well-being. Novartis is an integral part of the communities that host our operations. We pay living wages worldwide, contributing to the stability and prosperity of these communities. Every April, our Community Partnership Day provides an opportunity for our associates to express their personal commitment to corporate citizenship.

5.1 – CORPORATE CITIZENSHIP POLICY (Continued)

Environmental care

During the past 10 years, Novartis sales have more than doubled, but our emissions and use of natural resources have grown much more slowly. We aim to use natural resources efficiently and minimize the environmental impacts of our activities and products during their life cycles.

Two founding documents govern our responsibilities:

– Our corporate citizenship policy defines our responsibility as a company

– Our code of conduct defines the obligations of associates

A general overview of the Novartis Corporate Citizenship Guidelines can be found at:

http://www.novartis.com/about-novartis/corporate-citizenship/index.shtml

A copy of the Novartis Policy on Corporate Citizenship and the Novartis Code of Conduct is available at:

http://www.corporatecitizenship.novartis.com/managing-cc/governance/code-policies-guidelines.shtml

A description of the Corporate Implementation of our Global Compact commitment is located at:

http://www.novartis.com/about-novartis/corporate-citizenship/managing-cc/un-global-compact.shtml

The Novartis expectation for third party compliance is described, together with the Code for Third Party Suppliers, at:

http://www.novartis.com/about-novartis/corporate-citizenship/business-conduct/third-party.shtml

"Our customers want good products and they like a company with a desire to win in the marketplace. But we need to behave with integrity to keep our license to operate. If we don't have a set of values – and live by them – the company won't be successful."

Dr. Daniel Vasella, Chairman and CEO, Novartis

5.2 – NOVARTIS RECOGNISED AS AN 'ETHICAL' COMPANY

Novartis was named one of the four most ethical pharma and biotech companies on Ethisphere's 2009 World's Most Ethical Companies list for the third consecutive year. Ethisphere is a think tank dedicated to best practices in business ethics, corporate social responsibility and anti-corruption. After studying over 10,000 of the world's leading companies in 100 countries and 35 industries, Ethisphere analysts concluded that Novartis should be one the 99 finalists included on the list of the "World's Most Ethical Companies." Other companies in the pharma and biotech sector receiving the designation were AstraZeneca, Novozymes and Novo Nordisk.

"This year again, Novartis is honoured to be named one of the World's Most Ethical Companies. This award underscores our commitment to benefit societies by operating in a socially, environmentally and economically responsible way. Being a good corporate citizen means that we take on societal challenges in areas in which we are competent, helping where most needed while adhering to high ethical standards."

Thomas Wellauer, Head of Corporate Affairs

The 2009 World's Most Ethical Companies methodology committee was comprised of leading attorneys, professors, government officials and organization leaders. Ethisphere analysts reviewed codes of ethics, litigation and regulatory infraction histories; evaluated investment in innovation and sustainable business practices; looked at companies' activities to improve corporate citizenship; studied nominations from senior executives, industry peers, suppliers and customers; and worked with consumer action groups for feedback.

"The competition for this year's World's Most Ethical Companies was very strong and we applaud Novartis for rising to the top. Novartis recognizes that being ethical is not only the right thing to do, it is also good business practice and leads to more successful and profitable operations."

Alex Brigham, Executive Director of the Ethisphere Institute

More information on the programme can be found at www.ethisphere.com

5.3 – ENVIRONMENTAL TRAINING IN CHINA

A detailed environmental training session at the Novartis Pharma ChemOps/CHAD site in Changshu (China) was jointly delivered by Andreas Hartmann, Head of Novartis Pharma Global Environment and Vincent Boyton of Novartis Ringaskiddy Limited between the 15th and the 19th of December 2008. Topics covered included environmental targets (Corporate and local), Corporate Citizenship, energy and waste management and many others. The session built on two previous rounds of training delivered in China during 2006 and 2007. In addition to giving newly hired associates an opportunity to get an in-depth insight on both Novartis global environmental policies and standards as well as practical 'hands-on' environmental management experience from other Novartis Pharma sites; the environmental training also facilitated the local Novartis organisation taking ownership of meeting environmental training needs going forward.

5.4 – COMMUNITY PARTNERSHIP DAY

Community Partnership Day is an annual day of service celebrated by Novartis employees worldwide. Usually held in April, Community Partnership day gives Novartis associates the chance to support the communities in which they live and work. This is a unique event in that nearly every Novartis location worldwide participates at the same time – demonstrating on one day our personal commitment to Corporate Citizenship by helping the communities closest to us.

Community Partnership Day at Novartis Ringaskiddy Limited has grown in importance and popularity over the years – with more and more associates participating each year. A key feature is also the contribution made by many of the company's contractors. Consequently our personal contact with local communities has grown stronger over the years. Community Partnership Day gives employees at the Novartis Ringaskiddy campus a real opportunity to make a difference in the lives of some of the company's most important stakeholders – the people who live and work in the communities nearby.

The following five projects were undertaken during Community Partnership Day 2008:

Annual Senior Citizens Invitational Lunch

The 2008 annual lunch for local senior citizens proved to be another great success. Senior citizens from the community were invited to the Novartis campus where Gerry and his team in the cafeteria treated them to a delicious four-course meal. Music and dancing followed and guests left in a jubilant mood counting the days until next year.

Cheshire Homes, Lower Glanmire Road, Cork

Cheshire Homes is a voluntary and a charitable organisation offering residential respite and rehabilitation for the people of Cork. The Novartis volunteers worked hard carrying out maintenance work, carpentry, painting and gardening. The end result was a tired but happy group of volunteers and a much improved and brighter environment as a result of their work.

5.4 – COMMUNITY PARTNERSHIP DAY (continued)

Brothers of Charity Services School, Curraheen Road, Bishopstown, Cork

Brothers of Charity is a special school for children with severe to profound intellectual ability and autism. Novartis associates undertook painting of classrooms and corridors; and also helped to develop a garden/horticultural area at the rear of the school. The garden now provides a safe haven for pupils to relax during breaks and also at times when classroom activities become difficult. The school was delighted with what the Novartis volunteers achieved in just one day.

Sundays Well Life Centre, Winters Hill, Cork

Sundays Well Life Centre caters for young people on the margins of society. The ethos of the centre is focused on addressing trans-generational issues such as early school leaving, unemployment and related issues. The Novartis volunteers spent their community day painting and cleaning the centre, helping to make it a more welcoming environment for the young clients of the centre to attend.

O'Connell Court Sheltered Accommodation, Barrack Street, Cork

O'Connell Court Sheltered Accommodation provides special housing with care for the homeless and elderly with mental challenges. The Novartis associates contributed their skills in the areas of carpentry, painting, electrical work and gardening. Overall the facility at Barrack Street received a much needed overhaul and group members paid tributes to the dedication of the Novartis team on the day.






5.5 – BIODIVERSITY STUDY UPDATE

The landscaped grounds around the Novartis Campus at Ringaskiddy contain a variety of wildlife habitats that have been developed since early development of the site commenced back in 1989. Since 2005 local ecologist Tom Gittings has undertaken a number of surveys with the aim of monitoring the ecological development of these habitats.

The 2008 study identified a total of 29 bird species breeding in and around the Novartis Campus. Compared to pre-development surveys there has been a large increase in the number of insect–feeding birds, reflecting the increase in woodland cover, which is an important habitat for such species. The numbers of seed-eating birds have not increased, despite national increases, reflecting the amenity management of the grassland areas that limits the availability of suitable weedy habitats for these species. However, the recent implementation of recommendations made by Tom to manage some areas as semi-natural hay meadow should increase the habitat availability for these species.

Tom has previously made recommendations in respect of improving the (natural) floral diversity of the site and overseen the implementation of measures to improve the structural diversity of the woodland areas. In this respect the 2008 study demonstrated a big increase in the woodland ground flora since the original landscape management survey of 2005; and the development of understorey and woodland edge habitat will improve habitat conditions for woodland bird species.

Overall, the Novartis Campus has a diverse breeding bird population reflecting the ecological quality of the site and enhancing the amenity experience in the landscaped grounds. With appropriate management as the habitats continue to develop and the woodlands mature, additional species will colonise the site, further enhancing its biodiversity




6 · ENVIRONMENTAL OBJECTIVES

6.1 – INTRODUCTION

Novartis Ringaskiddy Limited is convinced that the Environmental Management System (EMS) that it has in place delivers the highest standards in environmental protection. Novartis Ringaskiddy Limited was one of the first companies in Ireland to submit an overview of its EMS, together with an Environmental Management Programme (EMP) based on the EMS, to the EPA in 1995. The EMS and associated EMP received the approval of the EPA in January, 1996.

The company has subsequently updated the original document on an annual basis and has appraised the EPA of the revisions. The company also provides an annual report on the implementation of the EMP to the Agency. All of the information referred to above is also available to the public.

The site's current EMP outlines the company's current environmental objectives, which are supported through a system of target setting and tracking that was introduced in 2004. The company also continues to be committed to consolidation of the two main target areas up to the end of 2003: IPPCL Compliance; and Resource Conservation.

6.2 – IPPC LICENCE COMPLIANCE

The EMS in place at Novartis Ringaskiddy Limited delivers a high degree of compliance with the very strict conditions stipulated in the company's Integrated Pollution Prevention and Control Licence (IPPCL) (Register Number P0006-03) issued by the EPA. The company performed approximately 215,000 readings (tests) during 2008 to check its compliance with its IPPC licence.

This number has increased significantly from the date of issue of the last revision of the company's IPPC licence – from approximately 130,000 readings in 2005 to the current figure – or an increase of some 65%. For comparative purposes the total number of readings undertaken during 2007 was approximately 177,000 or a 21% increase. It is not anticipated that this figure will increase further during 2009 but it should serve to demonstrate the strict nature of the environmental regulatory regime that the company operates under.

Novartis Ringaskiddy Limited has set an internal target to show a minimum compliance of 99.9 %. This means that a maximum of 120 readings out of 100,000 could be associated with non-compliances presenting the potential for an adverse effect on the environment. This internal target was achieved during 2008 when 6 non-compliant results out of a total of more than 215,000 were notified to the EPA. All the reported deviations were of a minor technical nature and did not result in any adverse environmental effect.

6.3 – RESOURCE CONSERVATION

The significant environmental aspects of the company's operations have been minimised through careful design and planning. Implementation of the company's EMS should continue to minimise their impacts. The efficacy of the EMS in this respect will be ascertained by independent auditing. Its on-site implementation is overseen by the Site Environmental Committee, which meets formally six times a year.

Implementation of Novartis Ringaskiddy Limited's current EMP is, therefore, to consolidate on the progress made in the area of resource management at the facility – and this is to be effected through the setting of Process Unit and Support Unit specific targets as outlined in the following sub-section. Novartis Ringaskiddy Limited sees two advantages in following this approach: Further reduction in the environmental impact of operations at the facility; and allowing greater employee input to improving environmental performance.

Tracking of progress towards meeting the 2009 environmental targets is to be undertaken by the Site Environmental Committee at its scheduled meetings. A report on the progress towards meeting the targets specified for 2009 will be presented in the company's next full Environmental Statement, which is due to be published by June of 2010.

6.4 – ENVIRONMENTAL TARGETS 2009

Schedule of Environmental Targets for 2009

1. Diovan Process Unit. Maximise Batch Still throughput to reduce fresh solvent consumption and the amount of hazardous waste requiring final treatment.

   (To support the objective of reusing/recycling more of the hazardous waste that is generated on-site (optimisation of the use of natural resources); and the objective of striving for continual improvement in our HSE performance)

2. Diovan Process Unit. Maintain the rate reduction of 0.25 g/kg in the discharge of residual amounts of Diovan from the wastewater treatment plant that was achieved in 2007.

   (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

3. Ciclo/Peptides/SSF Process Unit. Review management of waste streams from the Ciclosporin Process purification process and update the process mass balance in the MMP.

   (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

4. Ciclo/Peptides/SSF Process Unit. Improve off-loading procedures and/or upgrade the exit area from the used AUXSP off-loading area to avoid potential losses to the surface water system.

   (To support the objective of minimising the environmental impact of our activities; and to support the objective of measuring progress and verifying compliance with National regulatory requirements)

5. Production Building 2. Reduce the amount of fugitive emissions of organic carbon from Production Building 2 by 5% using the 2008 discharge of 1,373 kgs as the baseline.

   (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

6. Production Building 2. Reduce electricity consumption by 2.5% relative to production (intermediates and products) to actively contribute to the site energy conservation target; and achieve an absolute reduction of 1.25 % based on implementation of specific projects.

   (To support the objective of minimising the environmental impact of our activities; the objective of conducting our business in as sustainable a manner as is possible; and the objective of striving for continual improvement in our HSE performance)

7. Production Building 2. Maintain a schedule of potential and realised improvements in increasing the efficiency of use of raw materials (for example through the implementation of Lean and IQP projects).

6.4 – ENVIRONMENTAL TARGETS 2009 (Continued)

(To support the objective of conducting our business in as sustainable a manner as is possible; the objective of optimising the use of natural resources; and the objective of striving for continual improvement in our HSE performance)

8. Fluvast/Glivec Process Unit. Achieve a 2.5 % rate reduction in the discharge of residual amounts of Fluvastatin from the wastewater treatment plant using 2008 discharge rate of 3.80 g/kg as the baseline. The work should focus in particular on implementation of the identified technical solutions to minimise losses of Fluvastatin to the wastewater treatment plant.

   (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

9. Fluvast/Glivec Process Unit. Facilitate the optimal treatment of aqueous wastes from the Fluvastatin pipeline. Minimise the discharge of TBME to the wastewater treatment plant.

   (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

10. Production Buildings 1 and 1A. Reduce the amount of fugitive emissions of organic carbon from Production Buildings 1 and 1A by 5% using the 2008 discharge of 2,362 kgs as the baseline.

    (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

11. Production Buildings 1 and 1A. Reduce electricity consumption by 2.5% relative to production (intermediates and products) to actively contribute to the site energy conservation target; and achieve an absolute reduction of 1.25 % based on implementation of specific projects.

    (To support the objective of minimising the environmental impact of our activities; the objective of conducting our business in as sustainable a manner as is possible; and the objective of striving for continual improvement in our HSE performance)

12. Production Buildings 1 and 1A. Maintain a schedule of potential and realised improvements in increasing the efficiency of use of raw materials (for example through the implementation of Lean and IQP projects).

    (To support the objective of conducting our business in as sustainable a manner as is possible; the objective of optimising the use of natural resources; and the objective of striving for continual improvement in our HSE performance)

13. Technical Services. Optimise management of the surface water protection system in line with the findings of the 2006 Environmental Liability Risk Assessment (ELRA) (to be in place before the end of June).

    (To support the objective of minimising the environmental impact of our activities)

6.4 – ENVIRONMENTAL TARGETS 2009 (Continued)

14. Technical Services. Reduce the amount of fugitive emissions of organic carbon arising from vent disconnections and/or unavailability by 5% using the 2008 figure of 1,621 kgs as the baseline.

    (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

15. Technical Services. Maintain a schedule of potential and realised improvements in increasing the throughput of solvent recovery operations.

    (To support the objective of reusing/recycling more of the hazardous waste that is generated on-site (optimisation of the use of natural resources); and the objective of striving for continual improvement in our HSE performance)

16. Technical Services. Achieve a 20% reduction in the number of OOE results for operation of environmental controls modules.

    (To support the objective of measuring progress and verifying compliance with National regulatory requirements)

17. HSE. Introduce an aqueous waste management system (in collaboration with Production Building 1 and Production Building 2 Process Units and Technical Services) to optimise on-site treatment and facilitate ease of 'trouble shooting' at times of sub-optimal wastewater treatment plant performance.

    (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

18. HSE. Coordinate the implementation of the EPA's protocol for bypass of air emissions abatement equipment.

    (To support the objective of measuring progress and verifying compliance with National regulatory requirements)

Update on Schedule of Environmental Targets for 2008

6.5 – UPDATE ON ENVIRONMENTAL TARGETS 2008

Novartis Ringaskiddy Limited undertook a large number of projects, which shared the common theme of working towards the company's goal of continuous improvement in its environmental performance, during 2008. Some of these projects were specific to certain departments within the company; and others were company-wide. They drew on the company's employees' skills and experience to make a real difference in helping to reduce the facility's environmental impact. Details on the individual programmes are summarised in this section.

Technical Services/PB1/PB2/HSE

1. Reduce the amount of hazardous waste generated relative to the amount of product shipped by 5% in 2008 using 2007 as the baseline year. Reduce the actual amount of solvent used per process by 5%.

   (To support the objective of reusing/recycling more of the hazardous waste that is generated on-site (optimisation of the use of natural resources); and the objective of striving for continual improvement in our HSE performance)

   Status: Not complete. The amount of hazardous waste relative to the amount of product shipped increased by approximately 5% between 2007 and 2008 – from a figure of 50.3 kg of hazardous waste/kg of product shipped in 2007 to a figure of 52.8 kg of hazardous waste/kg of product shipped during 2008. The unanticipated decrease in production volumes from 426 tonnes of product shipped during 2007 to 317 tonnes of product shipped in 2008 adversely impacted on waste minimisation efforts. This in turn was caused by the build-up of certain key life-saving drug substances during 2007 to cater for a then anticipated influenza pandemic and the subsequent need to adjust inventory levels during 2008 when the pandemic did not materialise. A number of key iniatives have been put in place for 2009 to reverse this trend.

2. Support the achievement of the facility's energy reduction targets:

   Relative reduction in energy consumption of 2.5 % per kg of product shipped using 2007 as the baseline year; and

   Absolute reduction of 1.25 % based on implementation of specific projects.

   (To support the objective of conducting our business in as sustainable a manner as is possible; the objective of optimising the use of natural resources; and the objective of striving for continual improvement in our HSE performance)

   Status: Not complete. The significant decrease of approximately 26% in production volumes between 2007 and 2008 (see above) also adversely affected the facility's relative energy performance. There was an increase in relative energy consumption from 1.22 GJ/kg of product shipped in 2007 to 1.57 GJ/k of product shipped during 2008. A number of key iniatives have been put in place for 2009 to reverse this trend – including greater devolution and accountability for implementation of specific energy conservation measures at Process Unit level within the company.

6.5 – UPDATE ON ENVIRONMENTAL TARGETS 2008 (Continued)

Technical Services

3. Introduce an aqueous waste management system (in collaboration with PB1, PB2 and HSE) to optimise on-site treatment and facilitate ease of 'trouble shooting' at times of sub-optimal wastewater treatment plant performance.

   (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

   Status: On-going. An easy to visualise system of tracking the main process inputs to the company's wastewater treatment plant was nearly finalised towards the end of 2008. To compliment this, process samples of the key influent wastewater streams were reassessed to determine their organic contribution to the overall aqueous waste entering the wastewater treatment plant. Some of this work will continue into 2009.

Technical Services

4. Reduce the amount of fugitive emissions of organic carbon arising from vent disconnections and/or unavailability by 5% using the 2007 figure of 2,060 kgs as the baseline.

   (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

   Status: Complete. Reduction of 21% achieved on the 2007 figure of 2,060 kgs.

Production Buildings 1 and 1A

5. Reduce the amount of fugitive emissions of organic carbon from Production Buildings 1 and 1A by 5% using the 2007 target of 3,890 kgs as the baseline.

   (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

   Status: Complete. Reduction of 39% achieved on the 2007 target figure of 3,890 kgs.

6. Reduce the amount of hazardous waste generated relative to the amount of product shipped by 5% in 2008 using 2007 as the baseline year. Reduce the actual amount of solvent used per process by 5%.

   To support the objective of reusing/recycling more of the hazardous waste that is generated on-site (optimisation of the use of natural resources); and the objective of striving for continual improvement in our HSE performance)

6.5 – UPDATE ON ENVIRONMENTAL TARGETS 2008 (Continued)

Status: Not complete. The overall site amount of amount of hazardous waste relative to the amount of product shipped increased by approximately 5% between 2007 and 2008 – from a figure of 50.3 kg of hazardous waste/kg of product shipped in 2007 to a figure of 52.8 kg of hazardous waste/kg of product shipped during 2008. The unanticipated decrease in production volumes from 426 tonnes of product shipped during 2007 to 317 tonnes of product shipped in 2008 adversely impacted on waste minimisation efforts.

7. Reduce electricity consumption by 2.5% relative to production (intermediates and products) to actively contribute to the site energy conservation target; and achieve an absolute reduction of 1.25 % based on implementation of specific projects.

   (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

   Status: Complete. A reduction in relative electricity consumption of 19% was achieved.

8. Quantify the environmental improvements (reduced raw material requirements; reduced hazardous waste generation; and reduced energy inputs) that have been secured though the optimisation (leaning) of the Fluvastatin and Glivec pipelines.

   (To demonstrate the company's commitment to optimise the use of natural resources; and the objective of striving for continual improvement in our HSE performance)

   Status: Not complete. Although some significant process improvements were made during the course of 2008 it was not possible to secure a dedicated resource from with the individual Process Units to quantify these. This arose from the internal reorganisation that the individual Process Units underwent during 2008. It is anticipated that this should be a more straightforward process to organise during 2009.

Production Building 2

9. Reduce the amount of fugitive emissions of organic carbon from Production Building 2 by 5% using the 2007 discharge of 1,900 kgs as the baseline.

   (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

   Status: Complete. Reduction of 28% achieved on the 2007 baseline figure of 1,900 kgs.

10. Reduce the amount of hazardous waste generated relative to the amount of product shipped by 5% in 2008 using 2007 as the baseline year. Reduce the actual amount of solvent used per process by 5%.

6.5 – UPDATE ON ENVIRONMENTAL TARGETS 2008 (Continued)

(To support the objective of reusing/recycling more of the hazardous waste that is generated on-site (optimisation of the use of natural resources); and the objective of striving for continual improvement in our HSE performance)

Status: Not complete. The overall site amount of amount of hazardous waste relative to the amount of product shipped increased by approximately 5% between 2007 and 2008 – from a figure of 50.3 kg of hazardous waste/kg of product shipped in 2007 to a figure of 52.8 kg of hazardous waste/kg of product shipped during 2008. The unanticipated decrease in production volumes from 426 tonnes of product shipped during 2007 to 317 tonnes of product shipped in 2008 adversely impacted on waste minimisation efforts.

11. Reduce electricity consumption by 2.5% relative to production (intermediates and products) to actively contribute to the site energy conservation target; and achieve an absolute reduction of 1.25 % based on implementation of specific projects.

    (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

    Status: Not complete. A relative increase of 34% in relative electricity consumption was recorded. Additional energy monitoring will be installed in Production Building 2 during 2009 to facilitate a better understanding of energy usage with a view to reducing relative consumption during 2009.

12. Quantify the environmental improvements (reduced raw material requirements; reduced hazardous waste generation; and reduced energy inputs) that have been secured though the optimisation (leaning) of the Diovan and Ciclosporin pipelines.

    (To demonstrate the company's commitment to optimise the use of natural resources; and the objective of striving for continual improvement in our HSE performance)

    Status: Not complete. Although some significant process improvements were made during the course of 2008 it was not possible to secure a dedicated resource from with the individual Process Units to quantify these. This arose from the internal reorganisation that the individual Process Units underwent during 2008. It is anticipated that this should be a more straightforward process to organise during 2009.

13. Implement measures and/or procedures to stop the loss of used aluminium oxide to the surface water drainage system to the west of PB2.

    (To support the objective of minimising the environmental impact of our activities)

    Status: Not complete. This item is to be actioned during 2009 as part of a number of environmental improvements to the Ciclosporin process.

6.5 – UPDATE ON ENVIRONMENTAL TARGETS 2008 (Continued)

Health, Safety and Environment

14. Update the ecological survey to quantify the site's biodiversity (original work took place over the years 2005 to 2007) – both flora and fauna.

    (To support the objective of conducting our business in as sustainable a manner as is possible)

    Status: Complete. Updated reports on the breeding bird population of the site; and a reappraisal of landscape management practices were issued.

15. Implement all action items arising from the Environmental Protection Agency audit of 17-May-2007.

    (To support the objective of measuring progress and verifying compliance with National regulatory requirements)

    Status: Complete. All action items closed out.

16. Implement an on-site programme in respect of the company's indirect environmental impacts to meet the requirements of Annex VI of 761/2001/EC – for 2008:

    Participate in the Wind Study project as part of the Lower Harbour Industry Group: and

    Participate in the Irish Business and Employers Confederation (IBEC) 'Sustainable Enterprise Working Group; and

    Evaluate the possibility of making 'tax-efficient' public transport tickets available to employees.

    (To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

    Status: Complete. Items 1 and 2 fully progressed; Item 3 could not be followed though on.

17. Develop a practical method for conducting an energy challenge on projects requiring a Capital Allocation Request (CAR) and the proposed implementation of which may result in a net increase or decrease in energy consumption.

    (To support the objectives of optimising the use of natural resources; minimising the environmental impact of our activities; and striving for continual improvement in our HSE performance)

    Status: On-going. Energy challenges are now formalised as a result of the issue of Corporate HSE Guidance on Energy Management. The site protocol will be fully implemented during 2009.

6.5 – UPDATE ON ENVIRONMENTAL TARGETS 2008 (Continued)

Human Resources

18. Coordinate the training of all new production operators in the Environmental Module of the Core Pharmaceutical Skills (for operators within the Active Pharmaceutical Ingredient (API)/Bulk Chemical Sector) training and certification programme.

    (To support the objective of provision of appropriate information and training to our employees and the development of their HSE skills)

    Status: Complete/On-going into 2009. The Environmental Module was delivered to all Production operators (excluding new hires); and it was delivered to a significant number of Technical Services operators (excluding new hires). The Environmental Module was revised during 2008 - the Human Resources Function coordinated the update.

Engineering/Projects

19. Integrate all transfers of waste off-site into the Waste Management System.

    (To support the objective of minimising the environmental impact of our activities; and the objective of cooperating with our contractors to offer assistance to enable them to achieve an HSE performance matching our own)

    Status: Complete. All waste transfers off-site from project related activity such as construction and demolition waste, used metal from replacement of pipework etc is now tracked via the Waste Management System.

7 - VERIFIERS DECLARATION

"Further to consideration of the documentation, data and information resulting from internal procedures examined during the verification process at Novartis Ringaskiddy Limited, it is evident that the Environmental Policy, Programme, Management System, Review (or Audit Procedure) and Environmental Statement meet the requirements of Regulation 761/2001 (the EMAS Regulation)"

Signed: AJ Thorpe

Amanda Thorpe.
SGS United Kingdom Limited.

EMAS Accreditation Number:
UK-V-0007

Rossmore Business Park,
Ellesmore Port,
Cheshire,
CH65 3EN,
United Kingdom.

Date: 01-Jul-2009.

The next externally verified Environmental Statement (covering the years 2007, 2008 and 2009) will be issued during June of 2010. The contents of this Interim Environmental Statement will be independently validated prior to publication.

8 - FURTHER INFORMATION

Further information regarding the contents of this Interim Environmental Statement is available from: Dr. Vincent Boyton at 00 353 (0)21 4862324. Copies of the two previous Environmental Statement of 2001 to 2003; and 2004 to 2006; and the Interim Environmental Statement of 2007 are also available.

Novartis Ringaskiddy Limited
Ringaskiddy, County Cork, Ireland

Novartis Ringaskiddy Limited is part of the pharmaceuticals division of Novartis AG.

Personnel (2008):	438
Site Area:	53 ha
Industry Sector (NACE Code):	D21.10

Activity: Manufacture of basic pharmaceutical products

Novartis Ringaskiddy Limited is engaged in the manufacture of active substances for speciality drugs used in the treatment of immunologic, dermatologic, cardiovascular and diseases.

APPENDIX 1
COMMITMENT TO BAT

Novartis Ringaskiddy Limited is fully committed to implementing the concept of Best Available Technology (BAT) (within the framework of Integrated Pollution Prevention and Control licensing in Ireland) at all stages in the hierarchy of:

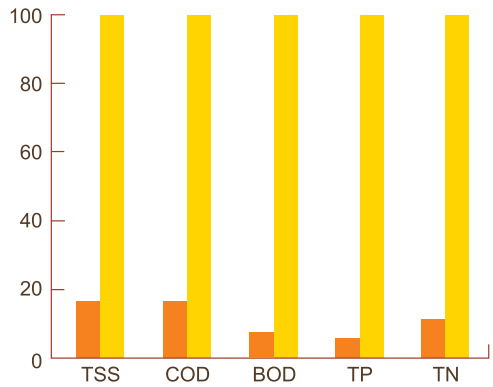
- Avoid
- Reduce
- Reuse/Recycle
- Contain
- Treatment/Disposal of Residual Material

The figures on this and the following pages are graphic representations of how the company's environmental performance during 2008 was better than the requirements of its Integrated Pollution Prevention and Control Licence (IPPCL) (Register Number P0006-03) issued by the EPA. This licence, *inter alia*, defines the minimum performance to be expected when BAT is implemented at a site.

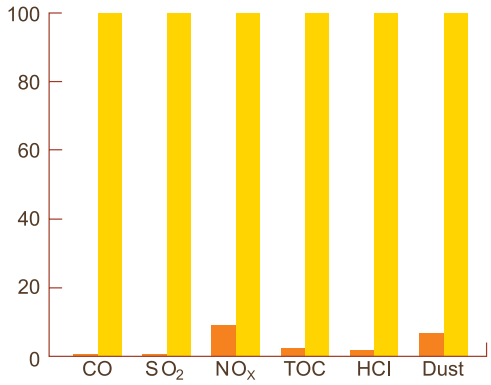
MASS DISCHARGES FROM WASTEWATER TREATMENT PLANT (orange column) EXPRESSED AS A PERCENTAGE OF THE DISCHARGE REGULATED UNDER IPPCL REGISTER NUMBER P0006-03 (yellow column): 2008

Legend:

TSS: Total Suspended Solids
COD: Chemical Oxygen Demand
BOD: Biochemical Oxygen Demand
TP: Total Phosphorus
TN: Total Nitrogen



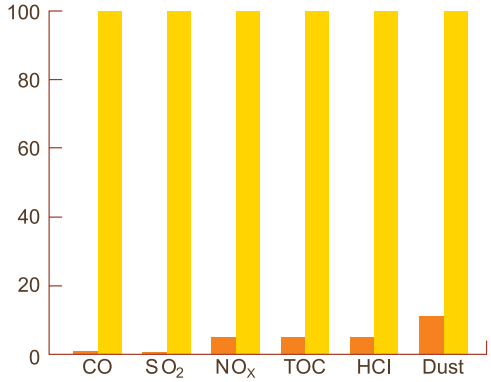
APPENDIX 1 (Continued)
COMMITMENT TO BAT



MASS EMISSIONS FROM LIQUID VAPOUR INCINERATOR (orange column) EXPRESSED AS A PERCENTAGE OF THE EMISSION REGULATED UNDER IPPCL REGISTER NUMBER P0006-03 (yellow column): 2008

Legend:

CO:	Carbon Monoxide
SO_2:	Sulphur Dioxide
NOx:	Oxides of Nitrogen
TOC:	Total Organic Carbon
HCl:	Hydrochloric Acid
Dust:	Particulates



MASS EMISSIONS FROM SOLID WASTE INCINERATOR (orange column) EXPRESSED AS A PERCENTAGE OF THE EMISSION REGULATED UNDER IPPCL REGISTER NUMBER P0006-03 (yellow column): 2008

Legend:

CO:	Carbon Monoxide
SO_2:	Sulphur Dioxide
NOx:	Oxides of Nitrogen
TOC:	Total Organic Carbon
HCl:	Hydrochloric Acid
Dust:	Particulates

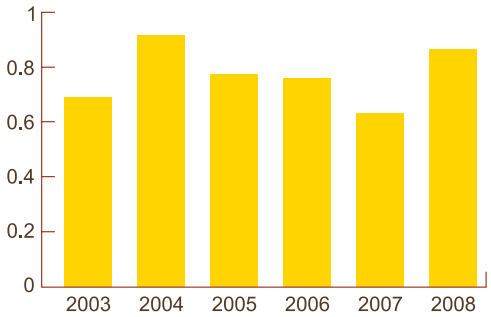
APPENDIX 2
ENVIRONMENTAL IMPACT DATA 2008

A.2.1 – TOTAL PRODUCTION

Novartis Ringaskiddy Limited shipped 317 tonnes of drug substances in 2008 compared to 426 tonnes in 2007. This significant decrease followed additional production activity during 2007 in anticipation of an influenza pandemic. The company's product portfolio for 2008 is described in detail on page numbers 4 to 7 of this document.

A.2.2 – WATER CONSUMPTION

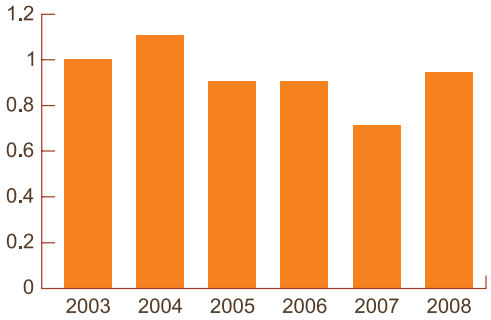
Average water consumption in 2008 was 0.95 m^3/kg of drug substance shipped compared to 0.72 m^3 /kg of drug substance shipped in 2007. This data is compared with data from the year 2003 in the accompanying bar chart.



WATER CONSUMPTION
(m^3 per kg product)

A.2.3 – ENERGY CONSUMPTION

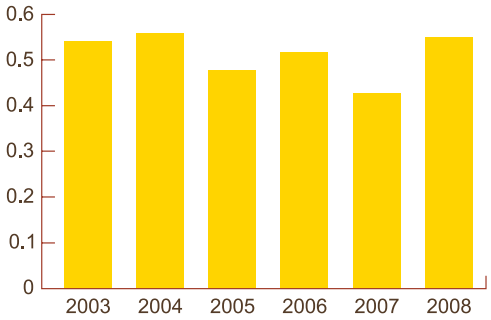
In 2008, Novartis Ringaskiddy Limited consumed a total of 499,096 GigaJoules (GJ) of energy compared to 515,386 GJ in 2007. There was an increase in the company's relative energy consumption when expressed as GJ per kg of product shipped: Up from 1.22 GJ/kg of product shipped during 2007 to a figure of 1.57 GJ/kg of product shipped during 2008. Note from the accompanying graphs for natural gas and electricity consumption that the overall long-term trend continues to be positive and a number of measures have been put in place for 2009 to consolidate this positive trend.



NATURAL GAS CONSUMPTION
(GJ per kg product)

Natural gas and electricity are the main energy types used on-site. Natural gas is used in the two utility boilers to generate steam and also in the liquid vapour incinerator and solid waste incinerator to ensure that adequate operating temperatures are maintained. The other types of energy consumed on-site are solvent material whose incineration incorporates heat recovery to generate steam; and gas oil, which is used in the facility's own electricity generator.

The following two charts indicate the company's performance in relation to consumption of electricity and natural gas during the years 2003 to 2008.



ELECTRICITY CONSUMPTION
(GJ per kg product)

A.2.4 – DISCHARGES TO WATER

Treated wastewater is discharged through the Cork County Council marine outfall to deep water near the mouth of Cork Harbour. Discharges to water are controlled under the company's IPPCL issued by the EPA.

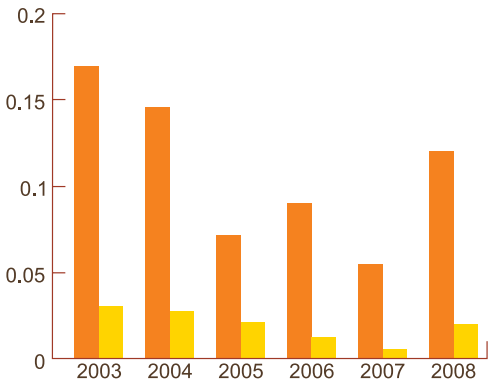
The key monitoring data are summarised on the following tables. Graphical comparisons of the relative discharges of some of the key parameters between 2003 and 2008 are also included in this section.

DISCHARGE TO WATER 2008	ANNUAL DISCHARGE
Suspended solids	14 tonnes
Biological oxygen demand (BOD)	6 tonnes
Chemical oxygen demand (COD)	38 tonnes
Total nitrogen	1 tonne
Total phosphorus	< 1 tonne

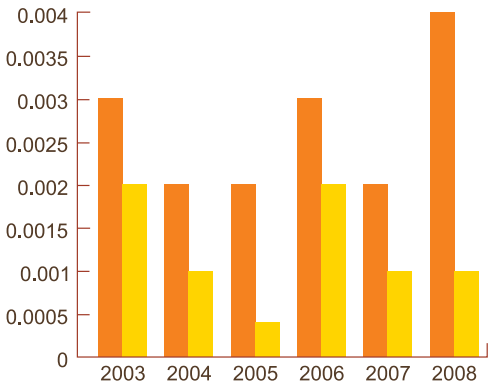
Notes: Suspended solids are a non-hazardous by-product of biological treatment. Discharges of such suspended solids are not significant in the context of an estuarine environment at the mouth of a large catchment area. Consequently, the following graphical comparisons focus on nitrogen and phosphorus discharges; and BOD and COD discharges.

Nitrogen and phosphorus discharges are associated with these solids. Nitrogen and phosphorus can act as inappropriate fertilisers in the aquatic environment and may cause algal blooms. The figures quoted for 2008 are not significant in this context.

BOD and COD measure the potential of the discharge to result in oxygen depletion in the aquatic environment. The figures quoted for 2008 do not represent a significant potential for oxygen depletion.



DISCHARGE OF COD (orange column)
DISCHARGE OF BOD (yellow column)
(kg per kg product)



DISCHARGE OF NITROGEN (orange column)
DISCHARGE OF PHOSPHORUS (yellow column)
(kg per kg product)

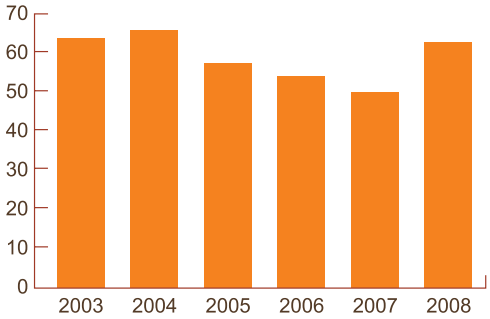
A.2.5 – EMISSIONS TO AIR

Emissions to air at Novartis Ringaskiddy Limited during 2008 came from four main sources: Two utility boilers fired on natural gas, the liquid vapour incinerator and the solid waste incinerator. The company's two incinerators are controlled under the company's IPPCL issued by the EPA.

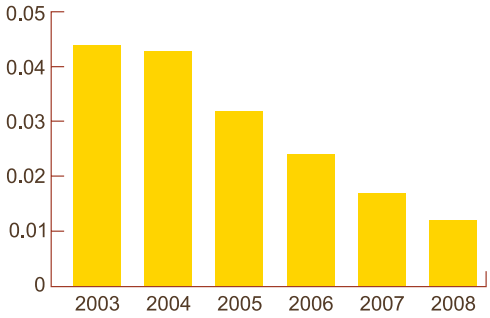
The emission monitoring methodology is based on European Community and German National standards. Careful design of the facility has routed all process-related emissions to one central treatment point. This has permitted detailed, and in many cases continuous, monitoring of emissions to atmosphere from the facility.

EMISSION TO AIR 2008	ANNUAL EMISSION
Carbon dioxide	19,831 tonnes
Carbon monoxide	< 1 tonne
Sulphur dioxide	< 1 tonne
Nitrogen oxides	20 tonnes
Particulates	< 1 tonne
Total organic carbon	< 0.2 tonne (LVI and SWI only)
Hydrochloric acid	< 0.2 tonne (LVI and SWI only)
Organic carbon	3.7 tonnes (fugitive emissions)

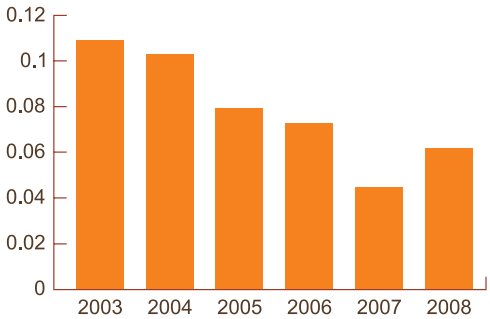
LVI: Liquid Vapour Incinerator
SWI: Solid Waste Incinerator



EMISSIONS OF CARBON DIOXIDE
(kg per kg product)



FUGITIVE EMISSIONS OF ORGANIC CARBON
(kg OC per kg product)



EMISSIONS OF NITROGEN OXIDES
(kg per kg product)

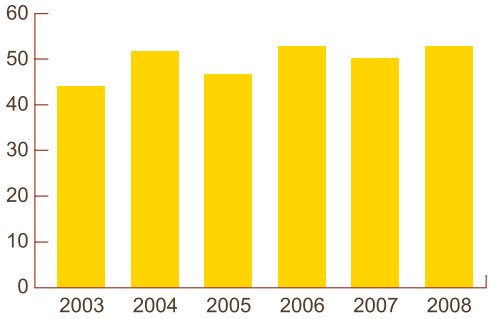
A.2.6 – HAZARDOUS WASTE

Hazardous waste generated during 2008 comprised mainly solvents, but also included smaller quantities of acids, alkalis and other chemical wastes. Significant efforts are underway to reuse/recycle as much of this material as possible. For example, additional solvent recovery capacity has been installed at the facility to increase the amount of rectified solvent that can be reused by the production buildings. The company is also recovering solvent material off-site that was here-to-fore being incinerated.

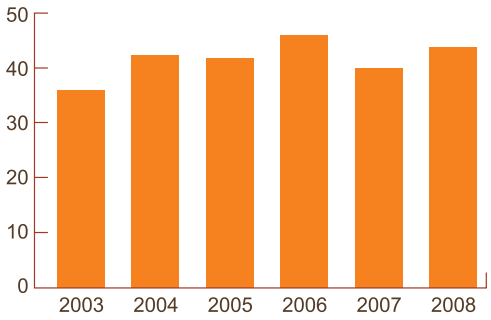
HAZARDOUS WASTE 2008	
Total hazardous waste generated	16,729 tonnes
Total recycled/reused	13,803 tonnes
On-site incineration with heat recovery	2,020 tonnes
On-site solvent recovery (see foot note)	3,588 tonnes
Off-site incineration with heat recovery	7,542 tonnes
Off-site solvent recovery	642 tonnes
Other waste for off-site recovery	10 tonnes
Total treated	2,927 tonnes
On-site incineration without heat recovery	1,208 tonnes
On-site wastewater treatment	363 tonnes
Off-site treatment (primarily incineration without heat recovery)	1,356 tonnes

Data rounded to the nearest tonne

Note: Solvents are recycled many times within the production buildings. Following such reuse the solvents are transferred to the solvent recovery unit. The figure quoted in the table for recycling refers only to recycling of solvents in the facility's solvent recovery unit, together with a smaller amount of solvent material that was recycled off-site.



TOTAL HAZARDOUS WASTE GENERATED
(kg per kg product)



HAZARDOUS WASTE REUSED/RECYCLED
(kg per kg product)

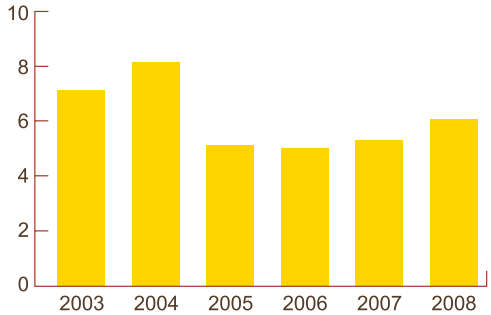
A.2.7 – NON-HAZARDOUS WASTE

Non-hazardous waste generated during 2008 at Novartis Ringaskiddy Limited included office, cafeteria, non-contaminated glass, metal and inert absorbent wastes, wastewater treatment plant sludge and bottom ash and slag. A significant quantity of these materials was sent off-site for recycling. Inert absorbent wastes, wastewater treatment plant sludge and bottom ash and slag data are based on weigh-bridge readings, while data for office, cafeteria, non-contaminated glass and metal waste are based on visual estimations of waste skip contents.

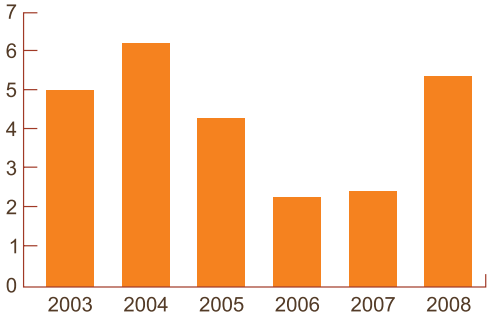
NON-HAZARDOUS WASTE 2008	
Non-hazardous waste generated	1,930 tonnes
Total recycled	1,699 tonnes
Total disposed	225 tonnes
Total treated	5 tonnes

Data rounded to the nearest tonne

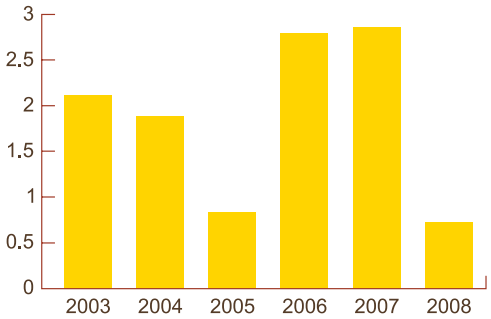
Note that an additional 1,272 tonnes of non-hazardous construction and demolition waste was consigned off-site during 2008. This waste, which was not process related, was primarily generated during excavation works over a number of years. This type of waste material was not reported in previous Environmental Statements or Interim Environmental Statements but will be going forward as the company's waste tracking system now effectively captures all off-site shipments of waste whether hazardous or (as in this case) not.



TOTAL NON-HAZARDOUS WASTE GENERATED
(kg per kg product)



NON-HAZARDOUS WASTE RECYCLED/REUSED
(kg per kg product)



NON-HAZARDOUS WASTE TREATED/DISPOSED
(kg per kg product)

A.2.8 – NOISE

Sound levels at the boundary of the facility have remained in compliance with the terms of the company's IPPCL and the relevant EPA Guidelines during 2008. This is based on the results of annual sound level monitoring that have been submitted to the Agency.

A.2.9 – AMBIENT AIR QUALITY

The company has discontinued monitoring of ambient air in the vicinity of the facility as there have been a number of other industrial developments in vicinity of Novartis Ringaskiddy Limited over the past number of years. In its place the company actively contributes to the local animal health surveillance scheme that is run by the Veterinary Department of the Local Authority on behalf of the EPA. This scheme, which has been running since 1993, has not identified any animal health issues in the Cork area that can be associated with industrial activity. The most recent report was issued during December 2005 and covers the years 2001 to 2004 and is available from the Agency.

A.2.10 – GROUNDWATER AND SURFACE WATER QUALITY

The quality of the groundwater beneath the 53 hectare site at Novartis Ringaskiddy Limited has remained the same as that prior to the commencement of operations at the facility. Groundwater is sampled twice a year from four on-site monitoring wells and is subject to detailed analysis. These data are compared with the data on the quality of the groundwater that was established prior to the commencement of manufacturing activities on-site.

There are limited groundwater reserves on-site and the groundwater in the local area, which is a small peninsula in Cork Harbour, is subject to saline intrusion. Consequently, it tends not to be used as a supply of potable water.

All surface water, mainly rainfall falling on paved areas, was analysed prior to leaving the facility to ensure that it was not contaminated. Surface water was routed by a gravity fed pipeline to one of two compartments of a large Storm Water Retention Pond (SWRP). Here the water was continuously analysed to confirm its suitability for discharge. If necessary the water was automatically quarantined; and subsequently manually sampled and analysed to ensure suitability for discharge from the site. If surface water was quarantined in one compartment then the other compartment was available for operational use.

A very significant upgrade was made to the company's wastewater treatment plant during 2008. The project involved the installation of additional containment around the process lift station and the neutralisation basin and is an additional safeguard to prevent any inadvertent contamination of soil or groundwater.

APPENDIX 3
RESOURCE CONSERVATION 2008

The company is continuing to seek to make environmental progress by effecting a relative reduction in the consumption of:

- Natural gas;
- Electricity; and
- Water;

effecting relative reductions in the amounts of:

- Hazardous waste (primarily liquid waste for incineration) requiring treatment;
- Non-hazardous waste requiring final disposal and treatment; and
- Fugitive emissions to the atmosphere;

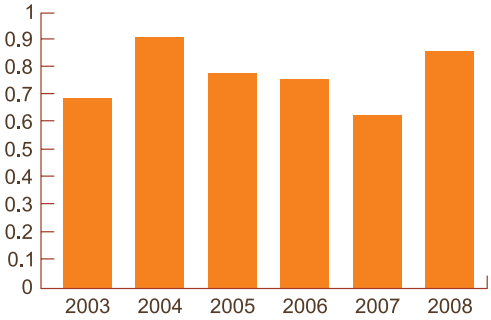
and rectifying more solvent for reuse via the company's solvent recovery facility.

A graphical representation of the company's performance in respect of these parameters from 2003 to 2008 is presented in this appendix.

Inputs in the assessments are expressed per kilogramme of final product manufactured. Note that savings in water, natural gas and electricity consumption should lead to reduced wastewater discharge volumes to be treated and to reduced emissions (less running time of boilers and utility plants).

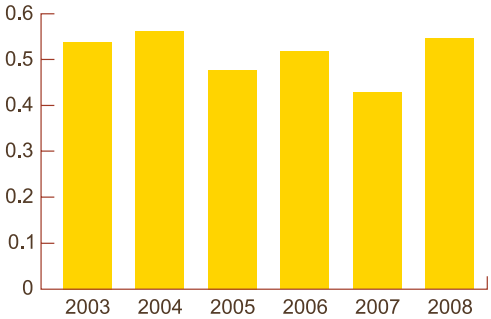
The 2003 to 2008 figures in the following graphs are based on actual data. Data on water, natural gas and electricity consumption are based on meter readings; data on fugitive emissions are based on regular measurements; while the data on hazardous and non-hazardous waste and rectified solvent are based on the company's measurements and/or records. All data have been made publicly available.

APPENDIX 3 (Continued)
RESOURCE CONSERVATION 2008



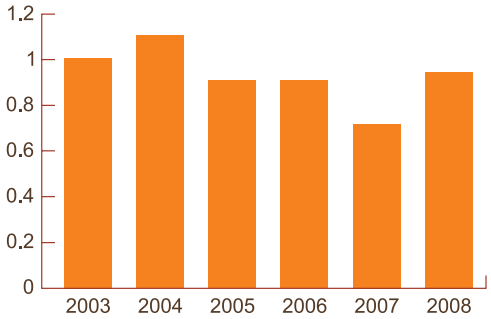
A.3.1 NATURAL GAS CONSUMPTION

Natural gas consumption is expressed as GigaJoule consumed per kilogramme of product manufactured.



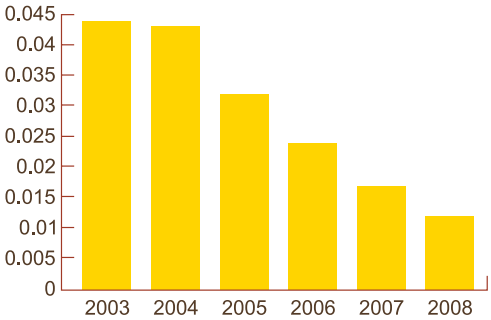
A.3.2 ELECTRICITY CONSUMPTION

Electricity consumption is expressed as GigaJoule consumed per kilogramme of product manufactured.



A.3.3 WATER CONSUMPTION

Water consumption is expressed as cubic metre consumed per kilogramme of product manufactured.

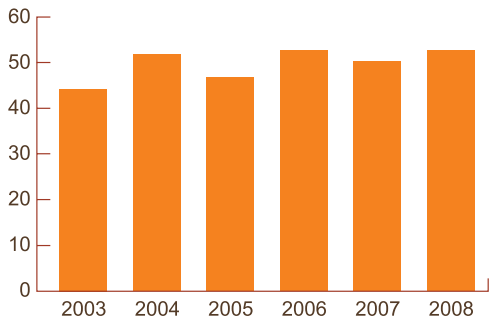


A.3.4 FUGITIVE EMISSIONS

Fugitive emissions are expressed as kilogramme of organic carbon per kilogramme of product manufactured.

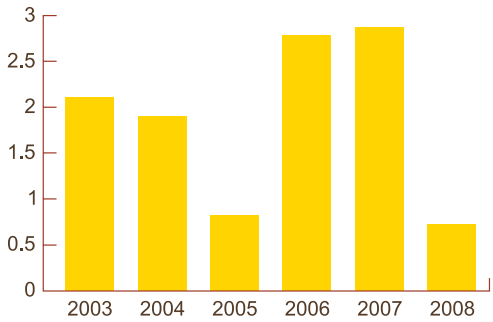
A.3.5 TOTAL HAZARDOUS WASTE GENERATED

Total hazardous waste generated is expressed as kilogramme generated per kilogramme of product manufactured.



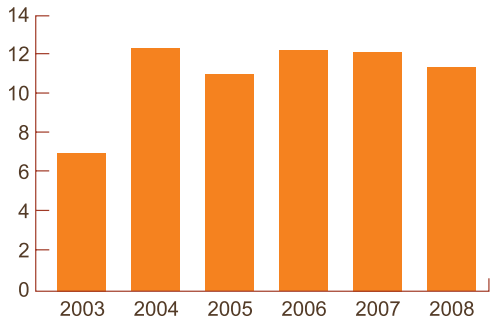
A.3.6 NON-HAZARDOUS WASTE TO BE DISPOSED/ TREATED

Non-hazardous waste to be disposed/ treated of is expressed as kilogramme per kilogramme of product manufactured.



A.3.7 SOLVENT TO BE RECTIFIED

Solvent to be rectified of is expressed as kilogramme of rectified solvent per kilogramme of product manufactured.



APPENDIX 4
ASSESSMENT OF SIGNIFICANCE OF ENVIRONMENTAL ASPECTS

Section 4 of Annex VI of the EMAS Regulation states that it is a requirement of participants to define the criteria for assessing the significance of the environmental aspects of its activities, products and services, to identify those that have a significant environmental impact. The criteria for determining significance need to be comprehensive, capable of independent checking and made publicly available.

Novartis Ringaskiddy Limited's methodology for assessing the significance of its direct and indirect environmental aspects has been developed in collaboration with RPS Group Limited and the following is an extract from the company's most recent review of its direct and indirect environmental aspects, which was undertaken in collaboration with RPS Group Limited.

The criteria used to assess the significance of each identified direct and indirect environmental aspect were:

- Legislative compliance
- Resource depletion
- Potential impact on air, water and land
- Stakeholder interest

The significance of each aspect was assessed using a matrix to rank its significance – refer to Table 4.1 below. The matrix allowed each aspect to be scored using the relevant criteria. Each criterion was assigned a weighting factor to reflect its importance. The environmental impact and resource depletion criteria were considered to be more important than legislation and stakeholder interest criteria and were therefore assigned a weighting factor of 3. The score from each criterion was multiplied by the relevant weighting factor and then all criteria scores were summed to give a total score for the aspect under normal operating conditions.

Aspect: **Impact:**						
Criteria	Score				Weighting Factor	Score
	3	2	1	0		
Legislation	Existing	Impending		None	2	
Resource depletion	High	Medium	Low	None	3	
Environmental impact	High	Medium	Low	None	3	
Stakeholder interest	High	Medium	Low	None	2	
Maximum possible score= 30, significant aspect score >15						

Table 4.1 Matrix for assessing the significance of a direct or indirect environmental aspect under normal operating conditions

The EMAS Regulation also requires that each aspect be assessed taking other operating conditions such as accident, previous, planned and abnormal conditions, into account. Assessment of the identified environmental aspects under 'other' conditions was undertaken using Table 4.2 below.

Aspect: **Impact:**					
Criteria	Score				Score
	12	6	3	0	
Abnormal operations		Increased environmental impact	No change	Reduced environmental impact	
Accident/ emergency		Increased environmental impact	No change	Reduced environmental impact	
Past activities	Evident/ requires action	Possible damage/ difficult to evaluate	-	No damage	
Planned activities	-	Increased environmental impact	No change	Reduced environmental impact	
Maximum possible score= 30, significant aspect score >15					

Table 4.2 Matrix for assessing the significance of a direct or indirect environmental aspect under 'other' conditions

The scores for normal operating and 'other' conditions were assessed and a significance threshold set for each direct or indirect environmental aspect. The threshold was set at 50% of the maximum possible score (>15) for both normal operating conditions and 'other' conditions. This threshold level allowed the significant aspects to be identified and included in the company's register of significant environmental aspects and the insignificant aspects scoped out.

Further information on the application of the methodology is available on request.

GENERAL FIGURES

Total HSE Investments:	€ 6,504,400
Investments for Environmental Protection:	€ 1,818,805
Total HSE Costs:	€ 13,419,556
Costs for Environmental Protection:	€ 11,707,959
Total HSE Personnel:	26
Environmental Protection Personnel:	20
Total Personnel:	438
Total Production:	316.899 tonnes

AIR EMISSIONS

Sulphur dioxide:	< 1 tonne
Nitrogen oxides:	20 tonnes
Particulates:	< 1 tonne
Carbon dioxide:	19,831 tonnes
Carbon monoxide:	< 1 tonne
Hydrochloric acid:	< 0.2 tonne (LVI and SWI only)
Total organic carbon:	< 0.2 tonne (LVI and SWI only)
Organic carbon:	3.7 tonnes (fugitive emissions)

Data rounded to the nearest tonne

CONSUMPTION OF NATURAL RESOURCES

Total water consumption:	300,495 m^3
Total energy consumption:	499,096 GigaJoules

WATER DISCHARGES

Total treated effluent discharged:	577 m^3/day
Suspended solids:	14 tonnes
Biochemical oxygen demand:	6 tonnes
Chemical oxygen demand:	38 tonnes
Total nitrogen:	1 tonne
Total phosphorus:	< 1 tonne

Data rounded to the nearest tonne

WASTE

Total Non-Hazardous Waste:	1,930 tonnes
Recycled:	1,699 tonnes
Treated:	5 tonnes
Disposed of:	225 tonnes
Total Hazardous Waste:	16,729 tonnes
Recycled/reused:	13,803 tonnes
On-site incineration with heat recovery:	2,020 tonnes
On-site solvent recovery:	3,588 tonnes
Off-site incineration with heat recovery:	7,542 tonnes
Off-site solvent recovery:	642 tonnes
Other waste for off-site recovery:	10 tonnes
Treated:	2,927 tonnes
On-site incineration without heat recovery:	1,208 tonnes
On-site wastewater treatment:	363 tonnes
Off-site treatment (primarily incineration without heat recovery):	1,356 tonnes

Data rounded to the nearest tonne

NOVARTIS

Novartis Ringaskiddy Limited
Ringaskiddy, County Cork, Ireland

www.ie.novartis.com

4.0 MANAGEMENT OF THE ACTIVITY

This section updates section 4.0 and associated sub-sections of the facility's original EMP (dated 16-Nov-1995); the first revision to that EMP (dated 21-Nov-1996); the second revision (dated 21-Nov-1999); the third revision (dated 07-Dec-1998); the fourth revision (dated 15-Dec-1999); the fifth revision (dated 01-Feb-2001); the sixth revision (dated 01-Feb-2002); the seventh revision (dated 31-Mar-2003); the eight revision (dated 01-Apr-2004); the ninth revision (dated 01-Apr-2005); the tenth revision (dated 01-Apr-2006); the eleventh revision (dated 01-Apr-2007); the twelfth revision (dated 01-Apr-2008); and the thirteenth revision (dated 01-Apr-2009). Cross-reference is made to the original document in the first instance and then to the subsequent revisions, where there have been no significant changes. The various sub-sections of this document retain the same headings and numbering systems as the preceding documents.

The various revisions are referred to in section 4.0 as follows:

Version	Date	Covering the Year	Referred to as
Original	16-Nov-1995	1996	Rev 0
First Revision	21-Nov-1996	1997	Rev 1
Second Revision	21-Nov-1997	1998	Rev 2
Third revision	07-Dec-1998	1999	Rev 3
Fourth Revision	15-Dec-1999	2000	Rev 4
Fifth Revision	01-Feb-2001	2001	Rev 5
Sixth Revision	01-Feb-2002	2002	Rev 6
Seventh Revision	31-Mar-2003	2003	Rev 7
Eight Revision	31-Mar-2004	2004	Rev 8
Ninth Revision	01-Apr-2005	2005	Rev 9
Tenth Revision	01-Apr-2006	2006	Rev 10
Eleventh Revision	01-Apr-2007	2007	Rev 11
Twelfth Revision	01-Apr-2008	2008	Rev 12
Thirteenth Revision	01-Apr-2009	2009-	Rev 13
Fourteenth Revision	01-Apr-2010	2010	Rev 14

4.1 Process Modifications Resulting in Improved Yields, Elimination or Reduction of Wastes or the Use of Alternative Less Hazardous Materials

Please refer to the corresponding sub-section of Rev 0 and subsequent revisions Revs 1 to 13.

Process Reduction of the PMI of Glivec®

One example of the company's approach to managing the environmental impacts arising from manufacturing activities can be seen in the case of Glivec®. As a result of exceptionally promising clinical trails towards the end of the 1990's Glivec® was given a fast track by the US FDA to ensure patients had access to this life saving. This meant that the then existing production process did not have a significant amount of time for optimisation. The balance here was clearly in favour of the patient. As the launch manufacturing site Novartis Ringaskiddy Limited working closely in collaboration with Novartis Pharma's Chemical and Analytical Development (CHAD) Group scaled up the original sysntesis route to bring the product to market; and then embarked on a longer journey to manage the Product Mass Intensity (PMI) of Glivec® through the implementation a telescoped process and a new and improved systhesis route in close collaboration with CHAD during the course of the 2000's:

The D Synthesis (Early 2000's)

The original synthesis route – named the D Synthesis – consisted of eight discreet steps where an intermediate was chemically synthesised and isolated prior to being fed into the next step of the synthesis. The D Synthesis was used to bring the product to market and supplied the market during the earlier part of the decade. The PMI of the D Synthesis can be summarised as follows:

Reactants: 18.40 kg/kg of Glivec®
Solvents: 115.23 kg/kg of Glivec®
Water: 75.32 kg/kg of Glivec®
Other material inputs: 6.77 kg/kg of Glivec®

Overall PMI D Synthesis: 215.72 kg/kg of Glivec®

The E Synthesis (Mid 2000's)

The first improvement on the D Synthesis came to be known as the E Synthesis and it consisted of the same synthesis pathway as the D Synthesis but telescoped two of the D Synthesis steps into one, which resulted in a process consisting of seven discreet steps. Telescoping two steps resulted in a very significant improvement to the process with an overall reduction of approximately 30% in the PMI:

Reactants: 12.06 kg/kg of Glivec®
Solvents: 116.13 kg/kg of Glivec®
Water: 22.54 kg/kg of Glivec®
Other material inputs: 1.85 kg/kg of Glivec®

Overall PMI E Synthesis: 152.58 kg/kg of Glivec®

Of especial note was the reduction of approximately 70% in water used compared to the original D Synthesis, which facilitated much improved waste management. Most of this water had to be treated thermally because of the highly hazardous nature of the isolated intermediates and reducing the water content of the liquid waste streams ensured that they could be treated (with heat recovery).

The F Synthesis (Late 2000's)

During the mid to late 2000's a new synthesis route was proposed by CHAD and this came to be known as the F Synthesis. The F Synthesis consists of a process with five discreet steps. Two of the latter purification steps of the E Synthesis were removed as a change in the chemistry of the earlier steps of the F Synthesis resulted in a higher quality starting material for the final steps of the synthesis pathway. Implementation of the F Synthesis during the latter half of the 2000's resulted in an overall reduction of 60% in the PMI when compared to the E Synthesis; and an overall improvement of approximately 70% when compared to the original D Synthesis. The data is summarized here:

Reactants: 6.04 kg/kg of Glivec®
Solvents: 46.22 kg/kg of Glivec®
Water: 2.44 kg/kg of Glivec®
Other material inputs: 3.79 kg/kg of Glivec®

Overall PMI F Synthesis: 58.49 kg/kg of Glivec®

Implementation of the F Synthesis effected a very significant reduction in solvent use: Down approximately 60% compared to the E Synthesis; and it also effected a very significant reduction in the use of water, which again significantly helped waste management processes.

84,345 kgs of Glivec® were shipped from Novartis Ringaskiddy Limited between 2007 and 2009, representing approximately 8% of all drug substances shipped from the facility.

4.1.1 Site Waste Management Group

Please refer to the corresponding sub-section of Rev 4.

4.1.2 Electronic Waste Tracking System

Please refer to the corresponding sub-section of Revs 3 and 4.

It was proposed to introduce a new electronic tracking system (the Waste Tracking System (WTS) for solid waste destined for the site's Solid Waste Incinerator during 2002 as part of the sixth revision to the EMP. The aim of the WTS was to replace the then existing paper based system and to incorporate the provisions of Schedule 3 (ii) of IPCL Register Number 545. During the course of 2002 it became clear that the proposed WTS could also be used to track other wastes on site and consequently, the roll-out of the WTS was deferred until 2003. Tracking stations were installed throughout the site and the software application to support the WTS was rolled out to a number of key workstations. The WTS went live during the first third of 2003 (as anticipated in Rev 7). During the last nine months of 2003 the WTS was used for the tracking of solid waste that was incinerated in the facility's Solid Waste Incinerator. From 2004 the WTS started to be used for tracking consignments of waste shipped off-site for treatment (as anticipated in Rev 8).

During 2005 the WTS was integrated successfully with a new weigh bridge (refer to section 4.1.5) that was installed at the facility. This permits the accurate weighing of each load of waste material leaving the

site and allows for an accurate reconciliation to be made between the site recorded weight and the weight that is returned to the site on the certificate of treatment/disposal in the case of hazardous waste).

The use of the WTS was further rolled out in 2006 and 2008 to include practically all non-hazardous waste shipments leaving the facility. The company also moved to making the WTS to be the reporting tool of choice to meet the requirements of Condition 11.10 of IPPCL Register Number P0006-03 (to be backed up with the relevant paper based documentation) during 2008. Of especial note during 2008 was the full integration of the projects department into the WTS, which ensures that all waste arising from project type activities – items such as construction and demolition waste, waste metal from pipework modifications etc – are now tracked electronically rather than using a paper based tracking system.

Capital of the order of € 100,000 was committed to this project (over the years 2003 to 2007); and an additional tranche of funding of the order of € 75,000 was committed to fully update the waste tracking system during 2008.

To compliment this work a more focused segregation at source of solid hazardous waste was rolled out across the facility during the course of 2009. This work involved retraining all personnel whose work involves packing and labelling of hazardous waste in the new segregation system and its interface with the WTS. All access to the WTS was disabled until successful completion of the training. The purpose of the new segregation system is to better separate the solid hazardous waste fractions arising at the facility so as to better optimise waste management and treatment.

4.1.3 Off-site Reuse of Inert Adsorbent

Please refer to the corresponding sub-section of Revs 6 to 8; and Rev 10

4.1.4 Biodegradable Sludge Management

Please refer to the corresponding sub-section of Revs 6 to 9; and Rev 11

The company proposed to use the ERAS ECO Limited (previously AVR Environmental Solutions Limited) facility in Foxhole, Youghal, County Cork (EPA Waste Permit Number W0211-01) to dry the company's non-hazardous sludge prior to subsequent treatment as part of the twelfth revision to the EMP (in addition to the other waste management facilities already used). One of the reasons for starting to utilise this waste management contractor is that there was no change in the relative amount of non-hazardous waste to be disposed between 2006 and 2007 – a figure of 0.0028 tonne/kg of product shipped was recorded for both years. The main reason for this was that practically all of the non-hazardous wastewater treatment plant sludge shipped from the facility during 2006 and 2007 was under a 'D' code. This changed to an 'R' code during 2008 as a result of using the AVR Environmental Solutions Limited facility, which helped maintain the progress towards maximising reuse and recycling of non-hazardous waste arising at the facility. During 2009 all sludge arising from wastewater treatment plant operations was shipped to the Youghal Facility – under an R1 code and comprising of some 977 tonnes

4.1.5 Installation of Weigh Bridge

Please refer to the corresponding sub-section of Rev 9; and Rev 11.

4.1.6 Diversion of Spent Lime and Activated Carbon to Beneficial Reuse

Please refer to the corresponding sub-sections of Rev 9 and Rev 10.

The following outlets are currently used by the company to treat the mixture of spent lime and activated carbon that arises as part of the flue gas cleaning system on the company's Solid Waste Incinerator (Emission Point Reference Number 3).

EWC Code	Description of Waste	Hazardous Waste Tag	D/R Code	Location of Disposal/Recovery	Name of Waste Disposal Recovery Contractor	Licence/Permit Reference
19 01 03	Flyash containing dangerous substances	41 Hazardous Thermal Treatment Residues	D10	(c) Veolia Es Onyx Limited. Charleston Road, Hardley, Southampton SO45 3NX., United Kingdom	Veolia Environmental Services Technical Solutions Limited, Corrin, Fermoy, County Cork, Ireland	EPA Waste Licence W0050-02
19 01 03	Flyash containing dangerous substances	41 Hazardous Thermal Treatment Residues	R4	(c) Revatech S.A., Zoning Industriel D'Ehein, B-4480, Belgium	Veolia Environmental Services Technical Solutions Limited, Corrin, Fermoy, County Cork, Ireland	EPA Waste Licence W0050-02

To facilitate this proposal a number of small physical modifications were proposed as part of the ninth revision to the EMP. These have since been implemented and include:

1. Replacement of the existing rotary valve at the off-load station with a smaller unit to increase the available height under the discharge point, which allows an FIBC 'big bag' to be fitted.

2. An ILC Dover attachment has been fitted to the new rotary valve. This allows the FIBC 'big bag' to be connected/disconnected in a contained manner and avoid local dusting. The stub end contains any spent lime and activated carbon that gets caught up in the discharge from the rotary valve.

3. There has been a change from the smaller plastic bags that were previously used to FIBC 'big bags'.

This work also included removal of redundant equipment around the discharge station, upgrading of local lighting and cleaning down the area. Some further small modifications were implemented during the course of Rev 11 to facilitate ease of movement of the packed spent lime and activated carbon. These will be complimented by some improvements in respect of containment during off-loading, which were completed during the course of the twelfth revision to the EMP.

As noted in sub-sections 4.1.3 and 4.1.4 the company has made significant progress in recent years to recycle and reuse specific waste streams that were previously landfilled. Implementation of this project has resulted in a reduction in the amount of non-hazardous waste going to landfill in that the lime

component of the spent lime and activated carbon was previously landfilled as part of a mixture of bottom ash and slag (once the carbon component had been incinerated).

4.1.7 New Segregation System for Non-Hazardous Waste

Please refer to the corresponding sub-section of Rev 9.

During the course of 2005 Novartis Ringaskiddy Limited rolled out an improved segregation system at the facility for solid non-hazardous waste (not including wastewater treatment plant sludge or used inert adsorbent) with the objective of diverting more material from landfill to reuse/recycling. Following a review the company focused on what might be called the residual non-hazardous waste that is generated at the facility, items such as paper, cardboard, plastic and glass. Some of these were already being recycled but the review indicated that with better on-site organisation that the amounts of these materials that could be reused and recycled could be increased quite dramatically.

During late 2004 a dedicated sorting and packing facility was built on site as part of the preparation for a major drive to start segregating this waste for reuse and recycling. This new facility is manned five days a week and from 2005 onwards commenced a support service for all of the major areas on site in respect of paper, cardboard, plastic and glass. A significant part of the process was to engage the company's employees directly in the process and this took place throughout 2005 as the new system was rolled out. Local segregation of these types of waste has now become the norm for all areas. During the course of the tenth and eleventh revisions to the EMP the work focused in consolidating the implementation of 'at source' segregation; optimisation of metal recycling; and to track the amounts of non-hazardous waste that are being generated using the company's new weighbridge (refer to sub-sections 4.1.2 and 4.1.5).

As noted in sub-section 4.1.2 of especial note during the course of Rev 13 was the full integration of the projects department into the WTS, which ensures that all waste arising from project type activities – items such as construction and demolition waste, waste metal from pipework modifications etc – are now tracked electronically rather than using a paper based tracking system.

4.2 Improved Process Control (Equipment and Management) to Reduce Waste

Please refer to the corresponding sub-section of Rev 0 and Revs 6 and 7.

4.2.1 Automation in Process Control

Please refer to the corresponding sub-section of Rev 0.

4.2.2 Sequence of Use of Automation in Production

Please refer to the corresponding sub-section of Rev 0.

4.3 Improvements in Equipment Cleaning Procedures Resulting in Reduced Materials Usage or Alternative Materials Usage

Please refer to the corresponding sub-section of Rev 0; Rev 2; and Rev 4.

4.4 Maintenance and Calibration of Key Control and Monitoring Equipment

Please refer to the corresponding sub-section of Rev 0.

It was proposed in Rev 10 to the EMP that environmentally critical instrumentation and equipment would have a dedicated field on the company's computerised maintenance management system to enable more transparent data searches. This work was successfully during the course of 2006 and is now fully functioning.

4.4.1 Maintenance and Calibration of Key Atmospheric Emissions Abatement/Treatment Control Equipment

Please refer to the corresponding sub-section of Rev 0.

Note that all maintenance work complies with Condition 2.2.2.9 of IPPCL Register Number P0006-03.

4.4.2 Maintenance and Calibration of Key Atmospheric Emissions Abatement/Treatment Monitoring Equipment

Please refer to the corresponding sub-sections of Revs 0 to 9.

Novartis Ringaskiddy Limited, in addition to its own internal calibration programme for both sets of Continuous Emission Monitors (CEMs) (for the Liquid Vapour Incinerator and the Solid Waste Incinerator), now has annual independent verification of their performance undertaken as an additional safeguard to ensure that emissions are accurately monitored and quantified. All maintenance work is undertaken and complies (in particular) with Conditions 2.2.2.9 and 4.1.1.(iii) of IPPCL Register Number P0006-03.

It was proposed to install new monitoring software for the CEMs during the course of the eleventh revision to the EMP. The software was to be fully compliant both with the requirements of IPPCL Register Number P0006-03; and the Incineration of Waste Directive 2000/76/EC. The software was only validated to the required standard by the sole European supplier during the first-half of 2007; and was installed on-site during the second-half of 2007.

The existing on-line particulate analysers for both the Liquid Vapour Incinerator and the Solid Waste Incinerator were replaced towards the end of the twelfth revision to the EMP and at the start of the thirteenth. Both units had been in use for over ten years and were at the end of their working lives. The

new monitoring system continues to meet the requirements of IPPCL Register Number P0006-03; and the Incineration of Waste Directive 2000/76/EC. A capital allocation of the order of €130,000 was made to effect the replacement – together with upgrading of the associated sampling system.

Both analysers underwent QAL-2 testing as part of the installation work and commissioning; and the QAL-2 testing was extended to the all of the remaining on-line analysers monitoring the emissions from the Liquid Vapour Incinerator and the Solid Waste Incinerator at the beginning of 2009. This work took slightly longer than was originally anticipated and following the outcome of stratification testing some new sampling points were installed to facilitate optimal sampling of all pollutants requiring on-line monitoring. The complete body of work was only finalised during later 2009 and a report is available for inspection by the Agency of the full QAL-2 testing programme and outcome.

4.4.3 Maintenance and Calibration of Key Sewer Emissions Abatement/Treatment Control Equipment

Please refer to the corresponding sub-section of Rev 0.

Note that all maintenance work complies with Condition 2.2.2.9 of IPPCL Register Number P0006-03.

4.4.4 Maintenance and Calibration of Key Sewer Emissions Abatement/Treatment Monitoring Equipment

Please refer to the corresponding sub-section of Rev 0.

Note that all maintenance work complies with Condition 2.2.2.9 of IPPCL Register Number P0006-03.

4.5 Improvements in Treatment/Abatement Systems to Reduce Emissions

Please refer to the corresponding sub-section of Rev 0; and Revs 2 to Rev 7.

As part of the continuing improvements at the facility Novartis Ringaskiddy Limited proposes to effect a number of modifications to the treatment/abatement systems for the Solid Waste Incinerator (Emission Point Reference Number 3), the Liquid Vapour Incinerator (Emission Point Reference Number 4) and the Wastewater Treatment Plant (Emission Point Reference Number 100) during the coming year. All of the proposed changes are designed to improve the operation of already reliable equipment.

4.5.1 Improvements Proposed for the Solid Waste Incinerator

4.5.1.1 Heat Exchanger Tube Bundle Replacement (from Rev 5 - Item complete)

4.5.1.2 Bagfilter Housing Upgrade (from Rev 5 - Item complete)

4.5.1.3 Introduction of New Control Software (from Rev 5 - Item complete)

4.5.1.4 Bagfilter Housing Replacement (from Rev 6 - Item complete)

4.5.1.5 Upgrade of Solid Waste Feed Hopper (from Rev 7 – Item complete)

4.5.1.6 Upgrade to Discharge of Spent Lime and Activated Carbon (from Rev 8 – Item complete)

4.5.1.7 Heat Exchanger Replacement (from Rev 10 – Item complete)

4.5.1.8 Study on Heat Recovery (from Rev 10 – Item complete)

4.5.1.9 Upgrading of Reburn Tunnels (New Access Points (from Rev 11 – Item complete)

4.5.1.10 Upgrading of Reburn Tunnels (Installation of Air Injection Plenum) (from Rev 11 – Item complete)

4.5.1.11 Installation of Waste Feed Conveyor System (From Rev 12 – Item complete)

Reason for modification:

The waste feed conveyor system will allow controlled feeding of different waste types and amounts to the Solid Waste Incinerator, which will allow optimisation of the treatment process. Up to thirty discreet lots of solid waste can be arranged prior to incineration – which allows waste of high calorific value to be buffered with waste of low calorific value; and the timing of entry of individual lots of waste to the Solid Waste Incinerator to be predetermined. A capital allocation of €160,000 has been provided for this project

Anticipated results from modification:

Optimised incineration of the solid waste presented for treatment. Reduced incidence of elevated levels of carbon monoxide generated during the initial combustion of the solid waste.

(**Note:** There was a minor fire on the conveyor system during June of 2009 – this required an overhaul of the system to incorporate better tracking and loading of waste onto the conveyor system; and additional local fire suppression systems. An improved at source segregation of solid hazardous waste system was rolled out across the facility. The Solid Waste Incinerator itself was not affected by the fire; and the Agency was kept informed at all times and conducted an on-site inspection the day that the fire occurred).

4.5.2 Improvements Proposed for the Liquid Vapour Incinerator

4.5.2.1 Bypass of Wastewater Treatment Plant by Quench and Scrubber Stream (from Rev 5 – Item complete)

4.5.2.2 Additional Control on Combustion Air from Wastewater Treatment Plant (from Rev 5 - Item complete)

4.5.2.3 Reuse of Condensate for Cooling of Induction Fans (from Revs 4 to 6 - Item complete)

4.5.2.4 New Fire Protection System for Computer Control System (from Rev 7 – Item complete)

4.5.2.5 Installation of New Air Conditioning System in CEMs Cabin (from Rev 8 – Item complete)

4.5.2.6 Replacement of Refractory Lining (from Rev 9 – Item complete)

4.5.2.7 Replacement of Flue Gas Reheater Heat Exchanger (from Rev 10 – Item complete))

4.5.2.8 Upgrade Induction Fan to a Variable Speed Drive (New Item)

Reason for modification:

Both existing induction fans have been operational for more than 10 years and require replacement.

Anticipated results from modification:

Installation of induction fans with variable speed drives will facilitate better optimisation of combustion (adjusting to the calorific load on the unit); and will also be more energy efficient.

4.5.3 Improvements Proposed for the Wastewater Treatment Plant

4.5.3.1 Provision of Additional Storage Space Near the Blower Building (from Rev 5 - Item complete)

4.5.3.2 Upgrading of Flow Control on Blowers to the Aeration Basins (from Revs 4 and 5 – Item complete)

4.5.3.3 Addition of Third Aeration Basin and Second Clarifier (from Rev 5 - Item complete)

4.5.3.4 Installation of Interconnection Line between the Aeration Basins and Second Clarifier (from Rev 6 - Item complete)

4.5.3.5 Replacement of Neutralisation Chamber Pumps (from Rev 6 - Item complete)

4.5.3.6 Installation of Duplex Filters in Lift Station (from Rev 6 - Item complete)

4.5.3.7 Installation of New Mechanical/Electrical Workshop in Environmental Controls Building (From Rev 6 - Item complete)

4.5.3.8 Installation of a New Conveyor System for Dewatered Sludge (from Rev 8 – Item complete)

4.5.3.9 Sealing of Neutralisation Basin and Spill Basins for Improved Odour Control (from Rev 9 – Item complete)

4.5.3.10 New Composite Samplers for Emission Point Reference Numbers 100 and W1 (from Rev 10 – Item complete)

4.5.3.11 Provision of Secondary Containment for Lift Station (from Rev 11 – Item complete)

4.5.3.12 Provision of Secondary Containment for Neutralisation Basin (from Rev 11 – Item complete)

4.5.3.13 Provision of Additional Groundwater Monitoring Well (from Rev 11 – on-going)

Reason for modification:

The Wastewater Treatment Plant Lift Station and Neutralisation Basin were identified as a potential source of groundwater contamination in the company's 2006 Environmental Liability Risk Assessment. To-date there has been no evidence of groundwater contamination. This modification is to enable additional groundwater monitoring to be undertaken in the vicinity of the Wastewater Treatment Plant if required.

Anticipated results from modification:

Significantly reduced risk of groundwater contamination from the Wastewater Treatment Plant Lift Station. Additional groundwater monitoring point available in the vicinity of the Wastewater Treatment Plant. This work was not undertaken during 2008 as the focus was on completing the more challenging work described in sub-sections 4.5.3.11 and 4.5.3.12 above. It will now be undertaken during the course of the current EMP.

4.5.3.14 Increase Capacity of Air Blowers for Biological Treatment (From Rev 13 – on-going)

Reason for modification:

The proposed upgrade to the system of aerating the biological section of treatment in the Wastewater Treatment Plant will allow for a faster response time in respect of controlling the amount of oxygen available to the microorganisms; and will also increase the volume of air that can be delivered to the system during times of peak demand. A capital allocation of the order of €140,000 has been made to facilitate this work.

Anticipated results from modification:

Improved control of the aeration process. This will minimise the possibility of excessively aerating the microorganisms, which can give rise to poor settlement in the final stages of wastewater treatment; in addition to providing additional capacity to cope with times of peak loading on the wastewater treatment plant.

4.5.3.15 Evaluation of Potential of Filtering Belt Filter Press Washwater (From Rev 13 – on-going)

Reason for modification:

It is proposed to undertake an evaluation of the potential for physically filtering the washwater from the process of dewatering sludge that is generated by the wastewater treatment process. This washwater contains the dewatered fraction from the sludge (which has already undergone biological treatment) together with process and potable water and some residual flocculating material. It may be beneficial to the overall treatment process to route this washwater past the biological section of treatment (as it has been treated already and only represents additional hydraulic loading on the wastewater treatment plant). A capital allocation of the order of €50,000 has been made to facilitate this work should the evaluation prove that this option is worthwhile.

Anticipated results from modification:

Reduced instances of increased periods of hydraulic loading ('surges') while excess biological sludge is being dewatered. These surges can affect the settlement in the final stages of wastewater treatment resulting in loss of biomass to sewer.

4.5.3.16 Installation of New Storage Area for WWTP Equipment (Now Item)

Reason for modification:

A secure location has been required for a number of portable items of wastewater treatment plant equipment – these (mainly sections of metallic piping that are used for temporary connections) have been stored in inappropriate locations from time-to-time (unpaved areas etc).

Anticipated results from modification:

Improved housekeeping in the vicinity of the wastewater treatment plant

4.5.4 Improvements Proposed for the Main Production Buildings

Please refer to the corresponding sub-section of Rev 4; and to subsection 4.1 of this document.

4.5.4.1 Addition of High Level Switch Protection to Emergency Relief Receivers
(From Rev 6 - Item complete)

4.5.4.2 Installation of Primary Bunding on the Ground Floor Corridor (from Rev 10 – Item complete)

4.6 The Use of Alternative Treatment/Abatement Systems

Please refer to the corresponding sub-section Rev 0 and Revs 3 to 7.

4.6.1 Redundancy Option on Liquid Vapour Incinerator (from Revs 5 to 8 – Item complete)

4.6.2 Wet Electrostatic Precipitator Option on Liquid Vapour Incinerator (from Rev 9 – Item still open)

Reason for modification:

Novartis Ringaskiddy Limited is currently evaluating the environmental benefits and cost implications of installing a wet electrostatic precipitator on the company's Liquid Vapour Incinerator, which would enable more consistent control of particulate emissions from the Liquid Vapour Incinerator. It should be noted that particulate emissions from the unit are generally much lower that those required under the relevant schedule of the company's Integrated Pollution Prevention and Control Licence. However, such a unit could provide for a greater degree of control that that currently afforded by the unit's quench and scrubber systems. If the company decides that such an option is worth following then a more detailed submission will be made to the Agency at the appropriate time.

Anticipated results from modification:

An additional level of control on particulate emissions from the Liquid Vapour Incinerator.

4.7 Recovery, Reuse, Recycling of Waste Material Both On-Site and Off-Site

4.7.1 Solvent Reuse and Recycling

Please refer to the corresponding sub-section of Rev 0; and Revs 2 to 5.

Project: Diovan® Solvent Recovery – Increased Solvent Recovery throughput.

Current Status / Progress:

Weekly average Diovan® Ethyl Acetate and Cyclohexane recovery volumes from start of September 2009 to date (after repair and repacking of the Ethyl Acetate dewatering column 107/110) is 151 tonnes/week.

The totalised Diovan® Ethyl Acetate and Cyclohexane recovery volume from January 2009 to October 2009 (following implementation of the batch still project) was 4,370 tonnes (For comparison: The totalised Diovan® Ethyl Acetate and Cyclohexane recovery volume for 2007 was 3,353 tonnes).

If the current recovery rate of 151 tonnes/week is maintained through 2010, then based on a 48 week year the total recovery figure will be in the region of 7,250 tonnes.

Three additional projects are to be implemented during the course of the current EMP to further optimise the Diovan® solvent recovery project.

4.7.2 Metal Recycling

Refer to the corresponding sub-section of Rev 3; and Rev 9

During the course of revision 10 to the EMP all metal waste consigned off site for recycling was weighted on the company's weight bridge and tracked through the company's Waste Tracking System (WTS). One of the company's targets during the course Rev 11 to evaluate the possibility of reuse/reconditioning of used metal drums in preference to recycling the used metal drums. However, on balance it was decided that it remained a preferable option to have these metal drums recycled rather than reconditioned in the unlikely event that there might be some residual contamination left in the drums.

4.7.3 Installation of Recycling Point

Refer to the corresponding sub-section of Revs 3 and 4.

4.7.4 Reuse of Inert Adsorbent Material

Refer to sub-section 4.1.3 of this document.

4.7.5 Recycling of Waste Oil

Refer to the corresponding sub-section of Revs 8, 9 and 10.

4.7.6 Improved Segregation of Non-Hazardous Waste

Refer to sub-section 4.1.7 of this document.

4.8 Reduction in Fugitive Emissions

Please refer to the corresponding sub-section of Revs 0 to 5.

The following table summarises the total fugitive emissions from the existing facility for the years 2004 - 2009.

The quoted 2009 fugitive emission figure for the site of 3,244 kgs is less than the figure of 3,739 kgs quoted for 2008. In relative terms the emission has reduced from a release rate of 0.012 kg/kg product

shipped in 2008 to 0.009 kg/kg product shipped in 2009. Although these levels are not significant in terms of environmental impact the company will monitor the emerging data for 2010 closely to ensure that all processes are run in as contained a manner as is possible. To this end each Process Unit at the facility has been given an individual target in respect of minimisation of fugitive emissions in order to consolidate the progress made during the years 2004 to 2009.

Fugitive Emissions From the Existing Facility (expressed as kg organic carbon/year)

2004	2005	2006	2007	2008	2009
12,921	11,778	8,166	7,396	3,740	3244

(Production volume 2004: 300 tonnes; Production volume 2009: 375 tonnes)

4.9 Prevention of Incidents with the Potential for Environmental Consequences and the Preparation and Implementation of Contingency Plans in the Event of an Incident

Please refer to the corresponding sub-section of Rev 0.

As indicated in Rev 6 during 2000 Novartis Ringaskiddy Limited prepared a Major Accident Prevention Policy (MAPP) document to meets its requirements under the Control of Major Accident Hazards Regulations, 2000 (S.I. Number 476 of 2000). This document was finalised towards the end of 2001 and forwarded to the relevant competent body in the State, the Health and Safety Authority (HSA). The MAPP document complements the contents of this section of the EMP, and was reproduced as an insert in Rev 7 of the EMP.

As noted in Rev 8 the company prepared a Safety Report in anticipation of (the then) future requirements arising under the Control of Major Accident Hazards Regulations 2000, which were subsequently updated to the European Communities (Control of Major Accident Hazards Involving Dangerous Substances) Regulations, 2006 (S.I. Number 74 of 2006). This Safety Report was forwarded to the relevant competent body in the State, the Health and Safety Authority (HSA) during the course of Rev 11. This was reviewed and approved by the HSA during the course of Rev 12. A full update to the Safety Report is required for any major changes to the facility that may impact on the risk presented both on- and off-site; or every five years. In the absence of any major change at the facility the next full update and review by the HSA is due for July 2012. In the interim a number of minor changes have been made to the original Safety Report to reflect small scale changes at the facility.

A copy of the Safety Report is retained on site for inspection by the Agency.

4.9.1 General Overview

Please refer to the corresponding sub-section of Rev 0 and the MAPP document (See Rev 7); and the company's Safety Report.

4.9.2 Prevention of Incidents with the Potential for Environmental Consequences

Please refer to the corresponding sub-section of Rev 0 and the MAPP document (See Rev 7); and the company's Safety Report.

4.9.3 Hazard Potential of Chemicals in use at Novartis Ringaskiddy Limited

Please refer to the corresponding sub-section of Rev 0 and the MAPP document (See Rev 7); and the company's Safety Report.

4.9.4 Preparation and Implementation of Contingency Plans in the Event of an Incident

Please refer to the corresponding sub-section of Revs 0 to 5 and the MAPP document (See Rev 7); and the company's Safety Report.

The components of the Novartis Emergency Management (NEM) system are fully described in section 4.9 of Rev 0 and the MAPP document (See Rev 7); and the company's Safety Report.

4.10 Savings in Energy and Materials Usage

4.10.1 Savings in Energy Usage

Please refer to the corresponding sub-section of Revs 0 to 12 and to section 4 of the 2008 Annual Environmental Report (AER).

The following is a summary of energy conservation initiatives undertaken since Rev 8:

4.10.1.1 Replacement of chilled water condensers (Electricity) (from Rev 8 - Item complete with an estimated GJ reduction of 900).

4.10.1.2 Reduction chilled water system users' setpoint to 1.2 bar (Electricity) (from Rev 8 - Item complete with an estimated GJ reduction of 200).

4.10.1.3 Reduction for evaporation requirements in the Cyclosporine process as a result of introduction of the new purification process (Electricity) (refer to subsection 4.1 of this document and Rev 8) (from Rev 8 - Item complete with an estimated GJ reduction of 12,779).

4.10.1.4 Reduction of lyophilizer drying time on the Fluvastatin process (Electricity) (Projected GJ saving of 1,452) (from Rev 8 - Project deferred to 2007).

4.10.1.5 Reduction of condensing pressure on process chillers and operation of both water chillers (Electricity) (from Rev 8 - Item complete with an estimated GJ reduction of 1,800).

4.10.1.6 Improved oxygen trim control on the company's second natural gas fired boiler (Natural Gas) (from Rev 8 - Study completed in 2004 and implemented in 2005 with an estimated GJ reduction of 2,010).

4.10.1.7 Reduction in the use of 'once through' hot water in mobile filters in the production areas (Natural Gas and Electricity) (from Rev 8 - Item complete with an estimated GJ reduction of 3,083).

4.10.1.8 Removal of the chilled water 'booster' pump (Electricity) (from Rev 8 - Item complete with an estimated GJ reduction of 133).

4.10.1.9 Operation of both water chillers (Electricity) (Projected GJ saving of 216) (from Rev 9 - Following a technical evaluation it was decided not to proceed with this project).

4.10.1.10 Produce a report on water usage at the facility focusing in particular on Cooling Tower make-up, reverse osmosis and 'once through' use of water (Water) (Potential GJ saving of 300) (from Rev 9 – Item complete – the report was prepared and a number of projects were initiated).

4.10.1.11 Installation of energy efficient lighting in Production Building 1 (Electricity) (from Rev 9 – Item complete with an estimated GJ reduction of 456).

4.10.1.12 Implementation of a new passivation procedure in Production Building 1 (Electricity) (from Rev 9 – Item complete with an estimated GJ reduction of 39)

4.10.1.13 Upgrade cooling water pumps (Electricity) (Projected GJ saving of 11,498) (From Rev 10 and also identified in the water usage report – Item complete with an estimated GJ reduction of 8,482))

4.10.1.14 Reduce chilled water flow rate (Electricity) (Projected GJ saving of 651) (From Rev 10 and also identified in the water usage report – project currently continuing on an on-going basis)

4.10.1.15 Develop a proposal for a new energy efficient replacement option for the company's existing use of glycol as a chiller refrigerant (From Rev 10 - ongoing) (Electricity) (Projected GJ saving of 4,982) (Note that actual implementation of this project will not take place during 2008/2009 – the preparatory work will be undertaken during 2008/2009)

4.10.1.16 Installation of energy efficient lighting in the Tank Farm area (Electricity) (From Rev 11 - Item complete with an estimated GJ reduction of 456)

4.10.1.17 Installation of NIR detector on Fluvastatin driers (Electricity) (From Rev 12 – Item compete with an estimated GJ reduction of 72)

Novartis Ringaskiddy Limited is currently installing instrumentation on the Valsartan and Fluvastatin production trains that use NIR spectroscopy to determine when an intermediate/product has been dried to specification. This information will be used to optimise dryer run time. In other words the dryer will only be active until such time as the end point for drying is reached. Previously this would have been done based on a sample and laboratory analysis; and in the dryer would have been maintained in an active setting until the laboratory result was received. It is anticipated that in addition to removing a number of production bottlenecks that this initiative will also generate significant energy savings.

4.10.1.18 Installation of NIR detector on Valsartan driers (Electricity) (From Rev 12 – Item complete with an estimated GJ reduction of 396)

See comments for item 4.10.1.18 above

4.10.1.19 Installation of Additional On-site Electricity Meters (Electricity) (From Rev 13 – Item complete)

4.10.1.20 Installation of New On-site Gas Meters (Natural Gas) (From Rev 13 – Item complete)

4.10.1.21 Installation of energy efficient lighting in Production Building 2 (Electricity) (From Rev 13 – Item complete with an estimated GJ saving of 456)

4.10.1.22 Modification to Glivec® Production Process (Electricity) (From Rev 13 – Item complete with an estimated GJ saving of 540)

4.10.1.23 Compressed Air System Upgrade (Electricity) (New Item) (Projected GJ saving of 9,163)

The existing air compressors are to be replaced with new energy efficient units that will deliver an estimated saving of 9,163 GJ per annum on electricity consumption.

4.10.1.24 Optimise Use of Cooling Water (Electricity) (New Item) (Projected GJ saving of 1,613)

Working in collaboration with the Production Process Units the Technical Services Support Unit will identify ways of only using the cooling water that is provided from the Utility area where it is really needed. This has been identified as an area where some progress can be made following an external review of patterns of energy consumption within the facility.

4.10.1.25 Optimise Use of Cooling Water (Electricity) (New Item) (Projected GJ saving of 1,613)

Working in collaboration with the Production Process Units the Technical Services Support Unit will identify ways of only using the cooling water that is provided from the Utility area where it is really needed. This has been identified as an area where some progress can be made following an external review of patterns of energy consumption within the facility.

4.10.1.26 Increase Supply Temperature of Cold Glycol (Electricity) (New Item) (Projected GJ saving of 1,512)

Working in collaboration with the Production Process Units the Technical Services Support Unit will identify ways to increase the supply temperature of cold glycol from the existing supply temperature of – 25 °C to – 20 °C. A number of production processes will need to be reviewed to ensure that the quality of the product is not adversely affected by increasing the supply temperature. However, this has been identified as an area where real progress can be made following an external review of patterns of energy consumption within the facility.

4.10.1.27 Reduce Refrigeration Condenser Pressure (Electricity) (New Item) (Projected GJ saving of 1,814)

The operational pressure of the Refrigeration Condenser, which is located in the Utility area, is to be reduced with an estimated annual reduction in electricity consumption of some 1,814 GJ.

4.10.1.28 Reduce Requirement for Pumping Hot Glycol (Electricity) (New Item) (Projected GJ saving of 3,323)

Working in collaboration with the Production Process Units the Technical Services Support Unit will identify ways of ensuring that the hot glycol that is supplied from the Utility area is used productively. This has been identified as an area where some progress can be made following an external review of patterns of energy consumption within the facility.

Implementation of these measures is overseen by the site's Energy Management Group, which is chaired by the Technical Services Support Unit but which has representatives from all of the main energy consuming areas on site. The Energy Management Group meets once a month to review progress on the implementation of the various energy conservation programmes.

4.10.2 Savings in Materials Usage

Refer to sub-section 4.7 of this document.

4.11 Prevention of Emissions of Carcinogenic Substances

Please refer to the corresponding sub-section of Rev 0; Rev 3; and Rev 4.

Novartis Ringaskiddy Limited is not using any of the compounds which are known to be carcinogenic for man (Category 1 Carcinogens) to which the Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001 (Statutory Instrument Number 78 of 2001) and the Safety, Health and Welfare at Work (Chemical Agents) Regulations, 2001 (Statutory Instrument Number 619 of 2001) and its associated Code of Practice of 2007 apply.

The company may use three compounds, in limited quantities, which carry the risk phrase "R45". "R45" is ascribed to substances that may cause cancer. Two of the compounds, Dimethyl Sulphate and Hydrazine Hydrate, have not been used at Novartis Ringaskiddy Limited to-date. The other, 2-Amino-4-Nitrotoluene, has been used in limited quantities under enclosed handling conditions.

The company has implemented the Third Schedule of the Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001 (Statutory Instrument Number 78 of 2001) which defines the approach to be taken when handling such materials. The company has planned to:

- ➔ Limit the quantities of these substances stored and used at Novartis Ringaskiddy Limited.
- ➔ Keep as low as possible the number of employees handling these materials.
- ➔ Avoid the release of these materials into the workplace or the environment through the used of Closed Production Systems.
- ➔ Define those personal protective measures that are required by personnel working with such materials.
- ➔ Use an extraction system to vent such Closed Production Systems to the site's Liquid Vapour Incinerator.
- ➔ Apply appropriate Standard Operating Procedures when handling these compounds.
- ➔ Operate a defined cleaning/hygiene regime in areas where such materials are being handled.
- ➔ Provide suitable training and information for employees working with these materials.
- ➔ Use sealed containers, clearly and visibly labelled, when storing, handling or transporting these materials.
- ➔ Provide a means for safe collection, storage and disposal of carcinogenic or mutagenic waste by employees, including the use of double lined and sealed containers that are clearly and visibly labelled.
- ➔ Designate special areas within the production building where these materials are handled. For example, 2-Amino-4-Nitrotoluene was only handled in two designated areas.

The aforementioned procedures are also implemented when physically isolating certain reaction mixtures that contain a constituent known to produce a positive Ames test. A positive Ames test for a substance indicates that there may be a possibility that the substance could be carcinogenic. This provides an additional safeguard in relation to the goal of preventing emissions of carcinogenic substances, both in the workplace and in the environment.

The company continuously updates its material safety data information to take account of new information becoming available on the materials which are in use at Novartis Ringaskiddy Limited and also to take cognisance of changing occupational exposure limits under the aforementioned legislation.

4.12 Relevant Employee Training

Please refer to the corresponding sub-section of Revs 0 to 10.

Novartis Ringaskiddy Limited is currently continuing its training and assessment programme for all production operators in respect of Core Pharmaceutical Skills (for operators within the Active Pharmaceutical Ingredient (API)/Bulk Chemical Sector. Upon satisfactory completion of the programme production operators will receive certification that is validated by the Further Training and Awards Council

(FETAC). Supervisors and engineers, who in turn have been certified by FETAC for this purpose, undertake the training and assessment.

Certified operators will be able to:

Identify and demonstrate the correct procedure in the event of spills, leaks or breakage.

Dispose of waste in their area as per the appropriate procedure.

Understand the need for environmental awareness in the workplace.

Recognise that the EPA has issued the Ringaskiddy facility with an Integrated Pollution Prevention and Control Licence.

Outline the functions and powers of the EPA.

Explain the aims of the company's Integrated Pollution Prevention and Control Licence.

Outline the key conditions of the company's Integrated Pollution Prevention and Control Licence.

Understand the company's current Environmental Policy.

Understand the company's Environmental Management System, where applicable.

Explain the role of the environmental audit.

Understand the requirement for site environmental procedures/instructions and be able to locate these as appropriate.

Understand the potential consequence of departing from site environmental procedures.

Outline the main environmental impacts of Novartis Ringaskiddy Limited.

Explain their role and responsibilities in ensuring that Novartis Ringaskiddy Limited complies with its environmental regulations.

Explain their role in an accidental release situation.

Understand the types of waste that are produced in their area and how they are managed.

Understand the role of waste minimisation in the protection of the environment.

Function specific training in the area of solvent recovery, control of emissions to atmosphere and wastewater treatment plant operations is scheduled for personnel in the Environmental Controls Department to build on targeted training received by this group under Revs 0 to 13.

The HSE Department also runs periodic induction courses for new personnel on site (both new company employees and contract personnel) which covers, among other things, the company's operation under the auspices of the EPA's IPPC licensing regime and the site's participation in the EMAS scheme.

Other conduits for raising general environmental awareness are the minutes of the meetings of the Site Environmental Committee; the workings of the Energy Management Group, and EMAS related documentation, which is available to all personnel via PC. The Health, Safety and Environmental Protection (HSE) Function also maintains an informative webpage on the company's internal intranet.

4.13 Novartis Ringaskiddy Limited: European Pollutant Release and Transfer Register

Please refer to the corresponding sub-section of Revs 0 to 13.

The company's E-PRTR report for the calendar year 2009 has been reported in electronic format to the Agency (31-Mar-2010). A hard copy of the electronic submission can be found in section 4.0 of the 2009 AER.

The company proposes to continue to include, where appropriate, the following pollutants from Annex II of the E-PRTR Regulation (EC) No 166/2006 concerning the establishment of a European Pollutant Release and Transfer Register, in its 2010 E-PRTR:

Annex II Number	Pollutant
2	Carbon monoxide
3	Carbon dioxide
7	Non-methane volatile organic compounds
8	Nitrogen oxides
11	Sulphur oxides
12	Total Nitrogen
13	Total Phosphorus
14	Hydrochlorofluorocarbons
20	Copper
24	Zinc
35	Dichloromethane
47	PCDD + PCDF (dioxins and furans)
73	Toluene
76	Total organic carbon
79	Chlorides

83	Fluorides

4.14 Novartis Ringaskiddy Limited: Public Information on Environmental Activities

Please refer to the corresponding sub-section of Rev 0; Rev 1; and Rev 2.

In addition to continuing the activities outlined in sub-section 4.14 of Rev 0 and subsequent revisions the company has issued the following document to the general public in 2009 (copies have also been provided to the EPA):

➔ Novartis Ringaskiddy Limited Interim Environmental Statement 2008 (Prepared to Meet the Requirements of the European Community's EMAS Regulation) (Covering the Site's Environmental Performance during the calendar year 2008).

It is anticipated that Novartis Ringaskiddy Limited will issue an independently verified Environmental Statement (covering the calendar years 2007, 2008 and 2009) during the first half of 2010. This document will be made available to a wide audience.

To meet the requirements of Condition 3.2 of IPPCL Register Number P0006-03 an Installation Notice Board has been erected at the main entrance to the facility. The board contains the following information:

The name and telephone number of the installation;

The normal hours of opening;

The name of the licence holder;

An emergency out of hours contact telephone number;

The licence reference number; and

Where environmental information relating to the installation can be obtained.

4.15 Sound Level Survey

Novartis Ringaskiddy Limited will submit a separate proposal in respect of the proposed sound level survey for 2010 to the Agency. This proposal will meet the requirements of Condition 6.10 and Schedule B.4 of IPPCL Register Number P0006-03. A report on the survey that is to be undertaken during 2010 will be included in the AER for 2011.

4.16 Programme for Reduction in Sound Level Emissions from Specified Sources

Please refer to the corresponding sub-section Rev 0 and Rev 8.

No further work is scheduled for 2010. The annual sound survey report included in the 2009 AER indicates that the company is complying with the terms of its IPPCL in respect of sound emissions from the facility.

4.17 Programme for the Protection of Surface Water

Please refer to the corresponding sub-section of Rev 0.

4.17.1 General Overview

Please refer to the corresponding sub-section of Rev 0 and Rev 2.

4.17.2 Warning and Action Levels

Please refer to the corresponding sub-section of Rev 0.

4.17.3 Reference Drawing Numbers

Please refer to the corresponding sub-section of Rev 0.

4.17.4 Improvements Proposed for the Surface Water Protection System

Please refer to the corresponding sub-section of Rev 4.

4.17.4.3 New Tanker Parking Facility (From Revs 6 and 7 – Item Complete)

4.17.4.4 Installation of New Submersible Pumps in Storm Water Retention Pond (From Rev 7 – Item Complete)

4.17.4.5 Installation of Retention Capacity Monitoring in Storm Water Retention Pond (from Rev 8 – Item Complete)

4.17.4.6 Installation of Primary Bunding on the Ground Floor Corridor (Also reference in sub-section 4.5.4.2 of this EMP) (from Rev 10 – Item Complete)

4.17.4.7 New Bunded Storage Facility (from Rev 10 – Item Complete)

4.17.4.8 Installation of a Class I Full Retention Separator (from Rev 10 – Item Complete)

4.17.4.9 Maximise Retention Capacity of Spill Basin 2 (from Rev 13 – Item Complete)

4.17.4.10 Increase Capacity of SWRP from 5,000 m^3 to 9,000 m^3 (New Item)

Reason for modification:

During 2009 Arup Consulting Engineers was asked to undertake a study of the company's surface water protection system. The purpose of the system is to intercept large spillages and cater for run-off of firewater in the event of a major incident on site.

The original design was to cater in a worst case scenario for the firewater that would be generated in fighting a fire for two hours in the Tank Farm in addition to the then worst case rainfall scenario. Since that time there have been a number of developments on site that have resulted in a greater amount of paved areas than was originally foreseen but perhaps more importantly the pattern of rainfall has also changed.

Arup subsequently issued a report on the outcome of the study titled 'Surface Water Drainage and Fire Water Retention Pond Assessment'. The report found that:

- *Based on an analysis of the surface water drainage network, it is evident that the existing network has the capacity to cater for the 20 year 24 hour rainfall event as well as the firewater flow from the tank farm.*
- *The network does experience a surcharge effect but this is an acceptable hydraulic effect during a rainfall event of this return period.*
- *The analysis of the capacity of the ponds has indicated that the capacity of the ponds is not capable of meeting the required rainfall and firewater flow rates and will need to have their existing capacity increased from a combined 5,000 m^3 to 9,000 m^3.*

Civil work was initiated and progressed during the last three months of 2009 with a view to increasing the retention capacity to 9,000 m^3 in line with the Arup report's recommendation. Additional work is also scheduled so that in addition to substantially increasing the retention capacity of the Storm Water Retention Pond its operational management will also be optimized.

Anticipated results from modification:

The holding capacity of the Storm Water Retention Pond will match site requirements taking into account all civil developments at the facility and also taking into account updated meteorological data.

4.17.4.11 Install a Low Flow Transfer Station at the SWRP (New Item)

Reason for modification:

In parallel with the study referred to in item 4.17.4.10 above a requirement for some facility for transferring surface water run-off collected under conditions of low flow but with a high concentration of Total Organic Carbon (TOC) directly to the Wastewater Treatment Plant was identified. This typically happens under conditions of low to no flow during dry periods and when the on-line TOC analyser has no real sample to analyse. This will result in the outlet of the Storm Water Retention Pond closing as a precautionary measure. The issue is when this type of event is followed by normal rainfall that the holding capacity of the Storm Water Retention Pond to cater for a real spillage is compromised pending a sample being taken for laboratory analysis.

Anticipated results from modification:

The new holding capacity of 9,000 m^3 at the Storm Water Retention Pond will be continuously available to meet the requirements of holding a significant spillage at the facility; or water used in the event of a major incident at the facility.

4.18 Groundwater Quality and Identification of Contamination

Please refer to the corresponding sub-section of Rev 0 and Rev 1.

The company's on-going programme of groundwater sampling and analysis will be continued in 2009 to meet the requirements of Schedule C.6 of IPPCL Register Number P0006-03. Data submitted to the Agency to-date have indicated that the quality of the groundwater beneath the site at Novartis Ringaskiddy Limited has remained the same as that prior to the commencement of the development.

The groundwater monitoring points listed in Schedule C.6 of IPPCL Register Number P0006-03 have been included in the site's maintenance programme and will be inspected on a biannual basis. Any necessary maintenance will be carried out based on this inspection.

Condition 9.4.4 of IPCL Register Number 545, which came into force on 31-Oct-2000, required that:

'The licensee shall undertake a programme of testing and inspection of underground tanks and pipelines to ensure that all underground effluent and foul sewer pipes are tested at least once every three years. A report on such tests shall be included in the Annual Environmental Report.'

A proposal in respect of testing and inspection of underground tanks and pipelines (based on a three year cycle) was included as part of the revision to the company's EMP included as part of the year 2000 AER. The provisions of Condition 9.4.4 of IPCL Register Number 545 were new at that time in respect of this facility. A report on the implementation of the relevant part of the EMP was subsequently furnished as part of the reporting requirements of IPCL Register Number 545 in the 2003 AER.

The company advised the Agency that the second round of testing and inspection of underground tanks and pipelines was to be undertaken before the end of 2006 in revision 10 to the EMP. This work was subsequently undertaken and was reported on separately in the AER for 2006.

Condition 9.4.4 of IPCL Register Number 545 has subsequently superseded by Condition 6.8 of IPPCL Register Number P0006-03, which requires that:

'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 shall be tested and demonstrated by the licensee. This testing shall be carried out by the licensee at least one every three years thereafter and reported to the Agency on each occasion. A written record of all integrity tests and any maintenance or remedial work arising from them shall be maintained by the licensee.

The third round of testing was completed in 2009 and a report on the outcome of the testing programme is to be submitted to the Agency as an addendum to the AER for 2009.

The fourth round of testing is scheduled to be completed no later than 2012 and a report on the outcome of the testing programme will be submitted to the Agency as an addendum to the AER for 2012.

5.0 EXPECTED RESULTS OF THE NOVARTIS RINGASKIDDY LIMITED ENVIRONMENTAL MANAGEMENT PROGRAMME

5.1 General Comments

Novartis Ringaskiddy Limited is convinced that the EMP that is in place guarantees the highest standards in safety and environmental protection. This EMP is revised and updated on an annual basis. The information provided in this document and the preceding revisions of the EMP, in the form of Annual Safety and Environmental Performance Reports, and in the site's Environmental Statements of 1996, 1998, 2000, 2003 and 2006; and Interim Environmental Statements of 2007 and 2008 confirm that this is the case. Novartis Ringaskiddy Limited is committed under the terms of its participation in the European Community's EMAS scheme to appraise the general public of its performance in this regard.

5.2 Emissions from Production and Chemical Storage Equipment

Please refer to the corresponding sub-section of Rev 0; and Revs 1 to 12.

Quantitative information in respect of this performance is available in summary form for 1994 on page number 8 of Rev 0; for 1995 on page number 10 of Rev 1 for 1996; for 1997 on pages number 8 and 9 of Rev 3; for 1998 on page number 19 of Rev 4; for 1999 on page number 19 of Rev 5; for 2000 on page number 21 of the insert in Rev 6; for 2001 on page number 48 of the insert in Rev 9; for 2002 on page number 49 of the insert in Rev 9; for 2003 on page number 50 of the insert in Rev 9; for 2004 on page number 71 of the insert in Rev 12; for 2005 on page number 72 of the insert Rev 12; for 2006 on page number 73 of the insert in Rev 12; for 2007 on page number 55 of the insert in Rev 12; and for 2008 on page number 47 of the insert in this document.

The data for 1994 to 2008 have been independently verified as part of the company's participation in EMAS.

Novartis Ringaskiddy Limited is currently reporting on the results of implementation of Rev 13 of the EMP to the EPA as part of the company's AER for 2009; and the company is scheduled to report on the effects of implementing this current (Rev 14) proposal as part of the AER for 2010.

5.3 Compliance with Integrated Pollution Prevention and Control Licence Register Number P0006-03

The EMP in place at Novartis Ringaskiddy Limited guarantees an extremely high degree of compliance with the very strict conditions stipulated in the company's IPCL. The company performs approximately 200,000 readings (tests) per year to check its compliance with the aforementioned licence. The company has set an internal objective to show a minimum compliance of 99.9 %. This means that 200 readings out of 200,000 could be associated with non-compliances presenting the potential for an adverse effect on the environment. However, the company is confident that all non-compliances will be shown to be minor deviations and not, in fact, presenting the potential for having an adverse effect on the environment. The company will report all non-compliances, if there are any, together with an evaluation of their implication, to the EPA.

The overall environmental compliance of Novartis Ringaskiddy Limited in respect of the imposed licence conditions was greater than 99.99 % during the period from January to December, 2009 (inclusive). Nine readings out of a total of more than 200,000 were judged to be in non-compliance and were reported to the Environmental Protection Agency. All non-compliances were judged to be minor deviations and did not present the potential for having an adverse effect on the local environment.

It is noteworthy that despite this transparent decade long commitment to improving environmental performance that implementation of IPPCL Register Number P0006-03 necessitated an approximate 50% increase in environmental analyses (from approximately 133,000 analyses per annum in 2005 to approximately 200,000 analyses per annum in 2009); together with additional regulatory requirements.

5.4 Expected Progress 2010

Novartis Ringaskiddy Limited sees, at this point in time, no major opportunity to decrease its emissions because they are already at a very low level for an operation of this nature and are better than the results which would be expected through the implementation of Best Available Technology as outlined in the relevant EPA Sector Guidance Documents.

Compliance with the company's strict IPPCL is very high and the company will make every effort to maintain this standard.

The company has also made significant progress in the area of resource management over the past number of years and will commit itself to monitor, report and maintain the high standard that has been set and where appropriate better these standards.

The key targets that form the basis of the 2010 EMP are summarised as follows. Some of these items will run over two years and this is indicated where appropriate:

Schedule of Environmental Targets for 2010:

Technical Services Support Unit. Maximise Batch Still throughput to reduce fresh solvent consumption and the amount of hazardous waste requiring final treatment. Contribute to achieving overall site hazardous waste reduction target of 5% based on the 2009 relative rate of hazardous waste generation.

(To support the objective of reusing/recycling more of the hazardous waste that is generated on-site (optimisation of the use of natural resources); and the objective of striving for continual improvement in our HSE performance)

Technical Services Support Unit. Coordinate site projects and activities to meet the overall site energy target of a 10% reduction on 2006 baseline relative energy consumption figure (equates to 2.5% for each year 2007, 2008, 2009 and 2010).

(To support the objective of conducting our business in as sustainable a manner as is possible; the objective of optimising the use of natural resources; and the objective of striving for continual improvement in our HSE performance)

Technical Services Support Unit. Install and commission a Low Flow Transfer Station at the Strom Water Retention Pond to further optimise the facility's firewater retention capacity (in line with the Environmental Liability Risk Assessment).

(To support the objective of minimising the environmental impact of our activities)

Technical Services Support Unit. Reduce the amount of fugitive emissions of organic carbon arising from vent disconnections and/or unavailability by 10% using the 2008 figure of 1,621 kgs as the baseline (note that the 2009 target was not achieved).

(To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

Technical Services Support Unit. Develop an implementation plan for the possible use of a Wet Electrostatic Precipitator at the Liquid Vapour Incinerator to facilitate more on-site treatment of waste with heat recovery; and further reduce emissions of inorganic particulate material.

(To support the objective of reusing/recycling more of the hazardous waste that is generated on-site (optimisation of the use of natural resources); and the objective of striving for continual improvement in our HSE performance)

Technical Services Support Unit. Achieve an internal compliance rate of 99.98% (or greater) in respect of the number of OOE results reported for operation of environmental controls modules.

(To support the objective of measuring progress and verifying compliance with National regulatory requirements)

Ciclo/Peptides/SSF Process Unit. Eliminate the discharge of residual amounts of Ciclosporin to the wastewater treatment plant; and minimise the discharge of aqueous solvent to the wastewater treatment plant from washing of the A-column.

(To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

Production Building 2. Reduce the amount of fugitive emissions of organic carbon from Production Building 2 by 10% using the 2008 discharge of 1,373 kgs as the baseline.

(To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

Production Building 2. Reduce electricity consumption by 2.5% relative to production (intermediates and products) to actively contribute to the site energy conservation target; and achieve an absolute reduction of 1.25 % based on implementation of specific projects.

(To support the objective of minimising the environmental impact of our activities; the objective of conducting our business in as sustainable a manner as is possible; and the objective of striving for continual improvement in our HSE performance)

Production Building 2. Maintain a schedule of potential and realised improvements in increasing the efficiency of use of raw materials (for example through the implementation of Lean and IQP projects).

(To support the objective of conducting our business in as sustainable a manner as is possible; the objective of optimising the use of natural resources; and the objective of striving for continual improvement in our HSE performance) (To support the objective of measuring progress and verifying compliance with National regulatory requirements)

Production Buildings 1 and 1A. Stabilise the amount of fugitive emissions of organic carbon from Production Buildings 1 and 1A at the 2009 discharge level of 1,133 kgs.

(To support the objective of minimising the environmental impact of our activities; and the objective of striving for continual improvement in our HSE performance)

Production Buildings 1 and 1A. Reduce electricity consumption by 2.5% relative to production (intermediates and products) to actively contribute to the site energy conservation target; and achieve an absolute reduction of 1.25 % based on implementation of specific projects.

(To support the objective of minimising the environmental impact of our activities; the objective of conducting our business in as sustainable a manner as is possible; and the objective of striving for continual improvement in our HSE performance)

Production Buildings 1 and 1A. Maintain a schedule of potential and realised improvements in increasing the efficiency of use of raw materials (for example through the implementation of Lean and IQP projects).

(To support the objective of conducting our business in as sustainable a manner as is possible; the objective of optimising the use of natural resources; and the objective of striving for continual improvement in our HSE performance) (To support the objective of measuring progress and verifying compliance with National regulatory requirements)

HSE. Coordinate the implementation of the EPA's requirements in respect of the quality of self-monitoring compliance data (as per the Agency's letter of 18-Nov-2009).

(To support the objective of measuring progress and verifying compliance with National regulatory requirements)

6.0 REFERENCES

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6.2 Integrated Pollution Control Licence Register Number 6. Issued to Sandoz Ringaskiddy Limited by the Environmental Protection Agency, 16-May-1995.

6.3 Integrated Pollution Control Licence Register Number 545. Issued to Novartis Ringaskiddy Limited by the Environmental Protection Agency, 31-Oct-2000.

6.4 Integrated Pollution Prevention and Control Licence Register Number P0006-03. Issued to Novartis Ringaskiddy Limited by the Environmental Protection Agency, 02-Feb-2006.

6.5 Greenhouse Gas Emissions Permit Register Number GHG078-1. Issued to Novartis Ringaskiddy Limited by the Environmental Protection Agency, 29-Mar-2004.

6.6 Greenhouse Gas Emissions Permit Register Number IE-GHG078-2. Issued to Novartis Ringaskiddy Limited by the Environmental Protection Agency, 23-Sep-2005.

6.7 Greenhouse Gas Emissions Permit Register Number IE-GHG078-3. Issued to Novartis Ringaskiddy Limited by the Environmental Protection Agency, 12-Aug-2008.

6.8 Sandoz Ringaskiddy Limited. Environmental Management Programme (16-Nov-1995).

6.9 Sandoz Ringaskiddy Limited: First Revision to Environmental Management Programme (18-Nov-1996).

6.10 Novartis Ringaskiddy Limited: Second Revision to Environmental Management Programme (21-Nov-1997).

6.11 Novartis Ringaskiddy Limited: Third Revision to Environmental Management Programme (07-Dec-1998).

6.12 Novartis Ringaskiddy Limited: Fourth Revision to Environmental Management Programme (15-Dec-1999).

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6.22 Sandoz Ringaskiddy Limited: Report on the Implementation of the Environmental Management Programme of 16-November-1995 (03-Feb-1997).

6.23 Novartis Ringaskiddy Limited: Report on the Implementation of the First Revision to Environmental Management Programme (11-Feb-1998).

6.24 Novartis Ringaskiddy Limited: Report on the Implementation of the Second Revision to Environmental Management Programme (23-Feb-1999).

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6.27 Novartis Ringaskiddy Limited: Report on the Implementation of the Fifth Revision to Environmental Management Programme (01-Feb-2002).

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6.29 Novartis Ringaskiddy Limited: Annual Environmental Report 2002 (01-Apr-2003).

6.30 Novartis Ringaskiddy Limited: Annual Environmental Report 2003 (01-Apr-2004).

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6.35 Novartis Ringaskiddy Limited: Annual Environmental Report 2008 (01-Apr-2009).

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6.37 Sandoz Ringaskiddy Limited. Safety and Environmental Performance 1994.

6.38 Sandoz Ringaskiddy Limited. Safety and Environmental Performance 1995.

6.39 Sandoz Ringaskiddy Limited: Environmental Statement 1996 (Covering the year 1995) (Prepared to Meet the Requirements of the European Community's EMAS Regulation).

6.40 Novartis Ringaskiddy Limited: Environmental Statement 1998 (Covering the years 1996 and 1997) (Prepared to Meet the Requirements of the European Community's EMAS Regulation).

6.41 Novartis Ringaskiddy Limited: Environmental Statement 1998 to 2000 (Prepared to Meet the Requirements of the European Community's EMAS Regulation).

6.42 Novartis Ringaskiddy Limited: Environmental Statement 2001 to 2003 (Prepared to Meet the Requirements of the European Community's EMAS Regulation).

6.43 Novartis Ringaskiddy Limited: Environmental Statement 2004 to 2006 (Prepared to Meet the Requirements of the European Community's EMAS Regulation).

6.44 Novartis Ringaskiddy Limited: Interim Environmental Statement 2007 (Prepared to Meet the Requirements of the European Community's EMAS Regulation).

6.45 Novartis Ringaskiddy Limited: Interim Environmental Statement 2008 (Prepared to Meet the Requirements of the European Community's EMAS Regulation).

6.46 Planning Register Reference Number S/2989/89 (Decision by An Bord Pleanála following appeal of Planning Register Reference Number S/2989/89 (Original Decision by Cork County Council).)

6.47 Council Regulation (EC) No 761/2001 of March 2001 Allowing Voluntary Participation by Organisations in a Community Eco-Management and Audit Scheme (EMAS).

6.48 Novartis Ringaskiddy Limited: Major Accident Prevention Policy. December, 2001. Prepared to meet the requirements of the Control of Major Accident Hazards Regulations, 2000 (S.I Number 476 of 2000).

6.49 Novartis Ringaskiddy Limited: Safety Case 2008. Prepared to meet the requirements of the European Communities (Control of Major Accident Hazards Involving Dangerous Substances) Regulations, 2006 (S.I. Number 74 of 2006).

Novartis Ringaskiddy Limited

Environmental Management Programme - Report 2009

Progress in Resource Conservation Activities

IPPCL Register Number P0006-03

Novartis Ringaskiddy Limited's thirteenth revision to its EMP (dated 01-Apr-2009) and covering the period 2009 continued to shift the emphasis from making continued progress in the area of resource management and conservation towards consolidating the progress that had been made over the past number of years. In addition to this process of consolidation a series of specific targets were elaborated for 2009 (continuing a process that commenced in 2004) and these are reported on elsewhere in this Annual Environmental Report. The following areas were identified as ones in which consolidation of previous progress would be maintained:

- Natural gas consumption.
- Electricity consumption.
- Water consumption.
- Fugitive emissions to atmosphere.
- Hazardous waste to be treated.
- Non-Hazardous waste to be disposed.
- Rectification of solvent material.

Updates on progress in relation to resource management and conservation based on implementation of the company's EMP during 2009 are presented on the following pages. Data on natural gas, electricity and water consumption are based on meter readings; data on fugitive emissions are based on regular measurements; while the data on hazardous and non-hazardous waste and rectified solvent material are based on the company's measurements and/or records.

Input in the following assessments is expressed per kilogramme of final product. Note that savings in water, natural gas and electricity consumption should lead to reduced wastewater discharge volumes to be treated and to reduced emissions (less running time of boilers and utility plant).

The 2004 to 2009 figures are based on actual data. The actual data for the years 2004 to 2008 have also been independently verified as part of the company's participation in EMAS and it is anticipated that the data for the year 2009 will be independently verified as part of the company's participation in EMAS during the first half of 2009.

- Water consumption. There was an on-going decrease in relative water consumption between 2008 and 2009, which continued the overall trend of a decrease in relative consumption over the past six years. Relative water consumption was 1.11 m^3/kg of product shipped in 2004 and stood at 0.73 m^3/kg of product shipped in 2009. This was driven by the implementation of a number of water conservation projects.

- Natural gas consumption. There was a decrease in relative natural gas consumption between 2008 and 2009, which continued the overall trend of a decrease in relative consumption over the past six years. Relative natural gas consumption was 0.91 GJ/kg of product shipped in 2004 and stood at 0.75 GJ/kg of product shipped in 2009. This decrease has been driven by the implementation of numerous energy conservation projects at the facility during this time.

- Electricity consumption. There was a decrease in relative electricity consumption between 2008 and 2009. As in the case of natural gas the overall trend in relative consumption indicates a decrease in relative consumption over the past six years. Relative electricity consumption was 0.56 GJ/kg of product shipped in 2004 and stood at 0.44 GJ/kg of product shipped in 2009. This decrease has been driven by the implementation of numerous energy conservation projects at the facility during this time.

- Fugitive emissions to atmosphere. There was another decrease in fugitive emissions between 2008 and 2009 – down to 0.0009 kg of organic carbon/kg of product shipped from 0.012 kg of organic carbon/kg of product shipped. Further work is due to be undertaken in this area during 2010 to consolidate this progress. The overall trend over the past six years has seen a reduction from 0.043 organic carbon/kg of product shipped in 2004 to 0.009 kg of organic carbon/kg of product shipped in 2009.

- Hazardous waste to be treated. There was a decrease in the relative amount of hazardous waste to be treated in 2009: Down to a figure of 0.005 tonne/kg of product shipped from the 2008 figure of 0.009 tonne/kg of product shipped. The overall trend over the past six years has seen a reduction in the relative amount of hazardous waste to be treated from 0.010 tonne/kg in 2004 to 0.005 tonne/kg in 2009. This decrease has been achieved though optimisation of production processes and by increasing the amount of solvent recovered on-site.

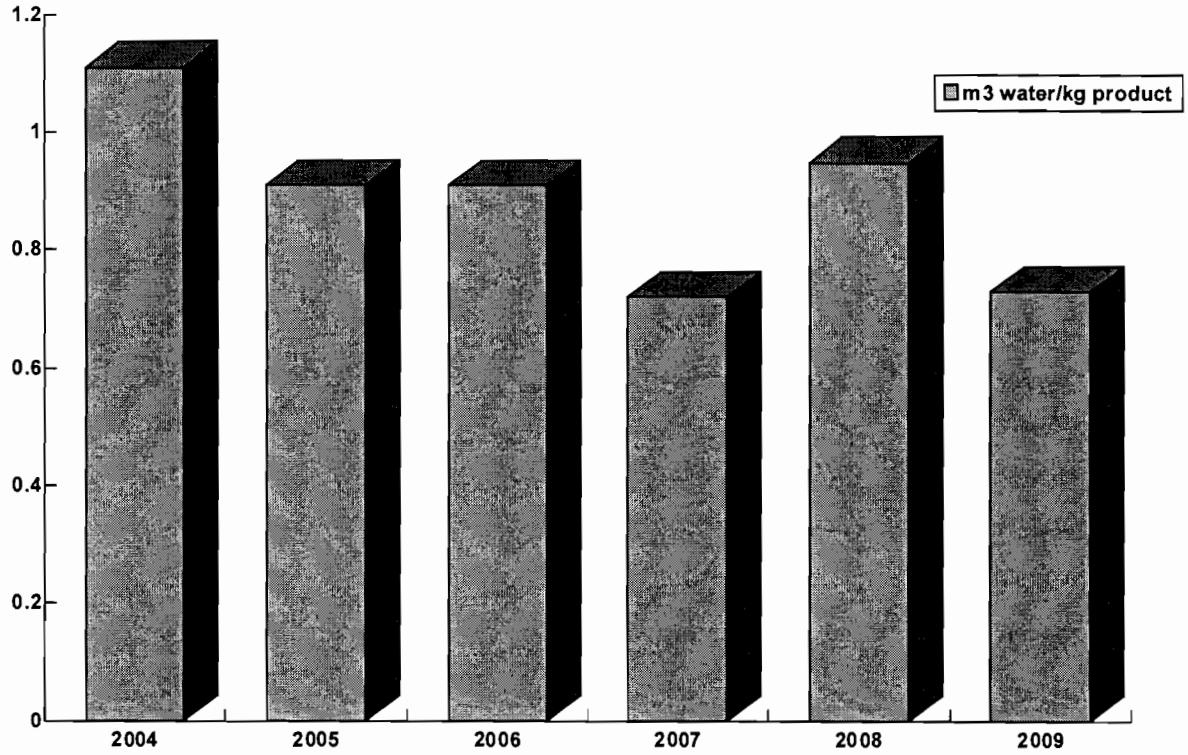
- Non-Hazardous waste to be treated/disposed. There was a decrease in the relative amount of non-hazardous waste to be treated/disposed between 2008 and 2009 –down from a figure of 0.0007 tonne/kg of product shipped to 0.0005 tonne/kg of product shipped. The latter figure was also significantly lower than the figure recorded for 2004, which was 0.0019 tonne/kg of product shipped.

- Rectification of solvent material. There was a significant increase in the actual amount of solvent material recovered in the facility's solvent recovery unit between 2008 and 2009: Up from a figure of 3,588 tonnes recovered during 2008 to a figure of 6,222 tonnes recovered during 2009. This reflected a significant allocation of resources to increasing solvent recovery efficiency at the facility and a number of additional projects are going to

be implemented during 2010 to consolidate this progress. The relative amount of solvent recovered has increased from 12.32 kg/kg of product shipped during 2004 to 16.58 kg/kg of product shipped during 2009.

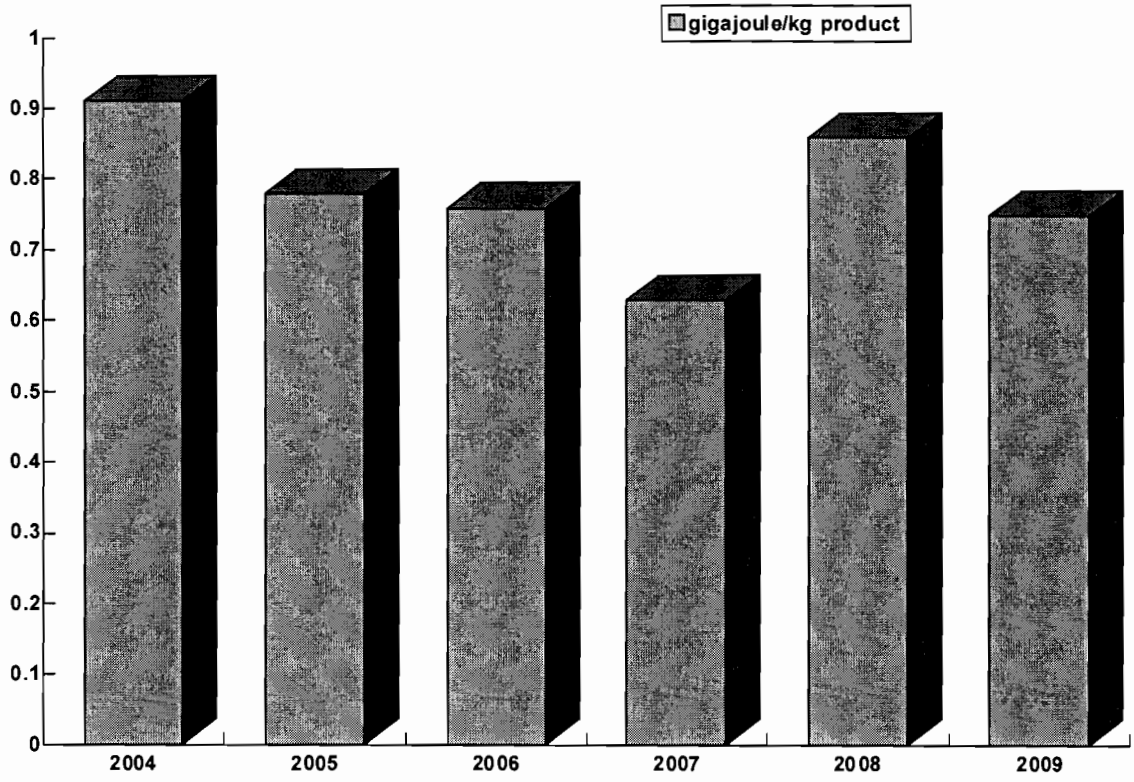
Water Consumption:

Water consumption is expressed as m^3 consumed per kilogramme of product manufactured.



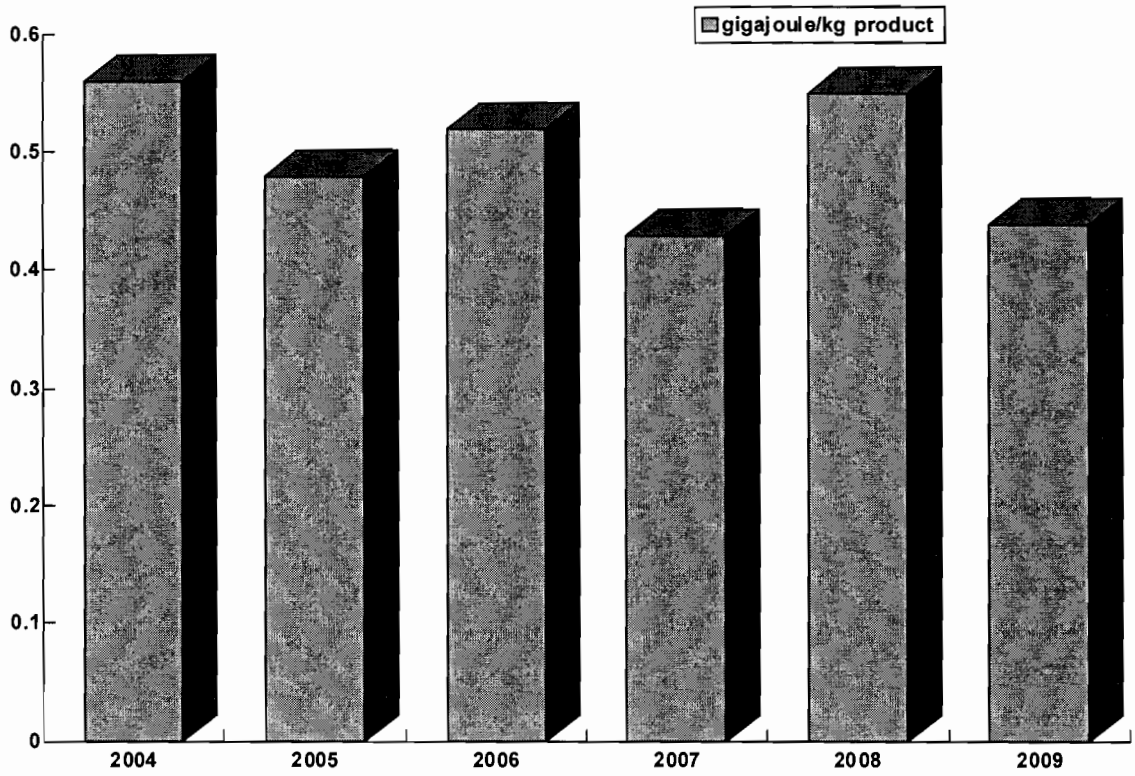
Natural Gas Consumption:

Natural Gas consumption is expressed as GigaJoule consumed per kilogramme of product manufactured.



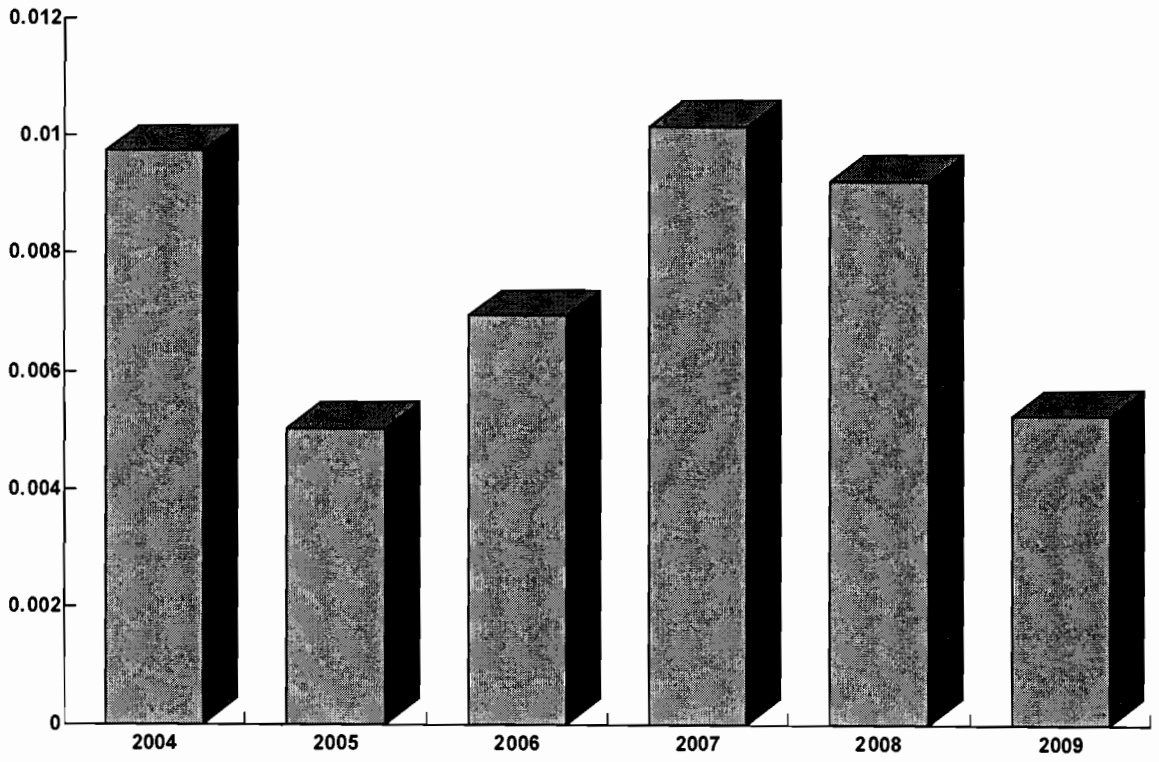
Electricity Consumption:

Electricity consumption is expressed as GigaJoule consumed per kilogramme of product manufactured.



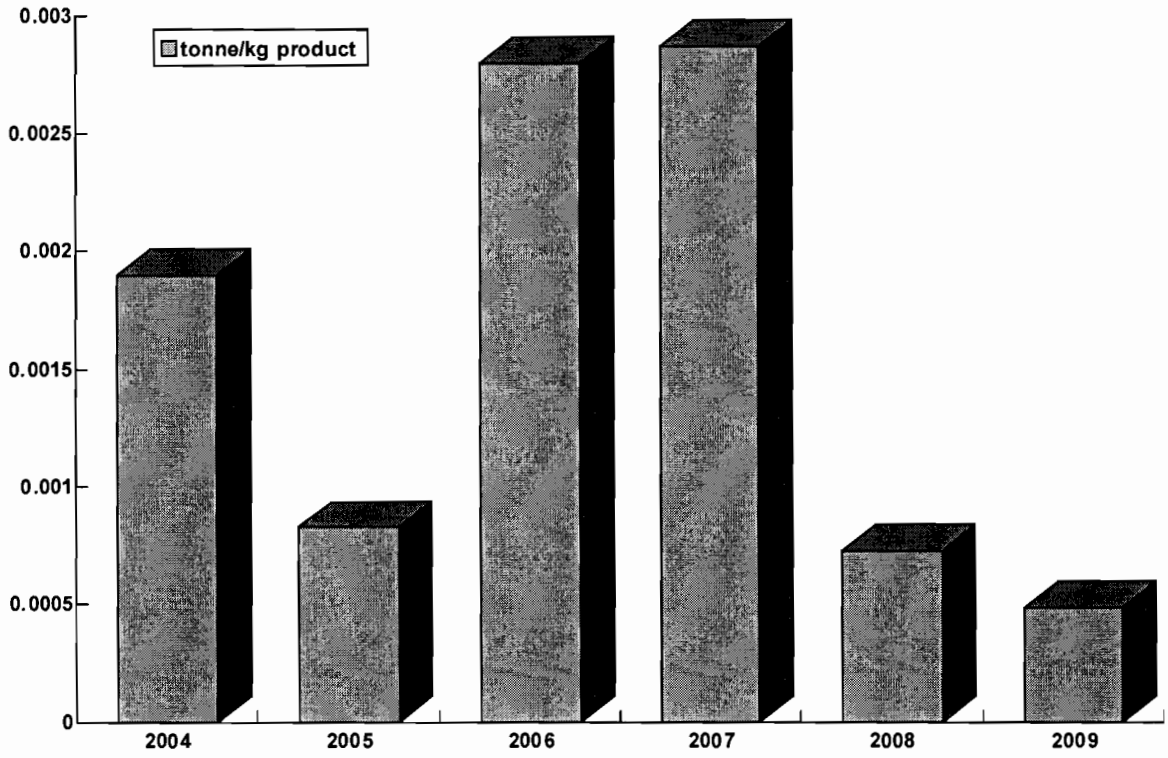
Hazardous Waste to be Treated:

Hazardous Waste to be treated is expressed as tonne treated per kilogramme of product manufactured.



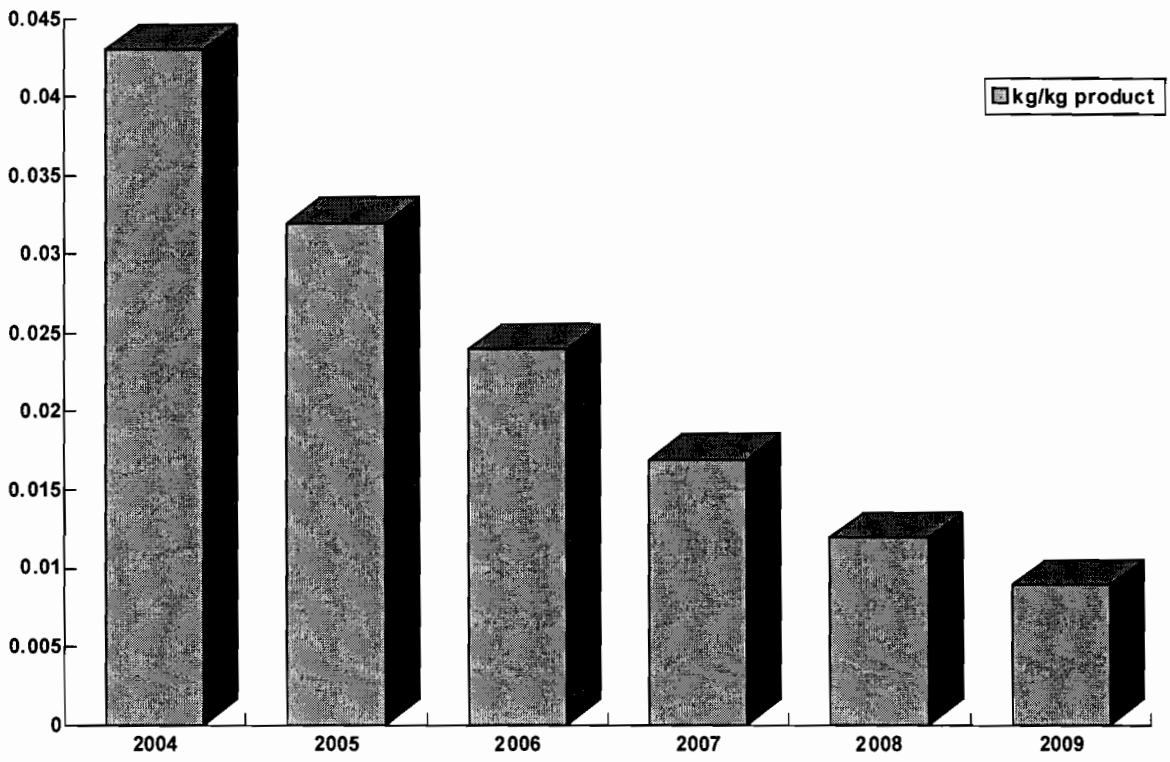
Non-Hazardous Waste to be Treated/Disposed:

Non-Hazardous Waste to be treated/disposed of is expressed as tonne per kilogramme of product manufactured.



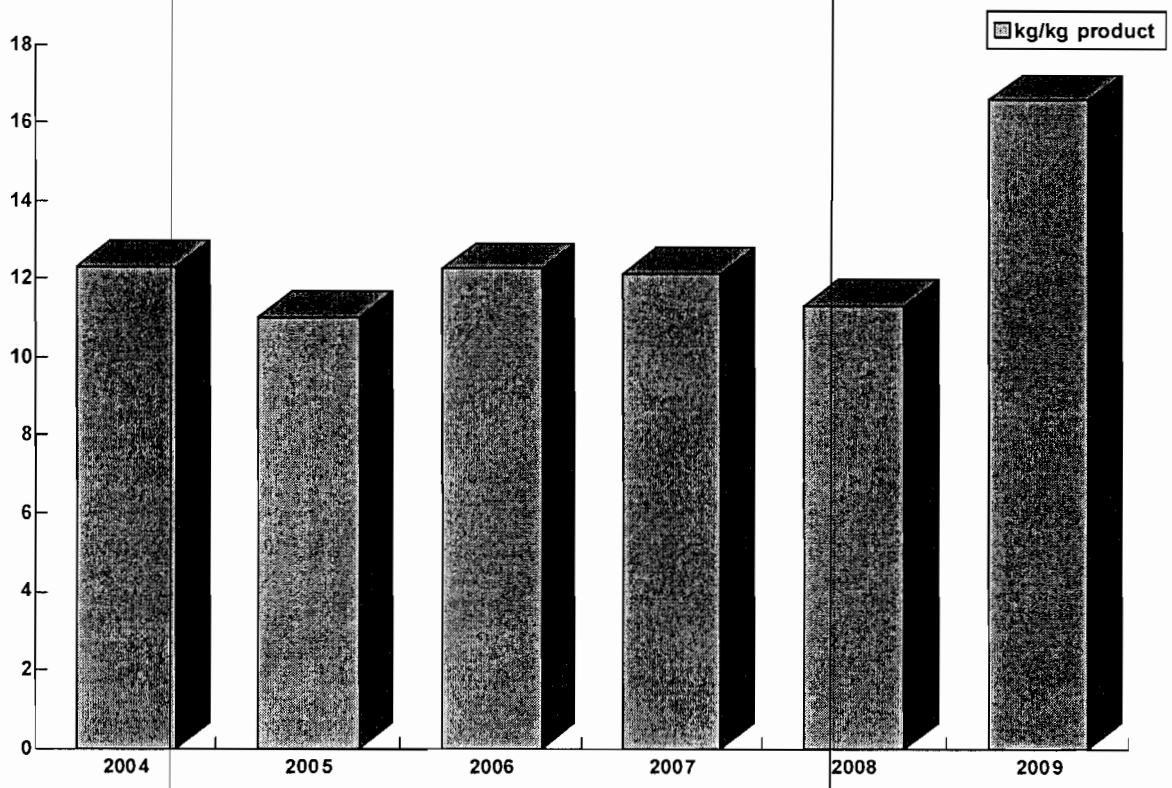
Fugitive Emissions:

Fugitive emissions from Production Buildings 1, 1A and 2 (the main production and purification buildings) are expressed as kilogramme of Organic Carbon emitted per kilogramme of product manufactured.



Rectified Solvent:

Solvent rectified (not including material recycled within the production buildings) is expressed as kilogramme per kilogramme of product manufactured.



Novartis Ringaskiddy Limited

Annual Environmental Report 2009

IPPCL Register Number P0006-03

Section 4: Licence Specific Reports:

Groundwater Monitoring Summary

Noise Monitoring Report

Report on List I and II Substance Reductions

Tank and Pipeline Testing and Inspection Report

Energy Audit Report

Effluent Toxicity Report

Environmental Liability Risk Assessment (Update)

Novartis Ringaskiddy Limited

Groundwater Monitoring Summary 2009

IPPCL Register Number P0006-03

Further to Schedule C.6 of IPPCL Register Number P0006-03, Novartis Ringaskiddy Limited wishes to present monitoring data for all parameters on groundwater sampled from the four monitoring wells specified in Schedule C.6 of the aforementioned licence.

Attachment I contains a copy of a report on groundwater quality of four samples taken from Monitoring Well Numbers MW1, MW2, MW3 and Artesian Well AW6 on 10-Jul-2009.

Attachment II contains a copy of a report on groundwater quality of four samples taken from Monitoring Well Numbers MW1, MW2, MW3 and Artesian Well AW6 on 17-Sep-2009.

The results indicate that the quality of the groundwater under the site at Novartis Ringaskiddy Limited has remained the same as that prior to the commencement of the development at Novartis Ringaskiddy Limited.

ATTACHMENT I

ENVIRONMENTAL
LABORATORY SERVICES
Acorn Business Campus,
Mahon Industrial Park,
Blackrock,
CorkTel: 021-4536141
Fax: 021-4536149

Analysis Report

Attention:		**Report No:**	14109
Vincent Boyton			
Novartis Ringaskiddy Limited		**Date of receipt:**	10/07/2009
IDA Estate,		**Date Started:**	13/07/2009
Ringaskiddy,			
Co. Cork			
Fax No:		**Issue Date:**	31/07/2009
Tel No:	021- 4862324	**Page**	1 **of** 3
PO Number:	OP-95758	**Delivery Mode**	Sampled by ELS Ltd
Sample Type	Ground Water	**No. of Samples**	4
Condition on receipt	Satisfactory	**Client Ref:**	Below

Test No	Parameter	Test Method
00025	Volatile Organic Compounds	EO 025 Purge and Trap/GC/MS
00089	Organic Solvents	Pre-concentration GC-FID
00016	Sulphates	EW016 Autoanalyser Spectrophotometry
00023	Phosphate	EW007 Phosphate by Autoanalyser Spectrophotometry
00034	Nitrate	EW034 -Nitrate by Autoanalyser Spectrophotometry
00035	Nitrite	EW035 Nitrite by Autoanalyser Spectrophotometry
00015	Chloride	EW015 Autoanalyser Spectrophotometry
00062	Alkalinity	EW062 Titralab
00130	Metals	EM130 ICP-MS
00019	pH	EW132 Electrometric Measurement
00042	Conductivity	EW139 Conductivity Titralab
00094	COD	EW094 by Closed Reflux Colorimetry

Technical Manager (or Deputy) Brendan Murray 31/07/2009

This report shall not be reproduced except in full, without the permission of the laboratory and only relates to the items tested.
See reverse side for INAB Accreditation Schedule. Only those tests,matrices ,ranges specified are accredited.
04/08/2009 09:26:57

			Amm	Cl	PO4	NO2	NO3	SO4	Al	Cd	Cr	Fe	Hg	Mn	Ni	Pb	Zn	Ca	Cu	Mg	Conductivity	BiCarbonate Alkalinity	Carbonate Alkalinity	pH	COD	TOC	Ground Water Depth
			mg/l NH4	mg/l	mg/l PO4	mg/l NO2	mg/l NO3	mg/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	mg/l	mg/l	mg/l	us/cm	mg/l HCO3	mg/l CO3	pH Units	mg/l	mg/l	-
Limit of Detection			0.009	1.4	0.028	0.043	0.53	1.0	5.0	0.1	1.0	5.0	0.02	1.0	0.5	0.3	1	1.0	0.003	0.3	0-1999	25	25	0.3	8	0.25	metres
Date Testing Initiated			14/07	13/07					13/07												13/07				21/07		10/07
ELS Reference	**Sampling Point Name**	**Date Sampled**																									
14109-1	AW-6	10/07/09	0.075	2.39	0.051	<0.043	<0.53	10.3	16	<0.1	1.1	13	<0.02	<1.0	1.2	<0.3	2.0	54.7	0.008	1.7	198	104	<25	7.8	<8	3.1	1.1
14109-2	MW-1	10/07/09	0.021	22.4	0.240	<0.043	9.31	31.2	241	<0.1	1.5	248	0.16	6.7	0.7	0.3	<1.0	128	0.007	9.0	565	265	<25	7.5	<8	0.8	7.6
14109-3	MW-2	10/07/09	0.057	13.4	0.078	0.073	3.00	39.3	246	<0.1	1.9	165	0.08	115	2.1	2.7	2.6	222	0.012	7.9	460	206	<25	7.5	<8	1.2	4.0
14109-4	MW-3	10/07/09	0.026	19.3	<0.028	<0.043	9.85	28.2	343	<0.1	1.6	509	0.21	4.9	1.0	0.6	<1.0	160	0.005	7.3	580	278	<25	7.5	<8	1.3	3.7

Solvent Analysis

Parameter	Units	Detection Limit	14109-1	14109-2	14109-3	14109-4
Methanol.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Ethanol.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Isopropyl Alcohol.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
n-Hexane.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
sec-Butyl Alcohol.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Acetic Acid.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Isopropyl Ether.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Ethyl Acetate.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Isopropyl Acetate.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Heptane.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
n-Butyl Alcohol.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Acetonitrile.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Cyclohexane.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Triethylamine.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
N,N-Dimethylformamide.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1

Appendix A

EO 025 Determination of Volatile Organic Carbons in Water by Purge and Trap/GC/MS

Analyte	LOD ug/l	14109-1	14109-2	14109-3	14109-4
Dichlorodifluoromethane	10.0	ND	ND	ND	ND
Chloromethane	0.5	ND	ND	ND	ND
Ethyl Chloride/Chloroethane	0.5	ND	ND	ND	ND
Vinyl Chloride/Chloroethene	0.5	ND	ND	ND	ND
Bromomethane	0.5	ND	ND	ND	ND
Trichloromonofluoromethane	0.5	ND	ND	ND	ND
Ethyl Ether/Diethyl Ether	0.5	ND	ND	ND	ND
11 Dichloroethene	0.5	ND	ND	ND	ND
Acetone	2.0	ND	ND	ND	ND
Iodomethane/Methyl Iodide	0.5	ND	ND	ND	ND
Carbon Disulphide	0.5	ND	ND	ND	ND
Allyl Chloride	0.5	ND	ND	ND	ND
Methylene Chloride/DCM	5.0	ND	ND	ND	ND
2-Propenenitrile/Acrylonitrile	2.0	ND	ND	ND	ND
Chlormethyl Cyanide/Chloroacetonitrile	0.5	ND	ND	ND	ND
Nitrobenzene	0.5	ND	ND	ND	ND
Propanenitrile	10.0	ND	ND	ND	ND
Hexachlorobutadiene	0.5	ND	ND	ND	ND
Trans-1,2 Dichloroethene	0.5	ND	ND	ND	ND
MtBE	0.5	ND	ND	ND	ND
11 Dichloroethane	0.5	ND	ND	ND	ND
22 Dichloropropane	0.5	ND	ND	ND	ND
cis-12 Dichloroethene	0.5	ND	ND	ND	ND
2-Butanone	5.0	ND	ND	ND	ND
Methyl Acrylate	5.0	ND	ND	ND	ND
Bromochloromethane	0.5	ND	ND	ND	ND
Methacrylonitrile	5.0	ND	ND	ND	ND
Tetrahydrofuran	5.0	ND	ND	ND	ND
Trichloromethane/ Chloroform	1.0	ND	ND	ND	ND
111 Trichloroethane	0.5	ND	ND	ND	ND
1-Chlorobutane	0.5	ND	ND	ND	ND
Carbon Tetrachloride	0.5	ND	ND	ND	ND
11 Dichloropropene	0.5	ND	ND	ND	ND
Benzene	0.1	ND	ND	ND	ND
12 Dichloroethane	0.1	ND	ND	ND	ND
Trichloroethylene/ Trichloroethene	0.1	ND	ND	ND	ND
12 Dichloropropane	0.5	ND	ND	ND	ND
Dibromomethane	0.5	ND	ND	ND	ND
Methyl Methacrylate	0.5	ND	ND	ND	ND
Bromodichloromethane	2.0	ND	ND	ND	ND
13 Dichloropropene,cis	2.0	ND	ND	ND	ND
MIBK/4 Methyl 2 Pentanone	2.0	ND	ND	ND	ND
Toluene	0.5	ND	ND	ND	ND
13 Dichloropropene,trans	2.0	ND	ND	ND	ND
Ethyl Methacrylate	2.0	ND	ND	ND	ND
112 Trichloroethane	0.5	ND	ND	ND	ND
Tetrachloroethylene/ Tetrachloroethene	0.1	ND	ND	ND	ND
13 Dichloropropane	0.5	ND	ND	ND	ND
2-Hexanone	1.0	ND	ND	ND	ND
Dibromochloromethane	1.0	ND	ND	ND	ND
12 Dibromoethane	0.5	ND	ND	ND	ND
Chlorobenzene	0.5	ND	ND	ND	ND
1112 Tetrachloroethane	2.0	ND	ND	ND	ND
Ethyl Benzene	0.5	ND	ND	ND	ND
m & p Xylene	0.5	ND	ND	ND	ND
o Xylene	0.5	ND	ND	ND	ND
Styrene	2.0	ND	ND	ND	ND
Bromoform	1.0	ND	ND	ND	ND
Isopropyl Benzene	0.5	ND	ND	ND	ND
Bromobenzene	0.5	ND	ND	ND	ND
1122 Tetrachloroethane	0.5	ND	ND	ND	ND
123 Trichloropropane	2.0	ND	ND	ND	ND
Trans 14 Dichloro 2 Butene, tran	2.0	ND	ND	ND	ND
Propyl Benzene	0.5	ND	ND	ND	ND
2-Chlorotoluene	0.5	ND	ND	ND	ND
4 Chlorotoluene	0.5	ND	ND	ND	ND
135 Trimethylbenzene	0.5	ND	ND	ND	ND
Tert Butyl Benzene	0.5	ND	ND	ND	ND
124 Trimethylbenzene	0.5	ND	ND	ND	ND
Sec Butyl Benzene	0.5	ND	ND	ND	ND
13 Dichlorobenzene	0.5	ND	ND	ND	ND
P Isopropyltoluene	0.5	ND	ND	ND	ND
14 Dichlorobenzene	0.5	ND	ND	ND	ND
12 Dichlorobenzene	0.5	ND	ND	ND	ND
N Butyl Benzene	0.5	ND	ND	ND	ND
Hexachloroethane	5.0	ND	ND	ND	ND
12 Dibromo 3 Chloropropane	2.0	ND	ND	ND	ND
124 Trichlorobenzene	0.5	ND	ND	ND	ND
Napththalene	2.0	ND	ND	ND	ND
123 Trichlorobenzene	0.50	ND	ND	ND	ND

NOTES

1. ND=Concentration was below the limit of detection

ENVIRONMENTAL
LABORATORY SERVICES
Acorn Business Campus,
Mahon Industrial Park,
Blackrock,
CorkTel: 021-4536141
Fax: 021-4536149

Supplement to Analysis Report Rev A

Attention:		**Report No:**	14109
Vincent Boyton			
Novartis Ringaskiddy Limited		**Date of receipt:**	10/07/2009
IDA Estate,		**Date Started:**	13/07/2009
Ringaskiddy,			
Co. Cork			
Fax No:		**Issue Date:**	23/03/2010
Tel No:	021- 4862324	**Page**	1 **of** 3
PO Number:	OP-95758	**Delivery Mode**	Sampled by ELS Ltd
Sample Type	Ground Water	**No. of Samples**	4
Condition on receipt	Satisfactory	**Client Ref:**	Below

Test No	Parameter	Test Method
00025	Volatile Organic Compounds	EO 025 Purge and Trap/GC/MS
00089	Organic Solvents	Pre-concentration GC-FID
00016	Sulphates	EW016 Autoanalyser Spectrophotometry
00023	Phosphate	EW007 Phosphate by Autoanalyser Spectrophotometry
00034	Nitrate	EW034 -Nitrate by Autoanalyser Spectrophotometry
00035	Nitrite	EW035 Nitrite by Autoanalyser Spectrophotometry
00015	Chloride	EW015 Autoanalyser Spectrophotometry
00062	Alkalinity	EW062 Titralab
00130	Metals	EM130 ICP-MS
00019	pH	EW132 Electrometric Measurement
00042	Conductivity	EW139 Conductivity Titralab
00094	COD	EW094 by Closed Reflux Colorimetry

SUPPLEMENT DETAILS
This report replaces report 14109 issued on 31/07/2009.The well water level was reported incorrectly

SIGNED **(23/03/2010)**

Technical Manager (or Deputy)
Brendan Murray

			Amm	Cl	PO4	NO2	NO3	SO4	Al	Cd	Cr	Fe	Hg	Mn	Ni	Pb	Zn	Ca	Cu	Mg	Conductivity	BiCarbonate Alkalinity	Carbonate Alkalinity	pH	COD	TOC	Ground Water Depth
			mg/l NH4	mg/l	mg/l PO4	mg/l NO2	mg/l NO3	mg/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	mg/l	mg/l	mg/l	us/cm	mg/l HCO3	mg/l CO3	pH Units	mg/l	mg/l	-
Limit of Detection			0.009	1.4	0.028	0.043	0.53	1.0	5.0	0.1	1.0	5.0	0.02	1.0	0.5	0.3	1	1.0	0.003	0.3	0-1999	25	25	0.3	8	0.25	metres
Date Testing Initiated			14/07	13/07					13/07												13/07				21/07		10/07
ELS Reference	**Sampling Point Name**	**Date Sampled**																									
14109-1	AW-6	10/07/2009	0.075	2.39	0.051	<0.043	<0.53	10.3	16	<0.1	1.1	13	<0.02	<1.0	1.2	<0.3	2.0	54.7	0.008	1.7	198	104	<25	7.8	<8	3.1	18.9
14109-2	MW-1	10/07/2009	0.021	22.4	0.240	<0.043	9.31	31.2	241	<0.1	1.5	248	0.16	6.7	0.7	0.3	<1.0	128	0.007	9.0	565	265	<25	7.5	<8	0.8	19.5
14109-3	MW-2	10/07/2009	0.057	13.4	0.078	0.073	3.00	39.3	246	<0.1	1.9	165	0.08	115	2.1	2.7	2.6	222	0.012	7.9	460	206	<25	7.5	<8	1.2	18.3
14109-4	MW-3	10/07/2009	0.026	19.3	<0.028	<0.043	9.85	28.2	343	<0.1	1.6	509	0.21	4.9	1.0	0.6	<1.0	160	0.005	7.3	580	278	<25	7.5	<8	1.3	10.7

Solvent Analysis

Parameter	Units	Detection Limit	14109-1	14109-2	14109-3	14109-4
Methanol.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Ethanol.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Isopropyl Alcohol.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
n-Hexane.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
sec-Butyl Alcohol.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Acetic Acid.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Isopropyl Ether.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Ethyl Acetate.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Isopropyl Acetate.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Heptane.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
n-Butyl Alcohol.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Acetonitrile	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Cyclohexane.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Triethylamine.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
N,N-Dimethylformamide.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1

Environmental Laboratory Services Ltd

Appendix A

EO 025 Determination of Volatile Organic Carbons in Water by Purge and Trap/GC/MS

Analyte	LOD ug/l	14109-1	14109-2	14109-3	14109-4
Dichlorodifluoromethane	10.0	ND	ND	ND	ND
Chloromethane	0.5	ND	ND	ND	ND
Ethyl Chloride/Chloroethane	0.5	ND	ND	ND	ND
Vinyl Chloride/Chloroethene	0.5	ND	ND	ND	ND
Bromomethane	0.5	ND	ND	ND	ND
Trichloromonofluoromethane	0.5	ND	ND	ND	ND
Ethyl Ether/Diethyl Ether	0.5	ND	ND	ND	ND
11 Dichloroethene	0.5	ND	ND	ND	ND
Acetone	2.0	ND	ND	ND	ND
Iodomethane/Methyl Iodide	0.5	ND	ND	ND	ND
Carbon Disulphide	0.5	ND	ND	ND	ND
Allyl Chloride	0.5	ND	ND	ND	ND
Methylene Chloride/DCM	5.0	ND	ND	ND	ND
2-Propenenitrile/Acrylonitrile	2.0	ND	ND	ND	ND
Chlormethyl Cyanide/Chloroacetonitrile	0.5	ND	ND	ND	ND
Nitrobenzene	0.5	ND	ND	ND	ND
Propanenitrile	10.0	ND	ND	ND	ND
Hexachlorobutadiene	0.5	ND	ND	ND	ND
Trans-1,2 Dichloroethene	0.5	ND	ND	ND	ND
MtBE	0.5	ND	ND	ND	ND
11 Dichloroethane	0.5	ND	ND	ND	ND
22 Dichloropropane	0.5	ND	ND	ND	ND
cis-12 Dichloroethene	0.5	ND	ND	ND	ND
2-Butanone	5.0	ND	ND	ND	ND
Methyl Acrylate	5.0	ND	ND	ND	ND
Bromochloromethane	0.5	ND	ND	ND	ND
Methacrylonitrile	5.0	ND	ND	ND	ND
Tetrahydrofuran	5.0	ND	ND	ND	ND
Trichloromethane/ Chloroform	1.0	ND	ND	ND	ND
111 Trichloroethane	0.5	ND	ND	ND	ND
1-Chlorobutane	0.5	ND	ND	ND	ND
Carbon Tetrachloride	0.5	ND	ND	ND	ND
11 Dichloropropene	0.5	ND	ND	ND	ND
Benzene	0.1	ND	ND	ND	ND
12 Dichloroethane	0.1	ND	ND	ND	ND
Trichloroethylene/ Trichloroethene	0.1	ND	ND	ND	ND
12 Dichloropropane	0.5	ND	ND	ND	ND
Dibromomethane	0.5	ND	ND	ND	ND
Methyl Methacrylate	0.5	ND	ND	ND	ND
Bromodichloromethane	2.0	ND	ND	ND	ND
13 Dichloropropene,cis	2.0	ND	ND	ND	ND
MIBK/4 Methyl 2 Pentanone	2.0	ND	ND	ND	ND
Toluene	0.5	ND	ND	ND	ND
13 Dichloropropene,trans	2.0	ND	ND	ND	ND
Ethyl Methacrylate	2.0	ND	ND	ND	ND
112 Trichloroethane	0.5	ND	ND	ND	ND
Tetrachloroethylene/ Tetrachloroethene	0.1	ND	ND	ND	ND
13 Dichloropropane	0.5	ND	ND	ND	ND
2-Hexanone	1.0	ND	ND	ND	ND
Dibromochloromethane	1.0	ND	ND	ND	ND
12 Dibromoethane	0.5	ND	ND	ND	ND
Chlorobenzene	0.5	ND	ND	ND	ND
1112 Tetrachloroethane	2.0	ND	ND	ND	ND
Ethyl Benzene	0.5	ND	ND	ND	ND
m & p Xylene	0.5	ND	ND	ND	ND
o Xylene	0.5	ND	ND	ND	ND
Styrene	2.0	ND	ND	ND	ND
Bromoform	1.0	ND	ND	ND	ND
Isopropyl Benzene	0.5	ND	ND	ND	ND
Bromobenzene	0.5	ND	ND	ND	ND
1122 Tetrachloroethane	0.5	ND	ND	ND	ND
123 Trichloropropane	2.0	ND	ND	ND	ND
Trans 14 Dichloro 2 Butene, tran	2.0	ND	ND	ND	ND
Propyl Benzene	0.5	ND	ND	ND	ND
2-Chlorotoluene	0.5	ND	ND	ND	ND
4 Chlorotoluene	0.5	ND	ND	ND	ND
135 Trimethylbenzene	0.5	ND	ND	ND	ND
Tert Butyl Benzene	0.5	ND	ND	ND	ND
124 Trimethylbenzene	0.5	ND	ND	ND	ND
Sec Butyl Benzene	0.5	ND	ND	ND	ND
13 Dichlorobenzene	0.5	ND	ND	ND	ND
P Isopropyltoluene	0.5	ND	ND	ND	ND
14 Dichlorobenzene	0.5	ND	ND	ND	ND
12 Dichlorobenzene	0.5	ND	ND	ND	ND
N Butyl Benzene	0.5	ND	ND	ND	ND
Hexachloroethane	5.0	ND	ND	ND	ND
12 Dibromo 3 Chloropropane	2.0	ND	ND	ND	ND
124 Trichlorobenzene	0.5	ND	ND	ND	ND
Napththalene	2.0	ND	ND	ND	ND
123 Trichlorobenzene	0.50	ND	ND	ND	ND

NOTES

1. ND=Concentration was below the limit of detection

ELS LTD INAB ACCREDITATION SCHEDULE SUMMARY SHEET

Miscellaneous (P,G,W,S)
Ammonia/Ammonium 0.007-1mg/l N EW003
Chloride 2.6-250 mg/l EW015
Flouride 0.1 - 2 mg/l EW137
COD 8-1500 mg/l EW094
Nitrate 0.12-50 mg/l N EW034
Nitrite 0.013-1 mg/l N EW035
pH 4 – 10 pH Units EW138
Phosphate 0.009-1 mg/l P EW007
Alkalinity 10-1000mg/l EW062
TOC 0.25-100mg/l EW123
BOD 1-1300mg/l EW001
Total Nitrogen 1-100mg/l N EW140
Total Phosphorous 0.01-40 mg/l P EW143

Miscellaneous (P,G,S)
Bromate 1 to 50ug/l BRO3 (EW137)
Colour 2.5-50mg/l PtCCo (EW021)
Conductivity 25-6000 us/cm EW139
Dissolved Oxygen 1 to 10 mg/l (EW043)
Sulphate 1-250mg/l SO4(EW016)
Suspended Solids 5-1000mg/l (EW013)
Total Dissolved Solids 1-1000mg/l (EW046)
Total Hardness 3-330mg/l CaCO3 (EM099)
Total Oxidised Nitrogen 0.138-51mg/l N (EW051)

ıls EM130 (P,G,S)
. ..inium 5.0 – 500 µg/l
Antimony 0.1 – 10µg/l
Arsenic 0.2 - 20µg/l
Barium 1.0 - 100µg/l
Boron 0.02 – 2mg/l
Cadmium 0.1 – 10µg/l
Calcium 1.0 – 100mg/l
Chromium 1.0 - 100µg/l
Cobalt 1.0 - 100µg/l
Copper 3 - 4000µg/l
Iron 5.0 - 500µg/l
Lead 0.3 - 30µg/l
Magnesium 0.3 – 20mg/l
Manganese 1.0 - 100µg/l
Mercury 0.02 - 2µg/l
Molybdenum 1.0 - 100µg/l
Nickel 0.5 - 50µg/l
Potassium 0.2 – 20mg/l
Selenium 0.2 - 20µg/l
Sodium 0.5 – 50mg/l
Strontium 1.0 - 100µg/l
Tin 1.0 - 100µg/l
Vanadium 1.0 - 100µg/l
Z.. - 1.0 - 100µg/l

) Potable Water VOCs & THM
EO025 (P,G,S)
Benzene 0.1-35 µg/l
1.2-Dichloroethane 0.1-35 µg/l
Tetrachloroethene 0.1-35 µg/l
Trichloroethene 0.1-35 µg/l
Chloroform 1.0-150 µg/l
Bromoform 1.0-35 µg/l
Dibromochloromethane 1.0-35 µg/l
Bromodichloromethane 2.0-35 µg/l

Other VOC's EO025 (P,G,S)
Bromomethane 0.5 - 35 µg/l
Ethyl Ether/Diethyl Ether0.5 - 35 µg/l
11 Dichloroethene0.5 - 35 µg/l
Iodomethane/Mehyl Iodide 0.5 - 35 µg/l
Carbon Disulphide 0.5 - 35 µg/l
Allyl Chloride0.5 - 35 µg/l
Methylene Chloride/DCM 5.0 - 35 µg/l
2-Propenenitrile/Acrylonitrile 2.0 - 35 µg/l
Chlormethyl Cyanide 0.5 - 35 µg/l
Hexachlorobutadiene0.5 - 35 µg/l
Trans-1,2 Dichloroethene0.5 - 35 µg/l
MtBE0.5 - 35 µg/l
11 Dichloroethane0.5 - 35 µg/l
22 Dichloropropane0.5 - 35 µg/l
Cis-12 Dichloroethene0.5 - 35 µg/l
Methyl Acrylate5.0 - 35 µg/l
Bromochloromethane0.5 - 35 µg/l
Tetrahydrofuran5.0 - 35 µg/l
111 Trichloroethane0.5 - 35 µg/l
1-Chlorobutane0.5 - 35 µg/l
Carbon Tetrachloride0.5 - 35 µg/l
11 Dichloropropene0.5 - 35 µg/l
12 Dichloropropane0.5 - 35 µg/l
Dibromomethane0.5 - 35 µg/l
Methyl Methacrylate0.5 - 35 µg/l
13 Dichloropropene, cis2.0 - 35 µg/l
MIBK/4 Methyl 2 Pentanone 2.0 - 35 µg/l
Toluene0.5 - 35 µg/l
13 Dichloropropene,trans2.0 - 35 µg/l
Ethyl Methacrylate2.0 - 35 µg/l
112 Trichloroethane0.5 - 35 µg/l
13 Dichloropropane0.5 - 35 µg/l
2 Hexanone1.0 - 35 µg/l
12 Dibromoethane0.5 - 35 µg/l
Chlorobenzene0.5 - 35 µg/l
1112 Tetrachloroethane2.0 - 35 µg/l
Ethyl Benzene0.5 - 35 µg/l
m & p Xylene0.5 - 35 µg/l
O Xylene0.5 - 35 µg/l
Stryene2.0 - 35 µg/l
Isopropyl Benzene0.5 - 35 µg/l
Bromobenzene0.5 - 35 µg/l
1122 Tetrachloroethane0.5 - 35 µg/l
123 Trichloropropane2.0 - 35 µg/l
Propyl Benzene0.5 - 35 µg/l
2-Chlorotoluene0.5 - 35 µg/l
4 Chlorotoluene0.5 - 35 µg/l
135 Trimenthylbenzene0.5 - 35 µg/l
Tert Butyl Benzene0.5 - 35 µg/l
124 Trimethlbenzene0.5 - 35 µg/l
Sec Butyl Benzene0.5 - 35 µg/l
13 Dichlorobenzene0.5 - 35 µg/l
P Isopropyltoluene0.5 - 35 µg/l
14 Dichlorobenzene0.5 - 35 µg/l
12 Dichlorobenzene0.5 - 35 µg/l
N Butyl Benzene0.5 - 35 µg/l
Hexachloroethane5.0 - 35 µg/l
12 Dibromo 3Chloropropane 2.0 - 35 µg/l
124 Trichlorobenzene0.5 - 35 µg/l
123 Trichlorobenzene0.5 - 35 µg/l

PAH EO129 (P,G,S)
Range 0.01 - 0.2 µg/l
Acenaphthene
Benzo (a) Anthracene
Benzo (a) Pyrene
Benzo (b) Fluoranthene
Benzo (ghi) Perylene
Benzo (k) Fluoranthene
Chrysene
Dibenzo (ah) Anthracene
Fluoranthene
Fluorene
Indeno (123-cd) Pyrene
Phenanthrene
Pyrene

Acid Herbicides (P,G,S)
Range 0.01 - 0.2 µg/l
2,4,5-T H
2,4-D H
2,4-DB H
MCPA H
Picloram H

Organophosphorus Pesticides(P,G,S)
Range 0.01 - 0.2 µg/l
Famphur OP
Methyl Parathion OP
Parathion OP
Thionazin OP

Organochlorine Pesticides (P,G,S)
Range 0.01 - 0.2 µg/l
Aldrin
BHC Alpha isomer OC
BHC Beta isomer OC
BHC Delta isomer OC
Dieldrin OC
Endosulphan Alpha isomer OC
Endosulphan Beta isomer OC
Endosulphan Sulphate OC
Endrin OC
Heptachlor Epoxide OC
Heptachlor OC
Lindane OC
P,P' DDE OC
P,P'-DDD OC
P,P'-DDT OC

Notes

ATTACHMENT II

ENVIRONMENTAL
LABORATORY SERVICES
Acorn Business Campus,
Mahon Industrial Park,
Blackrock,
CorkTel: 021-4536141
Fax: 021-4536149

Analysis Report

Attention:		**Report No:**	14845
Vincent Boyton			
Novartis Ringaskiddy Limited		**Date of receipt:**	18/09/2009
IDA Estate,Ringaskiddy,Co. Cork		**Date Started:**	18/09/2009
Fax No:		**Issue Date:**	20/10/2009
Tel No:	021- 4862324	**Page**	1 **of** 3
PO Number:	OP-95758	**Delivery Mode**	Sampled by ELS Ltd
Sample Type	Ground Water	**No. of Samples**	4
Condition on receipt	Satisfactory	**Client Ref:**	Below

Test No	Parameter	Test Method
00025	Volatile Organic Compounds	EO 025 Purge and Trap/GC/MS
00089	Organic Solvents	Pre-concentration GC-FID
00016	Sulphates	EW016 Autoanalyser Spectrophotometry
00023	Phosphate	EW007 Phosphate by Autoanalyser Spectrophotometry
00034	Nitrate	EW034 -Nitrate by Autoanalyser Spectrophotometry
00035	Nitrite	EW035 Nitrite by Autoanalyser Spectrophotometry
00015	Chloride	EW015 Autoanalyser Spectrophotometry
00062	Alkalinity	EW062 Titralab
00130	Metals	EM130 ICP-MS
00019	pH	EW132 Electrometric Measurement
00042	Conductivity	EW139 Conductivity Titralab
00094	COD	EW094 by Closed Reflux Colorimetry

SIGNED **(20/10/2009)**

Technical Manager (or Deputy)
Brendan Murray

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See reverse side for INAB Accreditation Schedule. Only those tests,matrices ,ranges specified are accredited

			Amm	Cl	PO4	NO2	NO3	SO4	Al	Cd	Cr	Fe	Hg	Mn	Ni	Pb	Zn	Ca	Cu	Mg	Conductivity	BiCarbonate Alkalinity	Carbonate Alkalinity	pH	COD	TOC	Ground Water Depth
			mg/l NH4	mg/l	mg/l PO4	mg/l NO2	mg/l NO3	mg/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	mg/l	mg/l	mg/l	us/cm	mg/l HCO3	mg/l CO3	pH Units	mg/l	mg/l	-
Limit of Detection			0.009	2.6	0.028	0.043	0.53	1.0	5.0	0.1	1.0	5.0	0.02	1.0	0.5	0.3	1	1.0	0.003	0.3	25	3	3	0.3	8	0.25	metres
Date Testing Initiated			21/09	18/09					21/09																21/09	22/09	
ELS Reference	**Sampling Point Name**	**Date Sampled**																									
14845-1	AW06	17/09/2009	0.048	<2.6	0.069	<0.043	0.732	10.8	160	<0.1	<1.0	284	<0.02	64.9	1.7	3.8	48.1	36.5	0.011	1.3	182	100	0	7.9	<8	3.1	Note 1
14845-2	MW-1	17/09/2009	0.080	17.8	0.036	0.052	7.52	29.6	<5.0	<0.1	<1.0	15.2	<0.02	2.5	1.0	<0.3	<1.0	109	<0.003	8.5	547	282	0	7.8	<8	1.4	8.2
14845-3	MW-2	17/09/2009	0.068	12.8	0.035	0.076	3.00	41.5	<5.0	<0.1	<1.0	13.3	<0.02	88.3	0.8	<0.3	<1.0	79.2	<0.003	6.5	459	218	0	7.9	<8	1.3	4.6
14845-4	MW-3	17/09/2009	0.093	20.5	0.204	0.158	7.19	32.7	240	0.2	<1.0	434	0.06	396	2.5	8.7	4.1	129	<0.003	7.3	579	295	0	7.9	<8	1.4	4.3

NOTE
1 Unable to measure water level due to depth

Solvent Analysis

Parameter	Units	Detection Limit	14845-1	14845-2	14845-3	14845-4
Methanol	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Ethanol	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Isopropyl Alcohol	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
n-Hexane	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
sec-Butyl Alcohol	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Acetic Acid	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Isopropyl Ether	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Ethyl Acetate	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Isopropyl Acetate	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Heptane	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
n-Butyl Alcohol	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Acetonitrile	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Cyclohexane	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Triethylamine	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
N,N-Dimethylformai	mg/l	0.1	<0.1	<0.1	<0.1	<0.1

Environmental Laboratory Services Ltd

Report Number 14845
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Appendix A

EO 025 Determination of Volatile Organic Carbons in Water by Purge and Trap/GC/MS

Analyte	LOD ug/l	14845-1	14845-2	14845-3	14845-4
Dichlorodifluoromethane	10.0	N.D	N.D	N.D	N.D
Chloromethane	0.5	N.D	N.D	N.D	N.D
Ethyl Chloride/Chloroethane	0.5	N.D	N.D	N.D	N.D
Vinyl Chloride/Chloroethene	0.5	N.D	N.D	N.D	N.D
Bromomethane	0.5	N.D	N.D	N.D	N.D
Trichloromonofluoromethane	0.5	N.D	N.D	N.D	N.D
Ethyl Ether/Diethyl Ether	0.5	Note 2	Note 2	Note 2	Note 2
11 Dichloroethene	0.5	N.D	N.D	N.D	N.D
Acetone	2.0	N.D	N.D	N.D	N.D
Iodomethane/Methyl Iodide	0.5	N.D	N.D	N.D	N.D
Carbon Disulphide	0.5	N.D	N.D	N.D	N.D
Allyl Chloride	0.5	N.D	N.D	N.D	N.D
Methylene Chloride/DCM	5.0	N.D	N.D	N.D	N.D
2-Propenenitrile/Acrylonitrile	2.0	Note 2	Note 2	Note 2	Note 2
Chlormethyl Cyanide/Chloroacetonitrile	0.5	N.D	N.D	N.D	N.D
Nitrobenzene	0.5	N.D	N.D	N.D	N.D
Propanenitrile	10.0	N.D	N.D	N.D	N.D
Hexachlorobutadiene	0.5	N.D	N.D	N.D	N.D
Trans-1,2 Dichloroethene	0.5	N.D	N.D	N.D	N.D
MtBE	0.5	N.D	N.D	N.D	N.D
11 Dichloroethane	0.5	Note 2	Note 2	Note 2	Note 2
22 Dichloropropane	0.5	Note 2	Note 2	Note 2	Note 2
cis-12 Dichloroethene	0.5	N.D	N.D	N.D	N.D
2-Butanone	5.0	N.D	N.D	N.D	N.D
Methyl Acrylate	5.0	N.D	N.D	N.D	N.D
Bromochloromethane	0.5	N.D	N.D	N.D	N.D
Methacrylonitrile	5.0	N.D	N.D	N.D	N.D
Tetrahydrofuran	5.0	Note 2	Note 2	Note 2	Note 2
Trichloromethane/ Chloroform	1.0	N.D	N.D	N.D	N.D
111 Trichloroethane	0.5	N.D	N.D	N.D	N.D
1-Chlorobutane	0.5	N.D	N.D	N.D	N.D
Carbon Tetrachloride	0.5	Note 2	Note 2	Note 2	Note 2
11 Dichloropropene	0.5	Note 2	Note 2	Note 2	Note 2
Benzene	0.1	N.D	N.D	N.D	N.D
12 Dichloroethane	0.1	N.D	N.D	N.D	N.D
Trichloroethylene/ Trichloroethene	0.1	N.D	N.D	N.D	N.D
12 Dichloropropane	0.5	N.D	N.D	N.D	N.D
Dibromomethane	0.5	N.D	N.D	N.D	N.D
Methyl Methacrylate	0.5	N.D	N.D	N.D	N.D
Bromodichloromethane	2.0	N.D	N.D	N.D	N.D
13 Dichloropropene,cis	2.0	N.D	N.D	N.D	N.D
MIBK/4 Methyl 2 Pentanone	2.0	N.D	N.D	N.D	N.D
Toluene	0.5	N.D	N.D	N.D	N.D
13 Dichloropropene,trans	2.0	N.D	N.D	N.D	N.D
Ethyl Methacrylate	2.0	N.D	N.D	N.D	N.D
112 Trichloroethane	0.5	N.D	N.D	N.D	N.D
Tetrachloroethylene/ Tetrachloroethene	0.1	N.D	N.D	N.D	N.D
13 Dichloropropane	0.5	N.D	N.D	N.D	N.D
2-Hexanone	1.0	N.D	N.D	N.D	N.D
Dibromochloromethane	1.0	N.D	N.D	N.D	N.D
12 Dibromoethane	0.5	N.D	N.D	N.D	N.D
Chlorobenzene	0.5	N.D	N.D	N.D	N.D
1112 Tetrachloroethane	2.0	N.D	N.D	N.D	N.D
Ethyl Benzene	0.5	N.D	N.D	N.D	N.D
m & p Xylene	0.5	N.D	N.D	N.D	N.D
o Xylene	0.5	N.D	N.D	N.D	N.D
Styrene	2.0	N.D	N.D	N.D	N.D
Bromoform	1.0	N.D	N.D	N.D	N.D
Isopropyl Benzene	0.5	N.D	N.D	N.D	N.D
Bromobenzene	0.5	N.D	N.D	N.D	N.D
1122 Tetrachloroethane	0.5	N.D	N.D	N.D	N.D
123 Trichloropropane	2.0	N.D	N.D	N.D	N.D
Trans 14 Dichloro 2 Butene, tran	2.0	N.D	N.D	N.D	N.D
Propyl Benzene	0.5	N.D	N.D	N.D	N.D
2-Chlorotoluene	0.5	N.D	N.D	N.D	N.D
4 Chlorotoluene	0.5	N.D	N.D	N.D	N.D
135 Trimethylbenzene	0.5	N.D	N.D	N.D	N.D
Tert Butyl Benzene	0.5	N.D	N.D	N.D	N.D
124 Trimethylbenzene	0.5	N.D	N.D	N.D	N.D
Sec Butyl Benzene	0.5	N.D	N.D	N.D	N.D
13 Dichlorobenzene	0.5	N.D	N.D	N.D	N.D
P Isopropyltoluene	0.5	N.D	N.D	N.D	N.D
14 Dichlorobenzene	0.5	Note 2	Note 2	Note 2	Note 2
12 Dichlorobenzene	0.5	N.D	N.D	N.D	N.D
N Butyl Benzene	0.5	N.D	N.D	N.D	N.D
Hexachloroethane	5.0	N.D	N.D	N.D	N.D
12 Dibromo 3 Chloropropane	2.0	N.D	N.D	N.D	N.D
124 Trichlorobenzene	0.5	N.D	N.D	N.D	N.D
Napththalene	2.0	N.D	N.D	N.D	N.D
123 Trichlorobenzene	0.50	N.D	N.D	N.D	N.D

NOTES

1. ND=Concentration was below the limit of detection
2. Not reported due to QC failure

ELS LTD INAB ACCREDITATION SCHEDULE SUMMARY SHEET

Miscellaneous (P,G,W,S)
Ammonia/Ammonium 0.007-1mg/l N EW003
Chloride 2.6-250 mg/l EW015
Flouride 0.1 - 2 mg/l EW137
COD 8-1500 mg/l EW094
Nitrate 0.12-50 mg/l N EW034
Nitrite 0.013-1 mg/l N EW035
pH 4 – 10 pH Units EW138
Phosphate 0.009-1 mg/l P EW007
TOC 0.25-100mg/l EW123
Total Phosphorous 0.03-1 mg/l P EW002

Miscellaneous (P,G,S)
Bromate 1 to 50ug/l BRO3 (EW137)
Colour 2.5-50mg/l PtCCo (EW021)
Conductivity 132-6000 us/cm EW139
Dissolved Oxygen 1 to 10 mg/l (EW043)
Sulphate 1-250mg/l SO4(EW016)
Suspended Solids 5-1000mg/l (EW013)
Total Dissolved Solids 1-1000mg/l (EW046)
Total Hardness 3-330mg/l CaCO3 (EM099)
' Oxidised Nitrogen 0.138-51mg/l N (EW051)

.als EM130 (P,G,S)
Aluminium 5.0 – 500 µg/l
Antimony 0.1 – 10µg/l
Arsenic 0.2 - 20µg/l
Barium 1.0 - 100µg/l
Boron 0.02 – 2mg/l
Cadmium 0.1 – 10µg/l
Calcium 1.0 – 100mg/l
Chromium 1.0 - 100µg/l
Cobalt 1.0 - 100µg/l
Copper 3 - 4000µg/l
Iron 5.0 - 500µg/l
Lead 0.3 - 30µg/l
Magnesium 0.3 – 20mg/l
Manganese 1.0 - 100µg/l
Mercury 0.02 - 2µg/l
Molybdenum 1.0 - 100µg/l
Nickel 0.5 - 50µg/l
Potassium 0.2 – 20mg/l
Selenium 0.2 - 20µg/l
Sodium 0.5 – 50mg/l
Strontium 1.0 - 100µg/l
Tin 1.0 - 100µg/l
' adium 1.0 - 100µg/l
1.0 - 100µg/l

SI439 Potable Water VOCs & THM
EO025 (P,G,S)
Benzene 0.1-35 µg/l
1.2-Dichloroethane 0.1-35 µg/l
Tetrachloroethene 0.1-35 µg/l
Trichloroethene 0.1-35 µg/l
Chloroform 1.0-150 µg/l
Bromoform 1.0-35 µg/l
Dibromochloromethane 1.0-35 µg/l
Bromodichloromethane 2.0-35 µg/l

Other VOC's EO025 (P,G,S)
Bromomethane 0.5 - 35 µg/l
Ethyl Ether/Diethyl Ether0.5 - 35 µg/l
11 Dichloroethene0.5 - 35 µg/l
Iodomethane/Mehyl Iodide 0.5 - 35 µg/l
Carbon Disulphide 0.5 - 35 µg/l
Allyl Chloride0.5 - 35 µg/l
Methylene Chloride/DCM 5.0 - 35 µg/l
2-Propenenitrile/Acrylonitrile 2.0 - 35 µg/l
Chlormethyl Cyanide 0.5 - 35 µg/l
Hexachlorobutadiene0.5 - 35 µg/l
Trans-1,2 Dichloroethene0.5 - 35 µg/l
MtBE0.5 - 35 µg/l
11 Dichloroethane0.5 - 35 µg/l
22 Dichloropropane0.5 - 35 µg/l
Cis-12 Dichloroethene0.5 - 35 µg/l
Methyl Acrylate5.0 - 35 µg/l
Bromochloromethane0.5 - 35 µg/l
Tetrahydrofuran5.0 - 35 µg/l
111 Trichloroethane0.5 - 35 µg/l
1-Chlorobutane0.5 - 35 µg/l
Carbon Tetrachloride0.5 - 35 µg/l
11 Dichloropropene0.5 - 35 µg/l
12 Dichloropropane0.5 - 35 µg/l
Dibromomethane0.5 - 35 µg/l
Methyl Methacrylate0.5 - 35 µg/l
13 Dichloropropene, cis2.0 - 35 µg/l
MIBK/4 Methyl 2 Pentanone 2.0 - 35 µg/l
Toluene0.5 - 35 µg/l
13 Dichloropropene,trans2.0 - 35 µg/l
Ethyl Methacrylate2.0 - 35 µg/l
112 Trichloroethane0.5 - 35 µg/l
13 Dichloropropane0.5 - 35 µg/l
2 Hexanone1.0 - 35 µg/l
12 Dibromoethane0.5 - 35 µg/l
Chlorobenzene0.5 - 35 µg/l
1112 Tetrachloroethane2.0 - 35 µg/l
Ethyl Benzene0.5 - 35 µg/l
m & p Xylene0.5 - 35 µg/l
O Xylene0.5 - 35 µg/l
Stryene2.0 - 35 µg/l
Isopropyl Benzene0.5 - 35 µg/l
Bromobenzene0.5 - 35 µg/l
1122 Tetrachloroethane0.5 - 35 µg/l
123 Trichloropropane2.0 - 35 µg/l
Propyl Benzene0.5 - 35 µg/l
2-Chlorotoluene0.5 - 35 µg/l
4 Chlorotoluene0.5 - 35 µg/l
135 Trimenthylbenzene0.5 - 35 µg/l
Tert Butyl Benzene0.5 - 35 µg/l
124 Trimethlbenzene0.5 - 35 µg/l
Sec Butyl Benzene0.5 - 35 µg/l
13 Dichlorobenzene0.5 - 35 µg/l
P Isopropyltoluene0.5 - 35 µg/l
14 Dichlorobenzene0.5 - 35 µg/l
12 Dichlorobenzene0.5 - 35 µg/l
N Butyl Benzene0.5 - 35 µg/l
Hexachloroethane5.0 - 35 µg/l
12 Dibromo 3Chloropropane 2.0 - 35 µg/l
124 Trichlorobenzene0.5 - 35 µg/l
123 Trichlorobenzene0.5 - 35 µg/l

PAH EO129 (P,G,S)
Range 0.01 - 0.2 µg/l
Acenaphthene
Benzo (a) Anthracene
Benzo (a) Pyrene
Benzo (b) Fluoranthene
Benzo (ghi) Perylene
Benzo (k) Fluoranthene
Chrysene
Dibenzo (ah) Anthracene
Fluoranthene
Fluorene
Indeno (123-cd) Pyrene
Phenanthrene
Pyrene

Acid Herbicides (P,G,S)
Range 0.01 - 0.2 µg/l
2,4,5-T H
2,4-D H
2,4-DB H
MCPA H
Picloram H

Organophosphorus Pesticides(P,G,S)
Range 0.01 - 0.2 µg/l
Famphur OP
Methyl Parathion OP
Parathion OP
Thionazin OP

Organochlorine Pesticides (P,G,S)
Range 0.01 - 0.2 µg/l
Aldrin
BHC Alpha isomer OC
BHC Beta isomer OC
BHC Delta isomer OC
Dieldrin OC
Endosulphan Alpha isomer OC
Endosulphan Beta isomer OC
Endosulphan Sulphate OC
Endrin OC
Heptachlor Epoxide OC
Heptachlor OC
Lindane OC
P,P' DDE OC
P,P'-DDD OC
P,P'-DDT OC

Notes
1.Sample Matrix:P=Potable Water (Drinking) , G=Ground Water , S=Surface Water, W=Waste Water

ENVIRONMENTAL
LABORATORY SERVICES
Acorn Business Campus,
Mahon Industrial Park,
Blackrock,
CorkTel: 021-4536141
Fax: 021-4536149

Supplement to Analysis Report Rev A

Attention:		**Report No:**	14845
Vincent Boyton			
Novartis Ringaskiddy Limited		**Date of receipt:**	18/09/2009
IDA Estate,Ringaskiddy,Co. Cork		**Date Started:**	18/09/2009
Fax No:		**Issue Date:**	23/10/2009
Tel No:	021- 4862324	**Page**	1 **of** 3
PO Number:	OP-95758	**Delivery Mode**	Sampled by ELS Ltd
Sample Type	Ground Water	**No. of Samples**	4
Condition on receipt	Satisfactory	**Client Ref:**	Below

Test No	Parameter	Test Method
00025	Volatile Organic Compounds	EO 025 Purge and Trap/GC/MS
00089	Organic Solvents	Pre-concentration GC-FID
00016	Sulphates	EW016 Autoanalyser Spectrophotometry
00023	Phosphate	EW007 Phosphate by Autoanalyser Spectrophotometry
00034	Nitrate	EW034 -Nitrate by Autoanalyser Spectrophotometry
00035	Nitrite	EW035 Nitrite by Autoanalyser Spectrophotometry
00015	Chloride	EW015 Autoanalyser Spectrophotometry
00062	Alkalinity	EW062 Titralab
00130	Metals	EM130 ICP-MS
00019	pH	EW132 Electrometric Measurement
00042	Conductivity	EW139 Conductivity Titralab
00094	COD	EW094 by Closed Reflux Colorimetry

SUPPLEMENT DETAILS

This report replaces report 14845 issued on 20/10/09.The well water level was reported incorrectly

SIGNED (23/10/2009)

Technical Manager (or Deputy)
Brendan Murray

			Amm	Cl	PO4	NO2	NO3	SO4	Al	Cd	Cr	Fe	Hg	Mn	Ni	Pb	Zn	Ca	Cu	Mg	Conductivity	BiCarbonate Alkalinity	Carbonate Alkalinity	pH	COD	TOC	Ground Water Depth
			mg/l NH4	mg/l	mg/l PO4	mg/l NO2	mg/l NO3	mg/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	ug/l	mg/l	mg/l	mg/l	us/cm	mg/l HCO3	mg/l CO3	pH Units	mg/l	mg/l	-
Limit of Detection			0.009	2.6	0.028	0.043	0.53	1.0	5.0	0.1	1.0	5.0	0.02	1.0	0.5	0.3	1	1.0	0.003	0.3	25	3	3	0.3	8	0.25	metres
Date Testing Initiated			21/09	18/09					21/09																21/09	22/09	
ELS Reference	**Sampling Point Name**	**Date Sampled**																									
14845-1	AW06	17/09/2009	0.048	<2.6	0.069	<0.043	0.732	10.8	160	<0.1	<1.0	284	<0.02	64.9	1.7	3.8	48.1	36.5	0.011	1.3	182	100	0	7.9	<8	3.1	Note 1
14845-2	MW-1	17/09/2009	0.080	17.8	0.036	0.052	7.52	29.6	<5.0	<0.1	<1.0	15.2	<0.02	2.5	1.0	<0.3	<1.0	109	<0.003	8.5	547	282	0	7.8	<8	1.4	20
14845-3	MW-2	17/09/2009	0.068	12.8	0.035	0.076	3.00	41.5	<5.0	<0.1	<1.0	13.3	<0.02	88.3	0.8	<0.3	<1.0	79.2	<0.003	6.5	459	218	0	7.9	<8	1.3	17
14845-4	MW-3	17/09/2009	0.093	20.5	0.204	0.158	7.19	32.7	240	0.2	<1.0	434	0.06	396	2.5	8.7	4.1	129	<0.003	7.3	579	295	0	7.9	<8	1.4	10

NOTE

1.Unable to measure water level due to depth

Solvent Analysis

Parameter	Units	Detection Limit	14845-1	14845-2	14845-3	14845-4
Methanol.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Ethanol	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Isopropyl Alcohol	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
n-Hexane.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
sec-Butyl Alcohol	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Acetic Acid.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Isopropyl Ether.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Ethyl Acetate.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Isopropyl Acetate	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Heptane	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
n-Butyl Alcohol	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Acetonitrile	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Cyclohexane	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
Triethylamine.	mg/l	0.1	<0.1	<0.1	<0.1	<0.1
N,N-Dimethylformar	mg/l	0.1	<0.1	<0.1	<0.1	<0.1

Appendix A

EO 025 Determination of Volatile Organic Carbons in Water by Purge and Trap/GC/MS

Analyte	LOD	14845-1	14845-2	14845-3	14845-4
	ug/l				
Dichlorodifluoromethane	10.0	N.D	N.D	N.D	N.D
Chloromethane	0.5	N.D	N.D	N.D	N.D
Ethyl Chloride/Chloroethane	0.5	N.D	N.D	N.D	N.D
Vinyl Chloride/Chloroethene	0.5	N.D	N.D	N.D	N.D
Bromomethane	0.5	N.D	N.D	N.D	N.D
Trichloromonofluoromethane	0.5	N.D	N.D	N.D	N.D
Ethyl Ether/Diethyl Ether	0.5	Note 2	Note 2	Note 2	Note 2
11 Dichloroethene	0.5	N.D	N.D	N.D	N.D
Acetone	2.0	N.D	N.D	N.D	N.D
Iodomethane/Methyl Iodide	0.5	N.D	N.D	N.D	N.D
Carbon Disulphide	0.5	N.D	N.D	N.D	N.D
Allyl Chloride	0.5	N.D	N.D	N.D	N.D
Methylene Chloride/DCM	5.0	N.D	N.D	N.D	N.D
2-Propenenitrile/Acrylonitrile	2.0	Note 2	Note 2	Note 2	Note 2
Chlormethyl Cyanide/Chloroacetonitrile	0.5	N.D	N.D	N.D	N.D
Nitrobenzene	0.5	N.D	N.D	N.D	N.D
Propanenitrile	10.0	N.D	N.D	N.D	N.D
Hexachlorobutadiene	0.5	N.D	N.D	N.D	N.D
Trans-1.2 Dichloroethene	0.5	N.D	N.D	N.D	N.D
MtBE	0.5	N.D	N.D	N.D	N.D
11 Dichloroethane	0.5	Note 2	Note 2	Note 2	Note 2
22 Dichloropropane	0.5	Note 2	Note 2	Note 2	Note 2
cis-12 Dichloroethene	0.5	N.D	N.D	N.D	N.D
2-Butanone	5.0	N.D	N.D	N.D	N.D
Methyl Acrylate	5.0	N.D	N.D	N.D	N.D
Bromochloromethane	0.5	N.D	N.D	N.D	N.D
Methacrylonitrile	5.0	N.D	N.D	N.D	N.D
Tetrahydrofuran	5.0	Note 2	Note 2	Note 2	Note 2
Trichloromethane/ Chloroform	1.0	N.D	N.D	N.D	N.D
111 Trichloroethane	0.5	N.D	N.D	N.D	N.D
1-Chlorobutane	0.5	N.D	N.D	N.D	N.D
Carbon Tetrachloride	0.5	Note 2	Note 2	Note 2	Note 2
11 Dichloropropene	0.5	Note 2	Note 2	Note 2	Note 2
Benzene	0.1	N.D	N.D	N.D	N.D
12 Dichloroethane	0.1	N.D	N.D	N.D	N.D
Trichloroethylene/ Trichloroethene	0.1	N.D	N.D	N.D	N.D
12 Dichloropropane	0.5	N.D	N.D	N.D	N.D
Dibromomethane	0.5	N.D	N.D	N.D	N.D
Methyl Methacrylate	0.5	N.D	N.D	N.D	N.D
Bromodichloromethane	2.0	N.D	N.D	N.D	N.D
13 Dichloropropene,cis	2.0	N.D	N.D	N.D	N.D
MIBK/4 Methyl 2 Pentanone	2.0	N.D	N.D	N.D	N.D
Toluene	0.5	N.D	N.D	N.D	N.D
13 Dichloropropene,trans	2.0	N.D	N.D	N.D	N.D
Ethyl Methacrylate	2.0	N.D	N.D	N.D	N.D
112 Trichloroethane	0.5	N.D	N.D	N.D	N.D
Tetrachloroethylene/ Tetrachloroethene	0.1	N.D	N.D	N.D	N.D
13 Dichloropropane	0.5	N.D	N.D	N.D	N.D
2-Hexanone	1.0	N.D	N.D	N.D	N.D
Dibromochloromethane	1.0	N.D	N.D	N.D	N.D
12 Dibromoethane	0.5	N.D	N.D	N.D	N.D
Chlorobenzene	0.5	N.D	N.D	N.D	N.D
1112 Tetrachloroethane	2.0	N.D	N.D	N.D	N.D
Ethyl Benzene	0.5	N.D	N.D	N.D	N.D
m & p Xylene	0.5	N.D	N.D	N.D	N.D
o Xylene	0.5	N.D	N.D	N.D	N.D
Styrene	2.0	N.D	N.D	N.D	N.D
Bromoform	1.0	N.D	N.D	N.D	N.D
Isopropyl Benzene	0.5	N.D	N.D	N.D	N.D
Bromobenzene	0.5	N.D	N.D	N.D	N.D
1122 Tetrachloroethane	0.5	N.D	N.D	N.D	N.D
123 Trichloropropane	2.0	N.D	N.D	N.D	N.D
Trans 14 Dichloro 2 Butene, tran	2.0	N.D	N.D	N.D	N.D
Propyl Benzene	0.5	N.D	N.D	N.D	N.D
2-Chlorotoluene	0.5	N.D	N.D	N.D	N.D
4 Chlorotoluene	0.5	N.D	N.D	N.D	N.D
135 Trimethylbenzene	0.5	N.D	N.D	N.D	N.D
Tert Butyl Benzene	0.5	N.D	N.D	N.D	N.D
124 Trimethylbenzene	0.5	N.D	N.D	N.D	N.D
Sec Butyl Benzene	0.5	N.D	N.D	N.D	N.D
13 Dichlorobenzene	0.5	N.D	N.D	N.D	N.D
P Isopropyltoluene	0.5	N.D	N.D	N.D	N.D
14 Dichlorobenzene	0.5	Note 2	Note 2	Note 2	Note 2
12 Dichlorobenzene	0.5	N.D	N.D	N.D	N.D
N Butyl Benzene	0.5	N.D	N.D	N.D	N.D
Hexachloroethane	5.0	N.D	N.D	N.D	N.D
12 Dibromo 3 Chloropropane	2.0	N.D	N.D	N.D	N.D
124 Trichlorobenzene	0.5	N.D	N.D	N.D	N.D
Napththalene	2.0	N.D	N.D	N.D	N.D
123 Trichlorobenzene	0.50	N.D	N.D	N.D	N.D

NOTES

1. ND=Concentration was below the limit of detection
2. Not reported due to QC failure

ELS LTD INAB ACCREDITATION SCHEDULE SUMMARY SHEET

Miscellaneous (P,G,W,S)

Ammonia/Ammonium 0.007-1mg/l N EW003
Chloride 2.6-250 mg/l EW015
Flouride 0.1 - 2 mg/l EW137
COD 8-1500 mg/l EW094
Nitrate 0.12-50 mg/l N EW034
Nitrite 0.013-1 mg/l N EW035
pH 4 – 10 pH Units EW138
Phosphate 0.009-1 mg/l P EW007
TOC 0.25-100mg/l EW123
Total Phosphorous 0.03-1 mg/l P EW002

Miscellaneous (P,G,S)

Bromate 1 to 50ug/l BRO3 (EW137)
Colour 2.5-50mg/l PtCCo (EW021)
Conductivity 132-6000 us/cm EW139
Dissolved Oxygen 1 to 10 mg/l (EW043)
Sulphate 1-250mg/l SO4(EW016)
Suspended Solids 5-1000mg/l (EW013)
Total Dissolved Solids 1-1000mg/l (EW046)
Total Hardness 3-330mg/l CaCO3 (EM099)
Total Oxidised Nitrogen 0.138-51mg/l N (EW051)

Metals EM130 (P,G,S)

Aluminium 5.0 – 500 µg/l
Antimony 0.1 – 10µg/l
Arsenic 0.2 - 20µg/l
Barium 1.0 - 100µg/l
Boron 0.02 – 2mg/l
Cadmium 0.1 – 10µg/l
Calcium 1.0 – 100mg/l
Chromium 1.0 - 100µg/l
Cobalt 1.0 - 100µg/l
Copper 3 - 4000µg/l
Iron 5.0 - 500µg/l
Lead 0.3 - 30µg/l
Magnesium 0.3 – 20mg/l
Manganese 1.0 - 100µg/l
Mercury 0.02 - 2µg/l
Molybdenum 1.0 - 100µg/l
Nickel 0.5 - 50µg/l
Potassium 0.2 – 20mg/l
Selenium 0.2 - 20µg/l
Sodium 0.5 – 50mg/l
Strontium 1.0 - 100µg/l
Tin 1.0 - 100µg/l
Vanadium 1.0 - 100µg/l
Zinc 1.0 - 100µg/l

SI439 Potable Water VOCs & THM

EO025 (P,G,S)

Benzene 0.1-35 µg/l
1,2-Dichloroethane 0.1-35 µg/l
Tetrachloroethene 0.1-35 µg/l
Trichloroethene 0.1-35 µg/l
Chloroform 1.0-150 µg/l
Bromoform 1.0-35 µg/l
Dibromochloromethane 1.0-35 µg/l
Bromodichloromethane 2.0-35 µg/l

Other VOC's EO025 (P,G,S)

Bromomethane 0.5 - 35 µg/l
Ethyl Ether/Diethyl Ether0.5 - 35 µg/l
11 Dichloroethene0.5 - 35 µg/l
Iodomethane/Mehyl Iodide 0.5 - 35 µg/l
Carbon Disulphide 0.5 - 35 µg/l
Allyl Chloride0.5 - 35 µg/l
Methylene Chloride/DCM 5.0 - 35 µg/l
2-Propenenitrile/Acrylonitrile 2.0 - 35 µg/l
Chlormethyl Cyanide 0.5 - 35 µg/l
Hexachlorobutadiene0.5 - 35 µg/l
Trans-1,2 Dichloroethene0.5 - 35 µg/l
MtBE0.5 - 35 µg/l
11 Dichloroethane0.5 - 35 µg/l
22 Dichloropropane0.5 - 35 µg/l
Cis-12 Dichloroethene0.5 - 35 µg/l
Methyl Acrylate5.0 - 35 µg/l
Bromochloromethane0.5 - 35 µg/l
Tetrahydrofuran5.0 - 35 µg/l
111 Trichloroethane0.5 - 35 µg/l
1-Chlorobutane0.5 - 35 µg/l
Carbon Tetrachloride0.5 - 35 µg/l
11 Dichloropropene0.5 - 35 µg/l
12 Dichloropropane0.5 - 35 µg/l
Dibromomethane0.5 - 35 µg/l
Methyl Methacrylate0.5 - 35 µg/l
13 Dichloropropene, cis2.0 - 35 µg/l
MIBK/4 Methyl 2 Pentanone 2.0 - 35 µg/l
Toluene0.5 - 35 µg/l
13 Dichloropropene,trans2.0 - 35 µg/l
Ethyl Methacrylate2.0 - 35 µg/l
112 Trichloroethane0.5 - 35 µg/l
13 Dichloropropane0.5 - 35 µg/l
2 Hexanone1.0 - 35 µg/l
12 Dibromoethane0.5 - 35 µg/l
Chlorobenzene0.5 - 35 µg/l
1112 Tetrachloroethane2.0 - 35 µg/l
Ethyl Benzene0.5 - 35 µg/l
m & p Xylene0.5 - 35 µg/l
O Xylene0.5 - 35 µg/l
Stryene2.0 - 35 µg/l
Isopropyl Benzene0.5 - 35 µg/l
Bromobenzene0.5 - 35 µg/l
1122 Tetrachloroethane0.5 - 35 µg/l
123 Trichloropropane2.0 - 35 µg/l
Propyl Benzene0.5 - 35 µg/l
2-Chlorotoluene0.5 - 35 µg/l
4 Chlorotoluene0.5 - 35 µg/l
135 Trimenthylbenzene0.5 - 35 µg/l
Tert Butyl Benzene0.5 - 35 µg/l
124 Trimethlbenzene0.5 - 35 µg/l
Sec Butyl Benzene0.5 - 35 µg/l
13 Dichlorobenzene0.5 - 35 µg/l
P Isopropyltoluene0.5 - 35 µg/l
14 Dichlorobenzene0.5 - 35 µg/l
12 Dichlorobenzene0.5 - 35 µg/l
N Butyl Benzene0.5 - 35 µg/l
Hexachloroethane5.0 - 35 µg/l
12 Dibromo 3Chloropropane 2.0 - 35 µg/l
124 Trichlorobenzene0.5 - 35 µg/l
123 Trichlorobenzene0.5 - 35 µg/l

PAH EO129 (P,G,S)

Range 0.01 - 0.2 µg/l

Acenaphthene
Benzo (a) Anthracene
Benzo (a) Pyrene
Benzo (b) Fluoranthene
Benzo (ghi) Perylene
Benzo (k) Fluoranthene
Chrysene
Dibenzo (ah) Anthracene
Fluoranthene
Fluorene
Indeno (123-cd) Pyrene
Phenanthrene
Pyrene

Acid Herbicides (P,G,S)

Range 0.01 - 0.2 µg/l

2,4,5-T H
2,4-D H
2,4-DB H
MCPA H
Picloram H

Organophosphorus Pesticides(P,G,S)

Range 0.01 - 0.2 µg/l

Famphur OP
Methyl Parathion OP
Parathion OP
Thionazin OP

Organochlorine Pesticides (P,G,S)

Range 0.01 - 0.2 µg/l

Aldrin
BHC Alpha isomer OC
BHC Beta isomer OC
BHC Delta isomer OC
Dieldrin OC
Endosulphan Alpha isomer OC
Endosulphan Beta isomer OC
Endosulphan Sulphate OC
Endrin OC
Heptachlor Epoxide OC
Heptachlor OC
Lindane OC
P,P' DDE OC
P,P'-DDD OC
P,P'-DDT OC

Notes

1.Sample Matrix:P=Potable Water (Drinking) , G=Ground Water , S=Surface Water, W=Waste Water

Novartis Ringaskiddy Limited

Noise Monitoring Report 2009

IPPCL Register Number P0006-03

Condition 6.10 of IPPCL Register Number P0006-03 requires that:

'The licensee shall carry out a noise survey of the site operations annually. The survey programme shall be undertaken in accordance with the methodology specified in the 'Environmental Noise Survey Guidance Document' as published by the Agency.'

Novartis Ringaskiddy Limited engaged the services of Dixon Brosnan Environmental Consultants of Shronagreehy, Kealkill, Bantry, County Cork to undertake the survey.

The survey was undertaken during the daytime of Thursday 16-Jul-2009 and on the night-time of Thursday 16 -Jul-2009 into Friday 17-Jul-2009 a t five monitoring points on the external perimeter of the facility:

Monitoring Point	Location
1	West perimeter. This is a noise sensitive location located approximately 270 West of the nearest operational building at the facility, which houses the main utility modules. This perimeter faces onto a ribbon development of residential dwellings and a main road.
2	South perimeter. This perimeter faces onto a main road and an industrially zoned area. The monitoring point is approximately 160 m South of the company's main environmental control modules.
3	North East perimeter. This section of the perimeter also faces onto an industrially zoned area and a secondary road. It is located approximately 270 m North East of the company's main environmental control modules.
4	North perimeter. This section of the perimeter faces onto an industrially zoned area and a secondary road. It is located approximately 250 m North of the company's main environmental control modules and approximately 190 m North of the company's solvent recovery facility.
5	North West perimeter. This section of the perimeter faces onto a residential area (to the West) and an industrially zoned area (to the North). A main road to the West and a secondary road to the North border it. The

monitoring point is approximately 660 m North West of the nearest operational building at the facility, which houses the main utility modules.

Dixon Brosnan's report is reproduced in full in the following pages; and the following is an extract from the report's executive summary:

---

1. Dixon Brosnan Environmental Consultants were commissioned by Environmental Laboratory Services Limited, on behalf of their client Novartis Ringaskiddy Limited, to undertake the 2009 annual noise survey in the vicinity of the latter's pharmaceutical facility at Ringaskiddy, County Cork. The purpose of the assessment was to document noise levels emanating from the facility in accordance with EPA IPPC Licence P0006-03 issued in respect of this site, and to determine if levels are in compliance with conditions attached to this licence.

2. A daytime noise survey was undertaken on Thursday 16-Jul-2009 at five stations in the vicinity of the site boundaries. The survey was repeated that night. On both occasions, emissions were audible from the Novartis facility.

3. Due to their steady and continuous nature, noise emissions from the Novartis facility are more accurately represented by the LA_{90} parameter, the LA_{eq} parameter being influenced by various offsite noise sources. The LA_{90} parameter was therefore used during the assessment of noise emissions.

4. Daytime $LA_{90\ 30\ min}$ levels recorded at all five stations were less than the 55 dB daytime limit specified in the site licence. Daytime $LA_{90\ 30\ min}$ levels ranged from 39 to 45 dB.

5. Night-time LA_{90} levels recorded at all five stations were less than the 45 dB limit specified in the site licence. Night-time $LA_{90\ 30\ min}$ levels ranged from 35 to 44 dB.

6. No impulsive noise emissions were noted. Tones detected in the 80 Hz band at two stations during the daytime survey were linked to offsite sources.

Sound Level Monitoring Report 2009

DixonBrosnan
environmental consultants
dixonbrosnan.com

Project

2009 annual noise survey at Novartis Ltd.
Ringaskiddy, Co. Cork

Client

Environmental Laboratory Services Ltd.

Project no	No pages	Client reference
06053	15	IPPC P0006-03

v280409

DixonBrosnan Shronagreehy Kealkill Bantry Co Cork
Tel 086 813 1195 | damian@dixonbrosnan.com | www.dixonbrosnan.com

Report no	Date	Status	Prepared by	Chkd
06053.4.1	20.07.09	Release to client	Damian Brosnan	CD

Do you *really* need a printed copy of this report?

Signed

20.07.09 on behalf of DixonBrosnan

Executive summary

DixonBrosnan Environmental Consultants were commissioned by Environmental Laboratory Services Ltd, on behalf of their client Novartis Ringaskiddy Ltd., to undertake the 2009 annual noise survey in the vicinity of the latter's pharmaceutical facility at Ringaskiddy, Co. Cork. The purpose of the survey was to document noise levels emanating from the facility in accordance with EPA IPPC licence P0006-03 issued in respect of this site, and to determine if levels are in compliance with conditions attached to this licence.

A daytime noise survey was undertaken on Thursday 16.07.09 at five stations in the vicinity of the site boundaries. The survey was repeated that night. On both occasions, emissions were audible from the Novartis facility.

Due to their steady and continuous nature, noise emissions from the Novartis facility are more accurately represented by the L_{A90} parameter, the L_{Aeq} parameter being influenced by various offsite noise sources. The L_{A90} parameter was therefore used during the assessment of noise emissions.

Daytime $L_{A90\ 30\ min}$ levels recorded at all five stations were less than the 55 dB daytime limit specified in the site licence. Daytime $L_{A90\ 30\ min}$ levels ranged from 35 to 45 dB. Night-time $L_{A90\ 30\ min}$ levels recorded at all five stations were less than the 45 dB limit specified in the site licence, ranging from 35 to 44 dB.

No impulsive noise emissions were noted. Tones detected in the 80 Hz band at two stations during the daytime survey were linked to offsite sources.

Contents

1 Introduction

1.1 DixonBrosnan Environmental Consultants were commissioned by Environmental Laboratory Services Ltd, on behalf of their client Novartis Ringaskiddy Ltd., to undertake the 2009 annual noise survey in the vicinity of the latter's pharmaceutical facility at Ringaskiddy, Co. Cork. The purpose of the survey was to document noise levels emanating from the facility in accordance with EPA IPPC licence P0006-03 issued in respect of this site, and to determine if levels are in compliance with conditions attached to this licence. Noise conditions specified in the licence are presented in **Appendix 2**.

1.2 The noise survey was undertaken at five monitoring stations during daytime and night-time hours on 16.07.09-17.07.09. The monitoring stations used are presented in **Appendix 3**. Survey methodology, weather conditions and equipment specifications are described in **Appendix 4**.

1.3 It is understood that the Novartis Ringaskiddy site was operating normally throughout the survey. Noise emissions arose from various processing plant around the site, and from trucks onsite. Offsite noise sources included traffic on local roads, barking dogs, passing aircraft and birdsong. At certain locations, noise emissions were audible from other facilities in the vicinity.

2 Results & analysis

2.1 Noise levels recorded are presented in **Appendix 5**. Intervals of 30 minutes were used at each station. An additional interval of 15 minutes was recorded at N1 during both daytime and night-time surveys. Recorded one third octave band frequency spectra are presented in **Appendix 6**.

2.2 During the daytime and night-time surveys it was noted that noise emissions from the Novartis Ringaskiddy facility were generally continuous and steady. Extraneous noise sources such as traffic and birdsong resulted in fluctuating noise levels with corresponding variations in L_{Aeq} levels. It is therefore considered that emissions from the study site are more accurately represented by the L_{A90} parameter. The L_{A90} is influenced by continuous emissions, but not transient emissions such as traffic or birdsong. The EPA document *Environmental noise survey guidance document* (2003) notes that in fluctuating noise environments:

...the L_{A90} index may be used to give a good indication of the actual noise output from the site, where the noise emissions on site are relatively steady.

2.3 L_{A90} levels recorded in this manner may be compared to L_{Aeq} limits specified. Accordingly, discussions below make reference to recorded L_{A90} levels.

2.4 Daytime $L_{A90\ 30\ min}$ levels exhibited a range of 35 to 45 dB. This range was lower than the 55 dB daytime limit specified in site licence P0006-03, and daytime noise levels were satisfactory at all stations. Continuous plant emissions from the Novartis Ringaskiddy facility were audible to some degree at four of the five stations, and were clearly audible at two of these (N3 and N4).

2.5 Night-time $L_{A90\ 30\ min}$ levels ranged from 35 to 44 dB. As during the daytime, continuous plant emissions from the Novartis Ringaskiddy facility were audible at four of the five stations, although the degree of audibility at each station was altered following a change in wind direction. At N2 and N3, emissions were noted from other industrial facilities to the north and south. All levels recorded were less than the 45 dB night-time limit.

2.6 There were no impulsive noise emissions noted at the measurement stations. One third octave band frequency analysis indicated the presence of a tone in the 80 Hz band at N1 during the daytime 15 minute interval. This tone was traced to a tractor and mower combination operating continuously at several hundred metres. The tone did not arise during the preceding 30 minute interval due to the absence of this plant. A similar tone was marginally detected at N3 during the daytime, most likely linked to agricultural/landscape plant operating offsite to the north.

3 Conclusions

3.1 Noise emissions from the Novartis Ringaskiddy facility are more accurately represented by the L_{A90} parameter, the L_{Aeq} parameter being influenced by various offsite noise sources.

3.2 Daytime $L_{A90\ 30\ min}$ levels recorded at all five stations were less than the 55 dB daytime limit specified in the site licence. Daytime $L_{A90\ 30\ min}$ levels ranged from 35 to 45 dB. Night-time $L_{A90\ 30\ min}$ levels were less than the night-time 45 dB limit at all five stations. Levels measured 35-44 dB.

3.3 No impulsive noise emissions were noted. Daytime tones detected in the 80 Hz band at two stations were linked to offsite noise sources.

Appendix 1: Glossary

Ambient	The total noise environment at a location, including all sounds present.
A-weighting	The weighting or adjustment applied to sound level recordings to approximate the non-linear frequency response of the human ear. The A-weighting is denoted by the suffix A in the parameters listed below such as L_{Aeq}, L_{A10}, etc.
Background noise	The A-weighted sound pressure level of the residual noise in decibels exceeded for 90% of a given time interval. The L_{A90}.
Decibel (dB)	The units of the noise measurement scale. Based on logarithmic scale so cannot be simply added or subtracted. A 3 dB difference is the smallest change perceptible to the human ear. A 10 dB difference is perceived as a doubling or halving of the sound level. **Throughout this report noise levels are presented as decibels relative to 20 µPa**. Examples of decibel levels are as follows: 20 Very quiet room; 35 Rural environment at night; 65 Conversation; 80 Busy pub; 100 Nightclub; 120 Jet take-off
Free-field	Noise environment away from all surfaces other than the ground. Noise levels recorded near walls will be artificially increased due to reflections. Where there is more than one wall, noise levels will be further increased. Levels recorded within such 'near-field' conditions will be increased by up to 3 dB, and up to 6 dB near a corner. In practice, free-field conditions will be achieved by maintaining a separation distance of at least 3.5 m from walls.
Frequency	The number of cycles per second of a sound or vibration wave. An example of a low frequency noise is a hum, while a whine represents a higher frequency. The range of human hearing approaches 20-20,000 Hz.
Hertz (Hz)	The unit of frequency measurement.
Impulse	A noise which is of short duration, typically less than one second, the sound pressure level of which is significantly higher than the background.
Interval	The time period t over which noise monitoring is conducted. May be 5-60 minutes, depending on the standard applied. The interval is usually denoted by t as in $L_{Aeq\,t}$, $L_{A90\,t}$, etc.
L_{AE}	The sound exposure level is a measure of the noise level of an event, standardised to an interval of one second, and containing the same acoustical energy as the actual event.
$L_{Aeq\,t}$	The equivalent continuous sound level during a measurement interval, effectively representing the average A-weighted noise level.

L_{AF}	The A-weighted sound pressure level measured using a fast time weighting and averaged over one second. The L_{AF} value therefore changes each second.
L_{Aieq}	The A-weighted sound pressure level at a particular instant, measured using an impulse time weighting on the sound level meter. May be used in the assessment of impulse noise.
$L_{An\,t}$	The A-weighted sound level which is exceeded for n% of the measurement interval.
L_{Cpeak}	The peak C-weighted sound pressure level recorded during the measurement interval. The highest peak on the sound pressure wave before any time constant is applied. The C-weighting is used rather than the A-weighting as the latter screens out low frequency sources.
$L_{Req\,t}$	The rating noise level, derived from the $L_{Aeq\,t}$ plus specified adjustments for tonal and impulsive characteristics.
L_{den}	A description of the day-evening-night noise level. Calculated from separate daytime, evening and night-time noise levels using a specified formula.
$L_{AF10\,t}$	The A-weighted sound level measured using a fast time weighting which is exceeded for 10% of the measurement interval, usually used to quantify traffic noise.
$L_{AF90\,t}$	The A-weighted sound level measured using a fast time weighting which is exceeded for 90% of the measurement interval, usually used to quantify background noise. May also be used to describe the noise level from a continuous steady or almost-steady source, particularly where the local noise environment fluctuates.
Near-field	Area where free field conditions do not apply.
Noise sensitive location	Any dwelling house, hotel or hostel, health building, educational establishment, place of worship or entertainment, or any other facility or area of high amenity which for its proper enjoyment requires the absence of noise at nuisance levels.
1/3 octave band analysis	Frequency analysis of sound such that the frequency spectrum is subdivided into bands of one third of an octave each. An octave is taken to be a frequency interval, the upper limit of which is twice the lower limit in Hertz.
Residual noise	The noise level remaining at a given position in a given situation when the specific noise source is absent or does not contribute to the noise level.
Specific noise	The noise source under investigation for assessing the likelihood of complaints.
Tone	A character of the noise caused by the dominance of one or more frequencies which may result in increased noise nuisance.
Z-weighting	Standard weighting applied by sound level meters to represent linear scale.

Condition 6.10.1

The licensee shall carry out a noise survey of the site operations annually. The survey programme shall be undertaken in accordance with the methodology specified in the Environmental noise survey guidance document as published by the Agency.

Condition 4.6.1

Noise from the installation shall not give rise to sound pressure levels (Leq, t) measured at the boundary of the installation which exceeds the limit value(s).

The limit values are set out in schedule B.4 of the licence. The limits specified are 55 dB during daytime hours, and 45 dB at night-time, measured as $L_{Aeq\ 30mins}$. Daytime and night-time periods are 0800-2200 and 2200-0800 respectively. The schedule states that *there shall be no clearly audible tonal component or impulsive component in the noise emission from the activity at any noise sensitive location.*

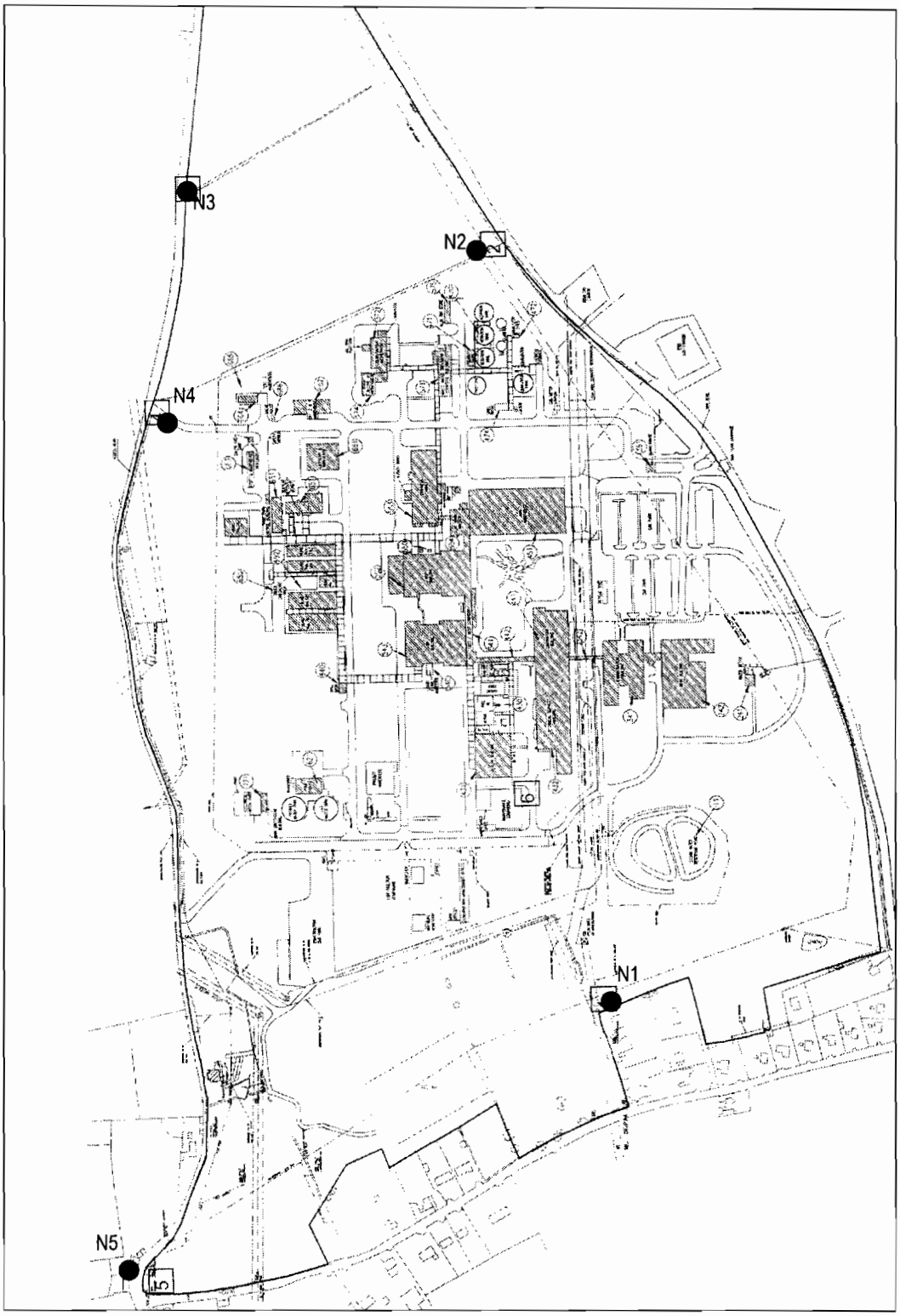
The licence does not specify monitoring points. Five monitoring points were agreed previously with the EPA. The monitoring points are presented in **Appendix 3**.

Appendix 3: Noise monitoring stations

Ref.	Location
N1	SW boundary of site, 15 m from residential boundary.
N2	SE corner of site operations area. Adjacent to Ringaskiddy Industrial Zone.
N3	NE corner of field on E boundary of site. Adjacent to Ringaskiddy Industrial Zone.
N4	At emergency entrance at NE corner of site operations area. Adjacent to Ringaskiddy Industrial Zone.
N5	Adjacent to road junction to NW of site.

The locations are indicated over.

Noise monitoring stations.



Appendix 4: Methodology

Survey	Project ref.	06053
	Purpose	2009 annual compliance noise survey
	Locations	N1 N2 N3 N4 N5
	Comment	Facility operational
Event	Date	Day: 16.07.09 Night: 16.07.09-17.07.09
	Day	Day: Thursday Night: Thursday-Friday
	Time	Day: Afternoon Night: Night & early morning
Operator	On behalf of DixonBrosnan	Damian Brosnan
Conditions	Cloud cover	Day: 50% increasing to 100% Night: 90-100%
	Precipitation	Day: Passing showers Night: 0 mm
	Temperature	18 ^{0}C decreasing to 15 ^{0}C Night: 14 ^{0}C
Wind	Speed	Day 0-1 m/s Night: 0-2 m/s initially, increasing to 1-4 m/s
	Direction	Day: SE-SW Night: NW
	Measurement	Anemo anemometer 2 m above ground level
Sound level meter	Instrument	Bruel & Kjaer Type 2250-L
	Instrument serial no.	2566801
	Microphone serial no.	2571655
	Application	BZ7130 Version 2.0
	Bandwidth	Broadband
	Max input level	142.66 dB
	Broadband weightings	Time: Fast Frequency: AC
	Peak weighting	Frequency: C
	Windscreen correction	UA-0237
	Sound Field correction	Free-field
	UKAS calibration	30.09.08
	UKAS calibration certificate	Available on request
Onsite calibration	Time	Day: 16/07/2009 12:54:38 Night: 07/16/2009 21:56:50
	Calibration type	External
	Sensitivity	Day: 41.29 mV/Pa Night: 40.04 mV/Pa
	Post measurement check	93.9 dB
Onsite calibrator	Instrument	Bruel & Kjaer Type 4231
	Instrument serial no.	1723667
	UKAS calibration	14.08.08
	UKAS calibration certificate	Available on request
Monitoring methodology	International Standard ISO 1996	*Acoustics: Description and measurement of environmental noise Part 1 (2003) & Part 2 (2007)*
	Exceptions	-
	Intervals	30 min with additional 15 min at N1

Appendix 5: Results

Daytime 16.07.09

Station	Time	$L_{Aeq\ 30\ min}$ dB	$L_{AF10\ 30\ min}$ dB	$L_{AF90\ 30\ min}$ dB	Noise audible
N1	1312-1342	42	43	40	Novartis emissions audible continuously at low level in background, not significant. Birdsong and crows. Frequent overhead aircraft. Distant traffic audible. Lightly rustling vegetation. Tractor with mower approaching towards end of interval.
N2	1424-1454	64	67	40	Novartis emissions continuously audible at low level. Intermittent local road traffic dominant. Overhead aircraft. Birdsong.
N3	1610-1640	47	47	44	Novartis emissions continuously audible and dominant. Agricultural/landscape machinery continuously audible several hundred metres to N. Birdsong. Overhead aircraft. Intermittent traffic audible on road to S. Sporadic local road traffic.
N4	1644-1714	47	46	45	Novartis emissions continuously audible and dominant. Agricultural/landscape machinery slightly audible continuously to NE. Birdsong. Overhead aircraft. Sporadic local road traffic.
N5	1719-1749	50	48	35	Local and distant traffic dominant, particularly regular traffic through nearby junction and on approaches. No emissions audible from Novartis facility. Overhead Aircraft. Crows and birdsong.

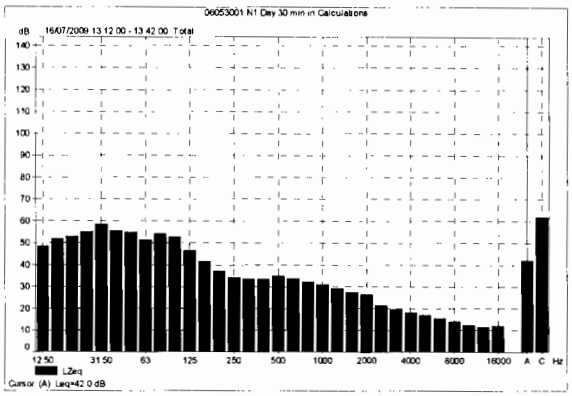
Night-time 16.07.09-17.07.07

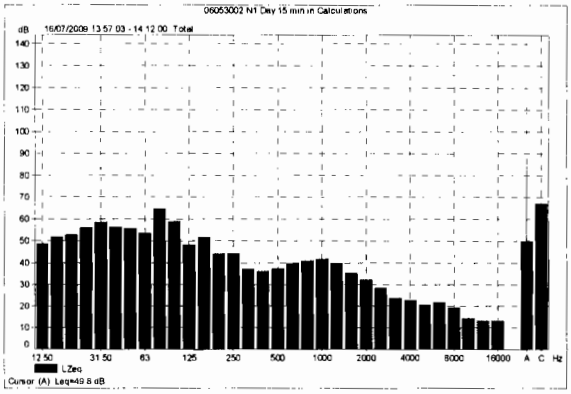
Station	Time	$L_{Aeq\ 30\ min}$ dB	$L_{AF10\ 30\ min}$ dB	$L_{AF90\ 30\ min}$ dB	Noise audible
N1	2200-2230	39	40	37	Novartis emissions audible continuously at low level, not significant. Traffic audible on local and distant roads. Overhead aircraft. Lightly rustling vegetation.
N2	2304-2334	59	52	44	Novartis emissions continuously dominant, apart from sporadic local traffic movements. Continuous venting emissions audible from facility to S.
N3	2346-0016	46	48	44	Novartis emissions continuously audible at moderate level. Emissions also continuously audible from facility to N. Rustling vegetation becoming dominant. Sporadic traffic movements on road to S audible.
N4	0020-0050	44	45	42	Novartis emissions continuously audible at low level. Sporadic road traffic audible in distance to N. Rustling vegetation significant.
N5	0058-0128	39	42	35	Facility not audible. Rustling vegetation. Local car x1. Distant traffic sporadically audible to N.

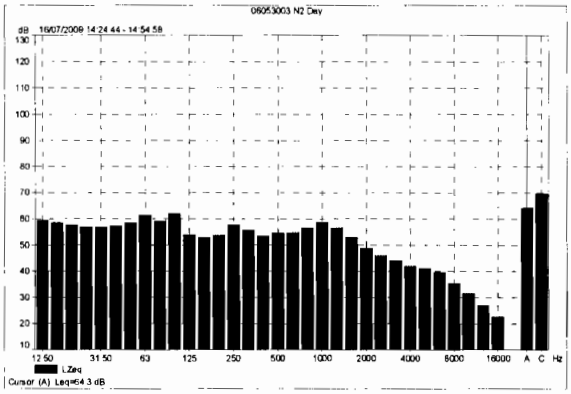
Additional 15 min intervals at N1

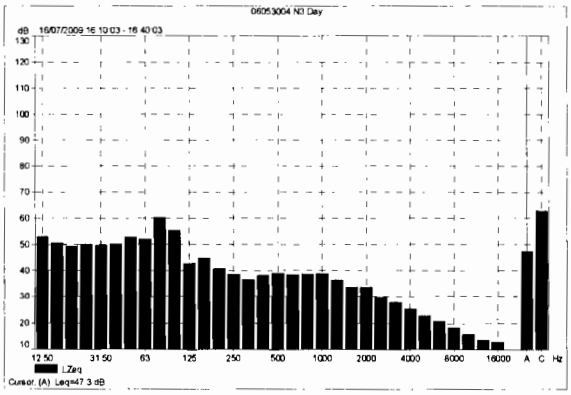
Period	Time	$L_{Aeq\ 15\ min}$ dB	$L_{AF10\ 15\ min}$ dB	$L_{AF90\ 15\ min}$ dB	Noise audible
Day	1357-1412	50	49	42	Tractor with mower audible continuously at low level at 100 m, with audible hum. Novartis emissions also slightly audible continuously. Birdsong and crows. Frequent overhead aircraft. Distant traffic audible. Lightly rustling vegetation.
Night	2231-2246	38	39	36	Novartis emissions audible continuously at low level, not significant. Traffic audible on local and distant roads. Overhead aircraft. Lightly rustling vegetation.

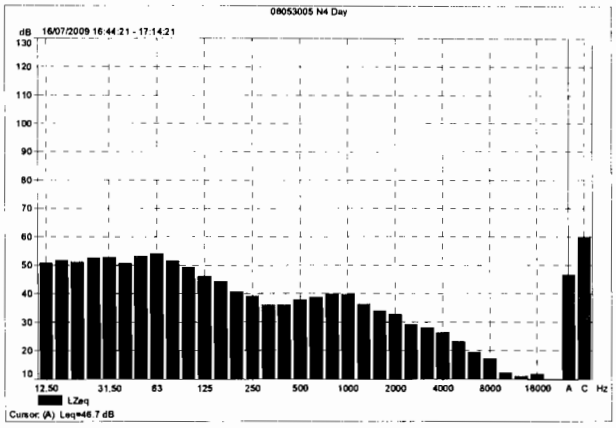
Appendix 6: Frequency spectra

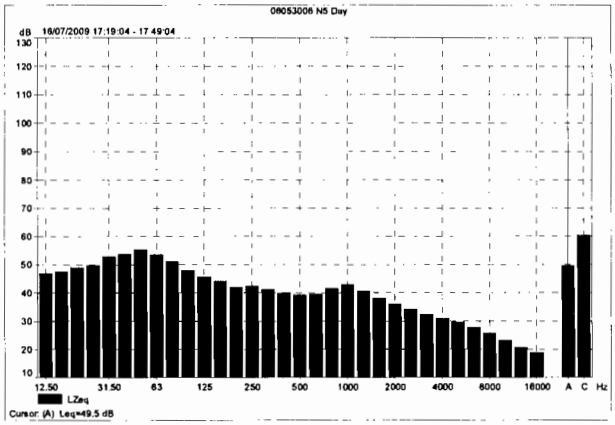


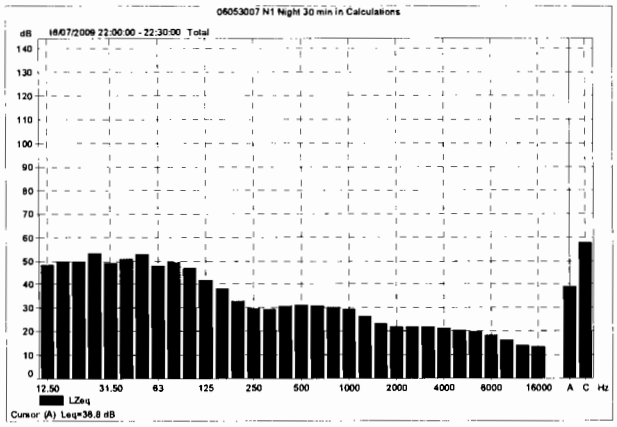


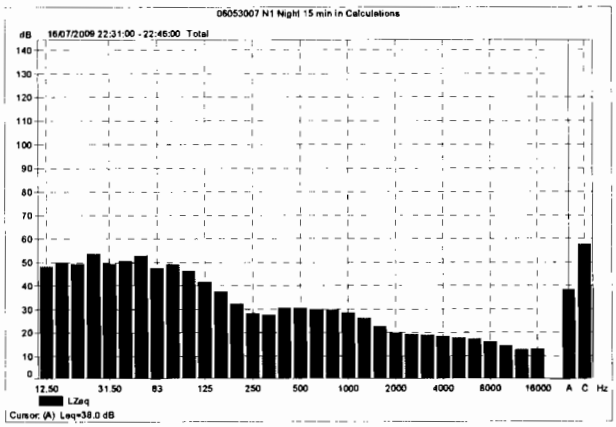


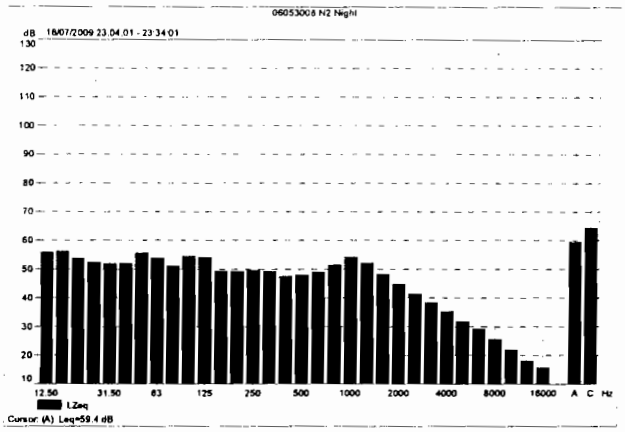


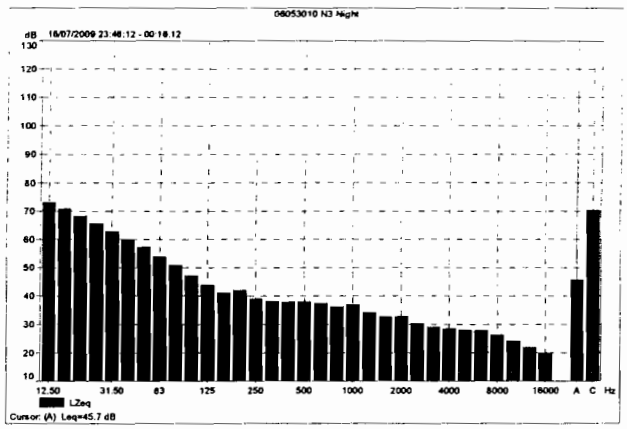

06053005 N4 Day
dB 16/07/2009 16:44:21 - 17:14:21
130
120
110
100
90
80
70
60
50
40
30
20
10
12.50
31.50
63
125
250
500
1000
2000
4000
8000
16000
A
C
Hz
LZeq
Cursor: (A) Leq=46.7 dB


06053006 N5 Day
dB 16/07/2009 17:19:04 - 17:49:04
130
120
110
100
90
80
70
60
50
40
30
20
10
12.50
31.50
63
125
250
500
1000
2000
4000
8000
16000
A
C
Hz
LZeq
Cursor: (A) Leq=49.5 dB


06053007 N1 Night 30 min in Calculations
dB 16/07/2009 22:00:00 - 22:30:00 Total
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
12.50
31.50
63
125
250
500
1000
2000
4000
8000
16000
A
C
Hz
LZeq
Cursor: (A) Leq=38.8 dB


06053007 N1 Night 15 min in Calculations
dB 16/07/2009 22:31:00 - 22:46:00 Total
140
130
120
110
100
90
80
70
60
50
40
30
20
10
0
12.50
31.50
63
125
250
500
1000
2000
4000
8000
16000
A
C
Hz
LZeq
Cursor: (A) Leq=38.0 dB


06053008 N2 Night
dB 16/07/2009 23:04:01 - 23:34:01
130
120
110
100
90
80
70
60
50
40
30
20
10
12.50
31.50
63
125
250
500
1000
2000
4000
8000
16000
A
C
Hz
LZeq
Cursor: (A) Leq=59.4 dB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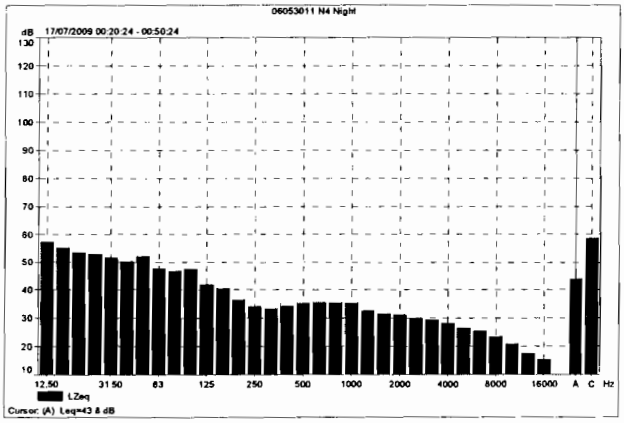
dB 16/07/2009 23:48:12 - 00:18:12
130
120
110
100
90
80
70
60
50
40
30
20
10
12.50
31.50
63
125
250
500
1000
2000
4000
8000
16000
A
C
Hz
LZeq
Cursor: (A) Leq=45.7 dB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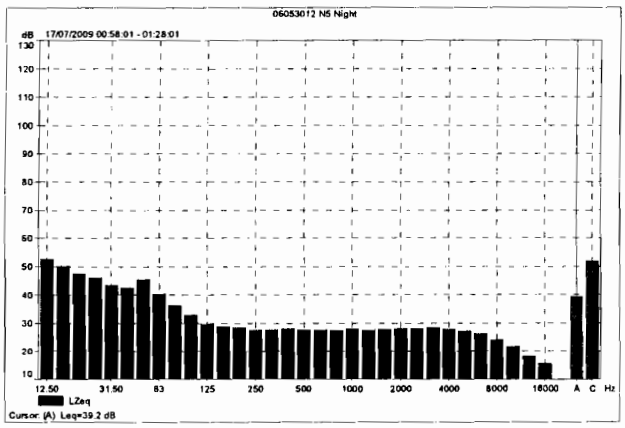
dB 17/07/2009 00:20:24 - 00:50:24
130
120
110
100
90
80
70
60
50
40
30
20
10
12.50
31.50
63
125
250
500
1000
2000
4000
8000
16000
A
C
Hz
LZeq
Cursor: (A) Leq=43.8 dB


06053012 N5 Night
dB 17/07/2009 00:58:01 - 01:28:01
130
120
110
100
90
80
70
60
50
40
30
20
10
12.50
31.50
63
125
250
500
1000
2000
4000
8000
16000
A
C
Hz
LZeq
Cursor: (A) Leq=39.2 dB

Novartis Ringaskiddy Limited

Report on List I and II Substance Reductions 2009

IPPCL Register Number P0006-03

There is no specific Condition in IPPCL Register Number P0006-03 in relation to reducing emissions of List I and II substances. However, Condition 2.4 and Schedule 6 (i) of IPCL Register Number 6 required that:

"The licensee shall put in place a programme to identify methods by which a reduction in the emissions of List II substances, and all priority candidate Black List substances, from the activity may be achieved. The licensee shall provide a report to the Agency on an annual basis, setting out the reductions achieved with regard to these compounds in the previous year, and also setting out targets for improvement in the following year."

Novartis Ringaskiddy Limited proposes, subject to the agreement of the Agency, that it continue to report in the format in which data on List I and II substances were reported during previous years. To this end information for the years 1994 to 2009 is summarised on the following pages:

1. No Black List substances were used in production at Novartis Ringaskiddy Limited during the years 1994 to 2009 (inclusive).

2. Of the so-called List II substances and priority candidate Black List substances Toluene was used between 1994 and 2009 (inclusive); and Cyclohexane was used between 1995 and 2009 (inclusive).

3. Total annual volume discharges of treated effluent from the wastewater treatment plant at Novartis Ringaskiddy Limited for the years 1994 to 2009 were as follows:

1994: 159,000 m^3	**1995: 137,400 m^3**
1996: 141,840 m^3	**1997: 148,545 m^3**
1998: 173,720 m^3	**1999: 193,000 m^3**
2000: 154,720 m^3	**2001: 207,320 m^3**
2002: 236,360 m^3	**2003: 245,910 m^3**
2004: 238,400 m^3	**2005: 246,280 m^3**
2006: 222,950 m^3	**2007: 212,320 m^3**
2008: 211,080 m^3	**2009: 206,415 m^3**

4. The total emission of Toluene from the facility to the aquatic environment between 1994 and 2009, based on independent characterisation by the EPA; Enterprise Ireland; BHP Laboratories and Environmental Laboratory Services Limited (data previously submitted both to Cork County Council (1994) and the EPA (1994 to 2009)) has been calculated as follows:

1994: < 0.159 kg

1995: < 0.446 kg

1996: < 0.250 kg

1997: < 0.200 kg

1998: < 0.220 kg

1999: < 0.193 kg

2000: < 0.400 kg

2001: < 207.32 kgs (*)
(*) based on limit of detection

2002: < 236.36 kgs (*)
(*) based on limit of detection

2003: < 245.91 kgs (*)
(*) based on limit of detection

2004: < 71.52 kgs (*)
(*) based on limit of detection

2005: < 1.48 kgs (*)
(*) based on limit of detection

2006: < 0.279 kg (*)
(*) based on limit of detection

2007: < 1.062 kg (*)
(*) based on limit of detection

2008: < 0.106 kg (*)
(*) based on limit of detection

2009: < 0.103 kg (*)
(*) based on limit of detection

Note that the figures are generally based on analytical results at the limit of detection of the Gas Chromatography/Mass Spectrometry technique used. This data can also be expressed as gram emission per kilogram of product produced:

1994: < 0.032 g/kg

1995: < 0.045 g/kg

1996: < 0.007 g/kg

1997: < 0.003 g/kg

1998: < 0.003 g/kg

1999: < 0.003 g/kg

2000: < 0.003 g/kg

2001: < 0.879 g/kg (*)
(*) based on limit of detection

2002: < 0.869 g/kg (*)
(*) based on limit of detection

2003: < 0.763 g/kg (*)
(*) based on limit of detection

2004:< 0.239 g/kg (*)
(*) based on limit of detection

2005:< 0.005 g/kg (*)
(*) based on limit of detection

2006:< 0.001 g/kg (*)
(*) based on limit of detection

2007:< 0.003 g/kg (*)
(*) based on limit of detection

2008:< 0.001 g/kg (*)
(*) based on limit of detection

2009:< 0.001 g/kg (*)
(*) based on limit of detection

5. The total emission of Cyclohexane from the facility to the aquatic environment between 1995 to 2009, based on independent characterisation by the EPA; Enterprise Ireland; BHP Laboratories and Environmental Laboratory Services Limited (data previously submitted both to Cork County Council (1994) and the EPA (1994 to 2009)) has been calculated as follows:

1995: < 0.900 kg

1996: < 1.000 kg

1997: < 0.800 kg

1998: < 0.910 kg

1999: < 0.965 kg

2000: < 0.774 kg

2001: < 207.32 kgs (*)
(*) based on limit of detection

2002: < 236.36 kgs (*)
(*) based on limit of detection

2003: < 245.91 kgs (*)
(*) based on limit of detection

2004: < 166.88 kgs (*)
(*) based on limit of detection

2005: < 2.47 kgs (*)
(*) based on limit of detection

2006: < 11.15 kgs (*)
(*) based on limit of detection

2007: < 10.62 kgs (*)
(*) based on limit of detection

2008: < 21.11 kgs (*)
(*) based on limit of detection

2009: < 20.65 kgs (*)
(*) based on limit of detection

The analytical method of Gas Chromatography/Mass Spectrometry was used in quantitation. This data can also be expressed as gram emission per kilogram of product produced:

1995: < 0.100 g/kg

1996: < 0.030 g/kg

1997: < 0.010 g/kg

1998: < 0.009 g/kg

1999: < 0.011 g/kg

2000: < 0.006 g/kg

2001: <0.879 g/kg (*)
(*) based on limit of detection

2002: < 0.869 g/kg (*)
(*) based on limit of detection

2003: < 0.763 g/kg (*)
(*) based on limit of detection

2004: < 0.557 g/kg (*)
(*) based on limit of detection

2005: < 0.007 g/kg (*)
(*) based on limit of detection

2006: < 0.033 g/kg (*)
(*) based on limit of detection

2007: < 0.025 g/kg (*)
(*) based on limit of detection

2008: < 0.067 g/kg (*)
(*) based on limit of detection

2009: < 0.056 g/kg (*)
(*) based on limit of detection

6. Because of the very low concentrations and total amounts of the substances in question, it is not possible to set meaningful targets for reduction in emissions of these substances to the aquatic environment. This is because most of the measurements used in quantifying the emissions were, generally, quoted as limits of detection. Where positive results were recorded they were in the range of the limits of detection.

7. Because the company is committed under the terms of its Integrated Pollution Prevention and Control Licence to regularly monitor the emissions of trace levels of organic compounds, including Toluene and Cyclohexane, it will be possible to ascertain whether the existing condition of very low emissions to the aquatic environment continues to prevail at Novartis Ringaskiddy Limited.

8. This data is presented in graphical form for the years 2004 to 2009 on the following pages.

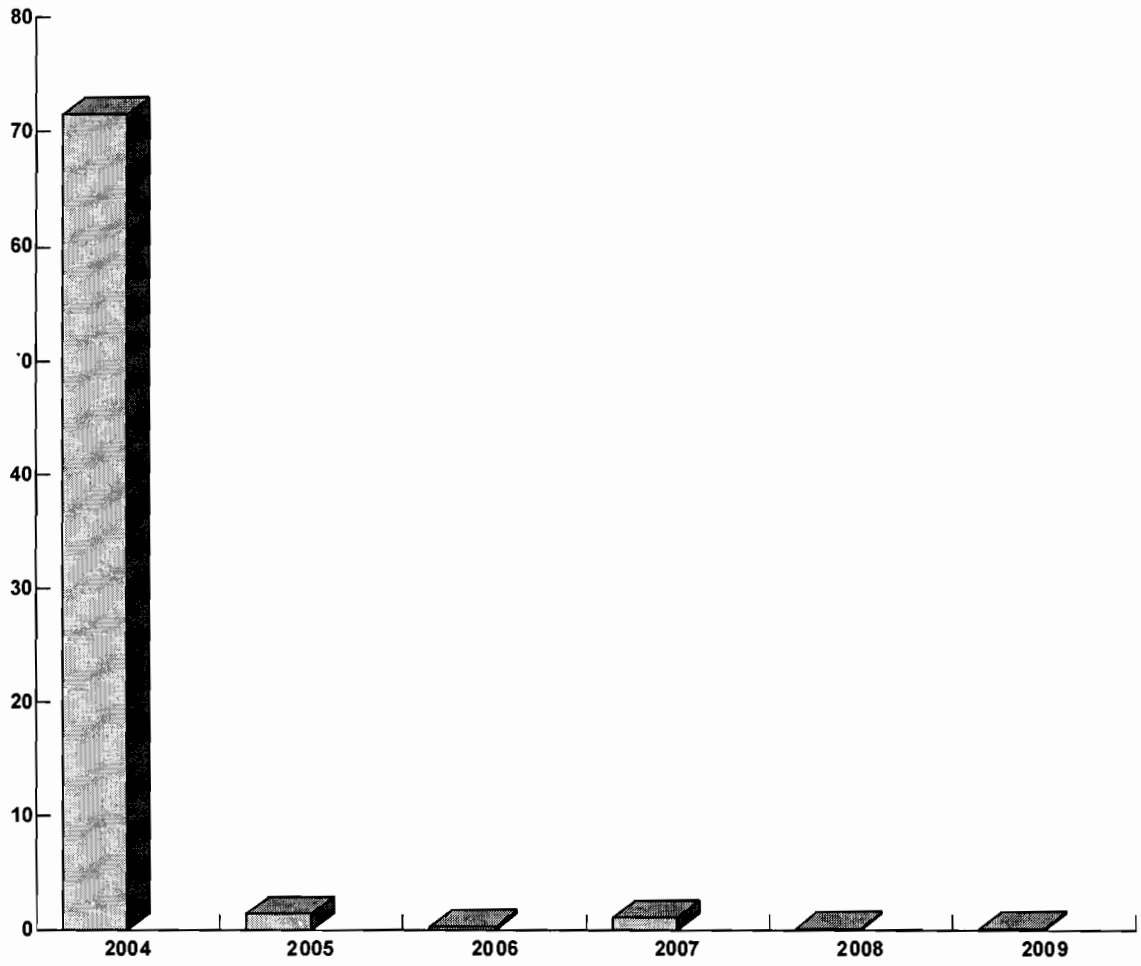


Figure 1. Emissions of Toluene (in kgs) to the Aquatic Environment from Novartis Ringaskiddy Limited (2004 to 2009)

(Note that the data for 2004 is based on higher limits of detection)

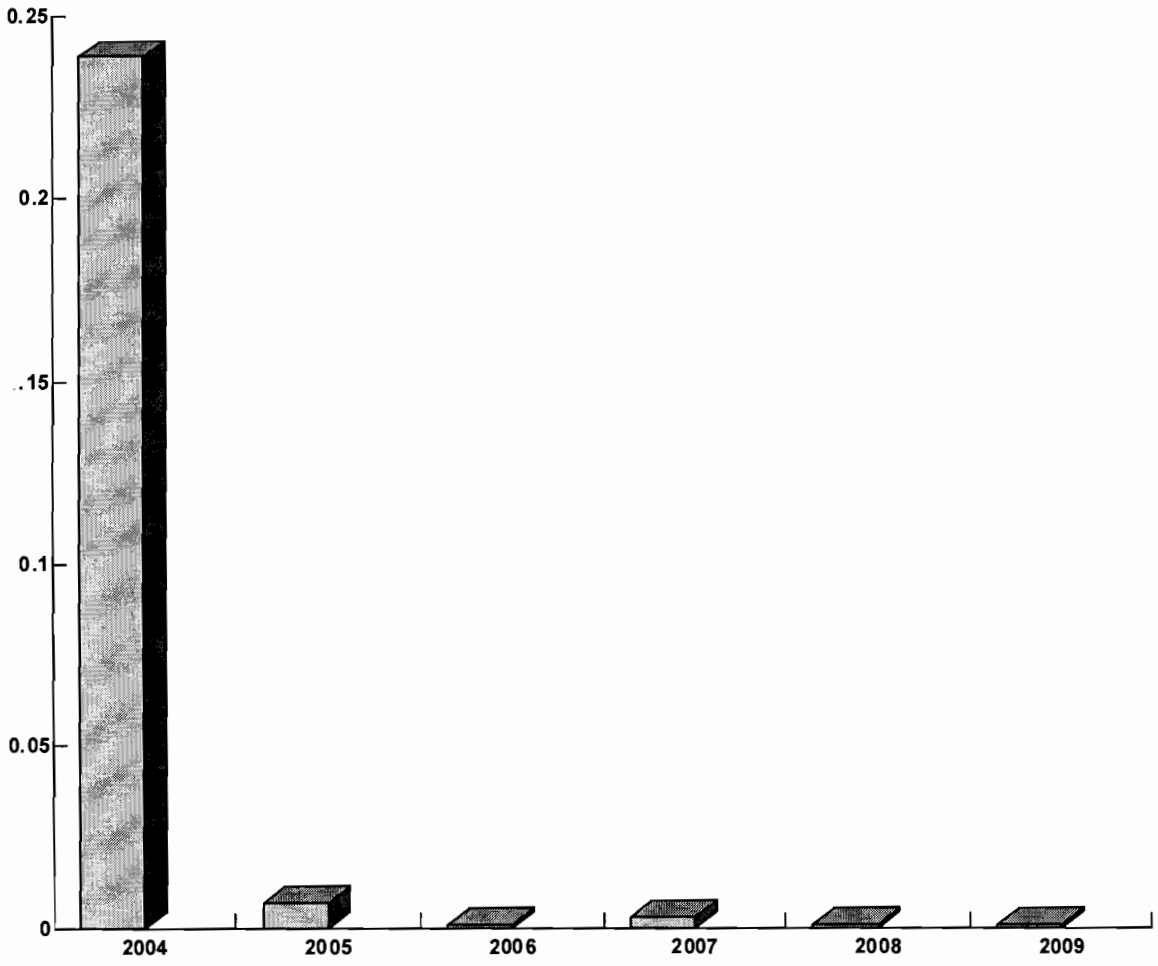


Figure 2. Emissions of Toluene (in g/kg product) to the Aquatic Environment from Novartis Ringaskiddy Limited (2004 to 2009)

(Note that the data for 2004 is based on higher limits of detection)

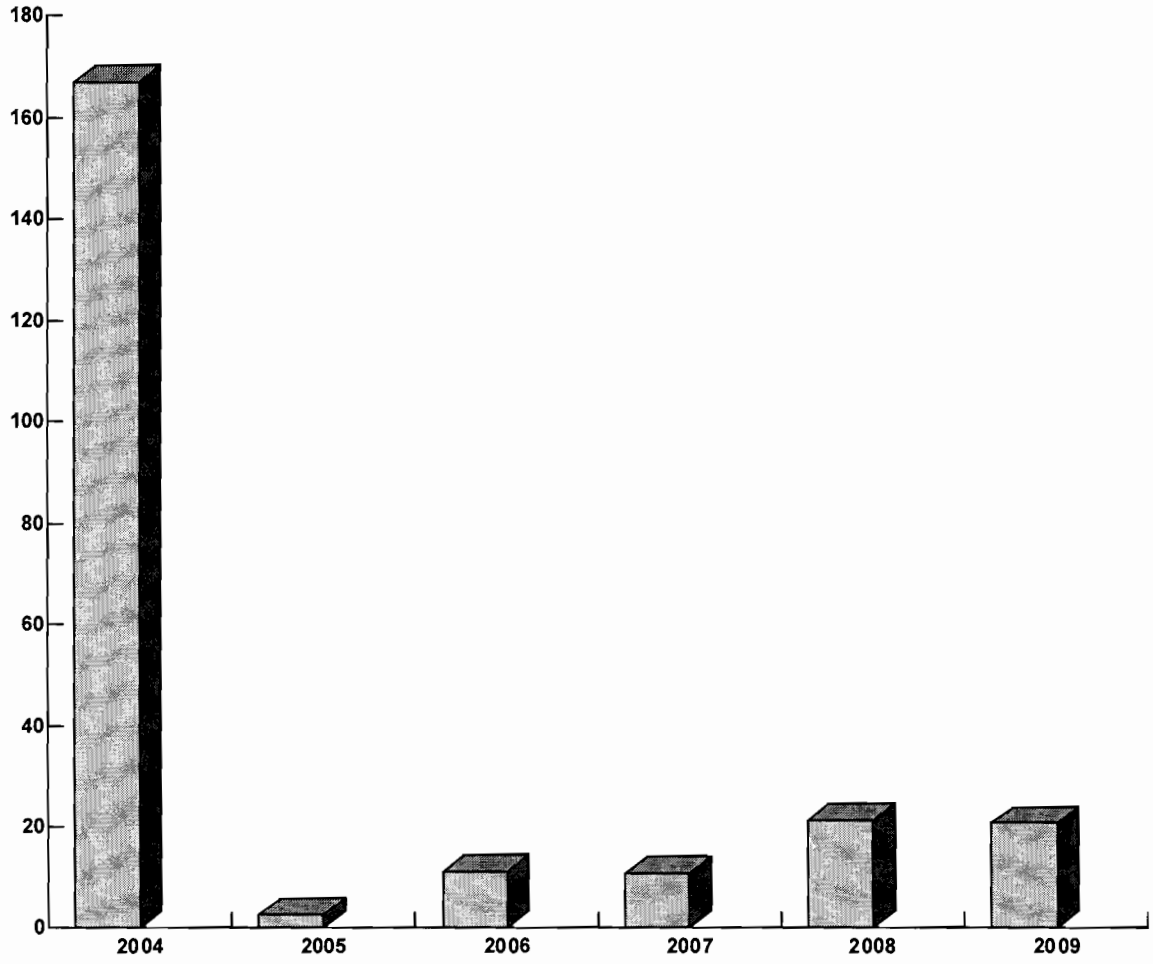


Figure 3. Emissions of Cyclohexane (in kgs) to the Aquatic Environment from Novartis Ringaskiddy Limited (2004 to 2009)

(Note that the data for 2004 is based on higher limits of detection)

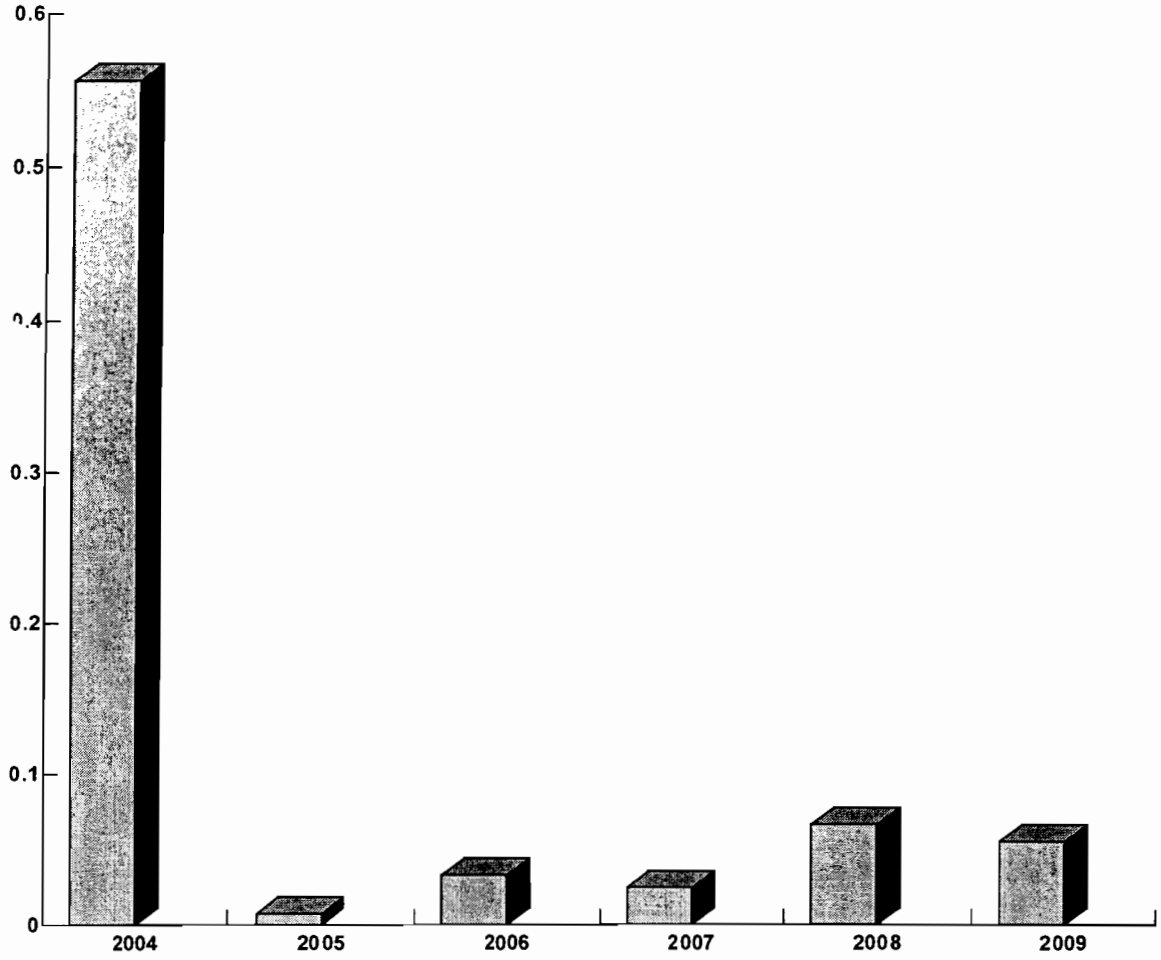


Figure 4. Emissions of Cyclohexane (in g/kg product) to the Aquatic Environment from Novartis Ringaskiddy Limited (2004 to 2009)

(Note that the data for 2004 is based on higher limits of detection)

Novartis Ringaskiddy Limited

Tank and Pipeline Testing and Inspection Report 2009

IPPCL Register Number P0006-03

Conditions 3.6.5; 3.11; and 6.8; and Schedule D, of IPPCL Register Number P0006-03 require that:

"The integrity and water tightness of all the bunding structures and their resistance to penetration by water or other materials stored therein shall be tested and demonstrated by the licensee at least once every three years. This testing shall be carried out in accordance with any guidance published by the Agency";

"The provision of a catchment system to collect any leaks from flanges and valves of all over ground pipes used to transport material other than water shall be examined. This shall be incorporated into a schedule of objectives and targets set out in Condition 2.2 of this licence for the reduction in fugitive emissions"; and

"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 shall be tested and demonstrated by the licensee. This testing shall be carried out by the licensee at least once every three years thereafter and reported to the Agency on each occasion. A written record of all integrity tests and any maintenance or remedial work arising from them shall be maintained by the licensee"

The company's first proposal in respect of testing and inspection of underground tanks and pipelines was included as part of the revision to the company's EMP included as part of the year 2000 AER. The provisions of Condition 9.4.4 of IPCL Register Number 545 were at that time new in respect of this facility. A report on the implementation of the first round of testing, which commenced during the latter part of the year 2003, and the inspection programme was submitted to the Agency as part of the AER for 2003.

A report on the implementation of the second round of testing, which commenced during the latter part of the year 2006, and the inspection programme was submitted to the Agency as part of the AER for 2006.

A report on the implementation of the third round of testing and the associated inspection programme is submitted as a separate appendix to the (current) AER for 2009

The company will advise the Agency when the fourth round of testing and inspection of underground tanks and pipelines is to be undertaken, which in any case will be completed no later than the end of 2012.

In respect of the requirement to examine he provision of a catchment system to collect any leaks from flanges and valves of all over ground pipes used to transport material other than water Novartis Ringaskiddy Limited wishes to point out that all such flanges and valves are effectively contained by the surface water protection system, which formed part of the design of the facility at Novartis Ringaskiddy Limited. A description of this protection system, which formed part of the company's proposal to the EPA (dated 03-Oct-1995) for the setting of action and warning levels with reference to the quality of surface water leaving the site, is included as part of the Annual Summary Report on Surface Water Emissions in this AER. Further information on this system is contained in Attachment Number 22 of the company's original application to the EPA for an Integrated Pollution Control Licence (dated 01-Sep-1994).

Information on the quality of surface water leaving Novartis Ringaskiddy Limited is summarised for the EPA on a quarterly basis. These quarterly reports are held at the facility for inspection by the Agency at any time. Any deviations in respect of surface water emissions are required to be notified to the Agency as part of the quarterly reporting process under IPPCL Register Number P0006-03. The monitoring data for 2009 indicated that all surface water leaving the facility was of a quality suitable for discharge to the local Cork County Council storm sewer.

Of further interest in this regard is the application of the Novartis principle of containment in the use of hard piped, closed systems. This concept has been extended to overhead pipes so that the number of flanges are minimised and where possible they are substituted by welds which are amenable to pressure and X-Ray testing.

Application of this system of containment from the design phase of the facility has ensured that the quality of groundwater under the site has remained the same as that prior to the commencement of the development at Novartis Ringaskiddy Limited. Confirmation of this is to be found in the company's reports on groundwater monitoring, which are submitted to the EPA on an annual basis. These reports confirm that the quality of the groundwater beneath the facility at Ringaskiddy has remained the same as that prior to the commencement of the development. The company is currently submitting groundwater monitoring data for 2009 (sampling dates: 10-Jul-2009 and 17-Sep-2009) as part of this AER. The data confirm that groundwater beneath the Ringaskiddy site has not been affected by manufacturing activities at Novartis Ringaskiddy Limited.

Consequently, the company is reporting that there were no reportable incidents involving leaks from over-ground pipes and valves during 2009; and that all such potential emissions are contained.

Novartis Ringaskiddy Limited

Energy Audit Report 2009

IPPCL Register Number P0006-03

Although the requirement for an Energy Audit was a new inclusion in the revised IPCL (Register Number 545) issued to Novartis Ringaskiddy Limited by the EPA on 31-Oct-2000; and is also included in Condition 7 of IPPCL (Register Number P0006-03) issued to Novartis Ringaskiddy Limited by the EPA on 02-Feb-2006, the company has in fact been active in this field since 1994, when manufacturing operations commenced at the facility. More detailed information is contained in the sub-section 4.10.1 of Revs 0 to 14 of the company's EMP.

The report prepared for the Agency in respect of Condition 11 of IPCL Register Number 545 ('Energy Audit') was forwarded on 12-Dec-2001 (our reference: IPC10222.doc) and was also included in the AER for 2001.

During 2002 Novartis Ringaskiddy Limited participated in the Negotiated Agreement Pilot Programme, coordinated by Sustainable Energy Ireland (SEI), as part of a National initiative to identify ways in which the country can meet its agreed targets in respect of stabilising and reducing emissions of Carbon Dioxide. Part of the programme required participants to carry out an independent in-depth energy audit. Novartis Ringaskiddy Limited's audit was carried out by Enviros Consulting Limited of Manchester, a company with significant international and industrial experience. A copy of the audit report was forwarded to the Agency as part of the AER for 2002.

The company suggests that both of the aforementioned documents meet the 'new' requirement of Condition 7.1 of IPPCL Register Number P0006-03.

As part of this on-going process the company, with the support of Sustainable Energy Ireland, commissioned a technical review of site operations in respect of good energy management by the Danish consultancy of Viegand Maagoe, which was undertaken during December of 2006. A copy of this report – together with a documentation gap analysis for the Irish Energy Management Standard IS 393 was submitted as part of the AER for 2006. The outcome of the technical review is currently being implemented (where appropriate) by the site Energy Management Group.

To consolidate the progress made in respect of the aforementioned audits an additional Novartis Pharma Corporate energy audit was undertaken by consultants BMG Engineering AG between 01-Sep-2009 and 03-Sep-2009. The auditors presented a number of recommended actions, which are currently being followed up on at site level.

Suggested improvements in energy management

- Develop a site energy strategy for the future. Such a concept should reflect the concept of low-exergetic heating as well as a 5 year site plan including strategic decisions on chillers etc. Part of such a site energy strategy should also be energy reduction targets.

- Evaluate CAR-approval of energy related projects under Novartis Corporate investment policy (pay back feasible if below the life time of the asset). This policy was stated and reiterated by Novartis top management and may allow the realization of energy related projects with pay-back > 3 to 5 years.

- Pursue extension of data monitoring & analysis with metering concept of main consumers of electricity and thermal energy (e.g. chiller system, CA compressors, HVAC) together with site engineering. Establish benchmarking of site energy consumption and energy efficiency for main consumers. So far, only limited benchmarking of single equipment efficiency has been conducted. Data availability for benchmarking and KPI monitoring is given as a very extensive and flexible data monitoring system is in place. More profound benchmarking has been identified as an area for improvement.

Suggested opportunities for energy cost savings

- Substantial energy saving potentials have been identified by this audit and are recommended for detailed evaluation and realization. BMG identified several energy saving potentials which have been prioritized together with site engineering. Based on the most interesting potentials total energy cost savings of roughly 600 – 1'130 k$/y were estimated by exergetic optimization of supply systems (considering only technically feasible retrofits). This corresponds to roughly 5-6% of total energy cost at the Ringaskiddy site (2008: 13 M$/y). These saving potentials were confirmed and agreed upon by site engineering.

- A further set of energy saving potentials (options for heat recovery) has been identified. These related projects need to be considered in the light of the overall site energy strategy which is to be developed.

- Further energy saving potentials were identified. But these potentials were considered as lower priority as they cannot be realized in an economically equally feasible manner by a retrofit. These additional potentials should be reconsidered in case of replacement of the corresponding equipment (see below for details).

Suggested engineering opportunities

- Continue the present culture of 'good engineering practice' with support from management (ensuring allocation of required resources).

- Contribute to the Novartis energy efficiency goals by supporting or coaching of other sites where similar energy saving concepts could be applied.

- Refine, sustain and update the energy flow diagram based on the audit result as a basis for further calculations.

Raising awareness

- Continue creating further awareness among all levels of personnel by corresponding awareness campaigns & specific training. The energy manager should update regularly on site energy efficiency and energy related topics relevant
- to management.

Possible use of renewable energy

- Pursue the evaluation of on site renewable wind energy (study ongoing).

During 2009 the company continued to optimise its use of the Energy Monitoring System (described in Rev 2 of the company's EMP); consolidated its participation in Sustainable Energy Ireland's (SEI) (previously known as the Irish Energy Centre) Annual Self Audit and Statement of Energy Accounts Scheme; and fostered employee awareness, for example by participating in the Electricity Supply Board's (ESB) Winter Demand Reduction Incentive; Energy Awareness Week; and by involving all of the main energy consuming Process Units at the facility in the E rgy Management Group. Further information is presented in the company's Environmental Management Programme, which is included elsewhere in this AER.

A comparison of the relative consumption of natural gas and electricity at the facility is presented on the following table. The table updates information that was forwarded as part of the Energy Audit Report of December, 2001.

Year	Energy Source	Relative Consumption
1996	Natural Gas	4.32 GJ/kg product
2004	Natural Gas	0.82 GJ/kg product
2005	Natural Gas	0.68 GJ/kg product
2006	Natural Gas	0.76 GJ/kg product
2007	Natural Gas	0.62 GJ/kg product
2008	Natural Gas	0.86 GJ/kg product
2009	Natural Gas	0.75 GJ/kg product
1996	Electricity	2.79 GJ/kg product
2004	Electricity	0.56 GJ/kg product
2005	Electricity	0.48 GJ/kg product
2006	Electricity	0.52 GJ/kg product

2007	Electricity	0.42 GJ/kg product
2008	Electricity	0.55 GJ/kg product
2009	Electricity	0.44 GJ/kg product

Natural gas and electricity are the two main sources of energy utilised at Novartis Ringaskiddy Limited.

BGM Engineering AG – Energy Audit Report September 2009

Efficiency and Risk Engineering

Report: Energy Audit Ringaskiddy NRL

Novartis Pharma AG

BMG Engineering AG

Audit Report

October 6, 2009
Contact
Dr. Reto Müller
Phone +41 44 732 92 86
Fax +41 44 730 66 22
reto.mueller@bmgeng.ch

BMG Report Energy Audit
Novartis PH Ringaskiddy
20090901-03.Doc / RTM

Date: September 01-03, 2009

Location: PH Ringaskiddy, Ireland

Participants:
Novartis:
Martin O'Sullivan
John Harrington
Padraig O'Brien
Edward Kellher
Eirdata:
Liam McLaughlin
Auditors:
Peter Wohlgemuth (Novartis Pharma, GPE)
Reto Müller (BMG Engineering Ltd.)

Distribution: Peter Wohlgemuth, John Harrington, Martin O'Sullivan (for internal distribution

Report of Energy Audit Novartis Pharma Ringaskiddy
Subject

Content

1 Background of energy audit

Based on the CHSE Guideline 13 it is a task of the Div/BU energy manager to establish an audit program among all major sites within the corresponding division / business unit. BMG is providing support to the Pharma Energy Manager to conduct some of the requested audits.

This report covers the 3rd of these audits for the PH site in Ringaskiddy conducted September 1st – 3rd, 2009. Main contact at the site was the energy manager in charge, Mr. John Harrington.

2 Goals of audit

The following goals have been defined:

- Establish a rough **energy balance** of the site and deliver an energy flow diagram (sankey)
- Audit the **energy management** on site by assessing the implementation of GL 13&14, e.g. evaluation of CHSE energy management fitness index (GN 13.2)
- Search and identify **energy saving potentials** in the energy supply, the utility systems and the HVAC installations. Prioritize potentials for detailed analysis and later technical realization.
- Define & assess **key performance indicators** KPI on site level (e.g. energy / gross floor area, MJ/m^2) and for single main consumer in the utilities systems (e.g. chiller COP, cooling tower COP, compressed air kWh/m^3)
- Evaluate possible application of **renewable energies**

3 Management summary

In September 2009 BMG Engineering Ltd. performed an energy audit (assigned by Novartis Pharma AG) of the Novartis Pharma site Ringaskiddy, Ireland. The focus of the audit was on site energy consumption with special emphasis on general utilities production and supply. The following conclusions were drawn and have been discussed and agreed upon in a final discussion with site engineering as well as site management (see also attached presentations).

Characterization of site energy management

An **energy management** system has been successfully developed and introduced as requested by the CHSE guideline 13.

- The function of a **site energy manager** was created with the allocation of required resources and responsibilities.
- The site established an **energy committee** consisting of the site energy manager and representatives of HSE, engineering, finance and IT.
- The site has an **energy policy** in place.
- The site has previously filled in the **energy management fitness index** (CHSE GN13.2) which allows a rough assessment of compliance with CHSE standards. The assessment during the audit (including the audit results) the site is at a current value of 45 pts. out of 46. This is an excellent result reflecting the long tradition of energy management on site. No major modifications are recommended to this system except some improvement in the field of benchmarking / KPIs.
- The site has a detailed and flexible data management system available to assess plant performance and trends.

Characterization of site engineering (regarding energy efficiency)

- Generally, **'good engineering practice'** is conducted at the site. The focus of site engineering tasks is on maintenance, improvements and extensions of existing systems as well as on design of new systems.
- Economically feasible **energy saving potentials** have been identified by the site continuously. Several low-cost energy saving measures ('low hanging fruits') have been identified during the audit and are recommended for immediate realization (see list below).
- Energy optimization has been a continuous topic in the past. Thus, Ringaskiddy is considered as a **mature site** regarding energy efficiency. This means that feasible low cost energy saving potentials (low hanging fruits) have been realized to a wide extent. There are still some areas for improvement where further optimization is feasible (see saving potentials below). Major further improvement can be achieved by optimization and integration of utility supply systems. Such concepts will require substantial modifications of current systems with the associated demand of work load and investment cost. Nevertheless, such concepts can be economically feasible and enhance the sites profitability.

Recommended actions

- **Energy management**
  - Develop a site energy strategy for the future. Such a concept should reflect the concept of low-exergetic heating as well as a 5 year site plan including strategic decisions on chillers etc. Part of such a site energy strategy should also be energy reduction targets.
  - Evaluate CAR-approval of energy related projects under Novartis Corporate investment policy (pay back feasible if below the life time of the asset). This policy was stated and reiterated by Novartis top management and may allow the realization of energy related projects with pay-back > 3 to 5 years.
  - Pursue extension of data monitoring & analysis with metering concept of main consumers of electricity and thermal energy (e.g. chiller system, CA compressors, HVAC) together with site engineering. Establish **benchmarking** of site energy consumption and energy efficiency for main consumers. So far, only limited benchmarking of single equipment efficiency has been conducted. Data availability for benchmarking and KPI monitoring is given as a very extensive and flexible data monitoring system is in place. More profound benchmarking has been identified as an area for improvement.

- **Energy cost savings**
  - Substantial energy saving potentials have been identified by this audit and are

recommended for detailed evaluation and realization. BMG identified several energy saving potentials which have been prioritized together with site engineering. Based on the most interesting potentials total energy cost savings of roughly **600 – 1'130 k$/y** were estimated by exergetic optimization of supply systems (considering only technically feasible retrofits). This corresponds to roughly 5-6% of total energy cost at the Ringaskiddy site (2008: 13 M$/y). These saving potentials were confirmed and agreed upon by site engineering.

- A further set of energy saving potentials (options for heat recovery) has been identified. These related projects need to be considered in the light of the overall site energy strategy which is to be developed.
- Further energy saving potentials were identified. But these potentials were considered as lower priority as they cannot be realized in an economically equally feasible manner by a retrofit. These additional potentials should be reconsidered in case of replacement of the corresponding equipment (see below for details).

- **Engineering**
  - Continue the present culture of 'good engineering practice' with support from management (ensuring allocation of required resources).
  - Contribute to the Novartis energy efficiency goals by supporting or coaching of other sites where similar energy saving concepts could be applied.
  - Refine, sustain and update the energy flow diagram based on the audit result as a basis for further calculations.

- **Awareness**
  - Continue creating further awareness among all levels of personnel by corresponding awareness campaigns & specific training. The energy manager should update regularly on site energy efficiency and energy related topics relevant to management.

- **Renewable energy**
  - Pursue the evaluation of on site renewable wind energy (study ongoing).

4 Procedure of audit

Preparation phase:

- Information on the energy consumption of the site was available from the Novartis DMS.
- Prior to the audit the energy manager sent information to BMG: site layout, HVAC zoning concept, energy consumption data, single line diagram
- Based on this information, BMG prepared the audit (data evaluation, set up of agenda).

The following agenda has been scheduled at the site (three days):

Day 1

- Kick-Off meeting (introduction, agenda, goals of audit)
- Introduction & overview of site (size, production, capacity)
- Overview of site energy management (energy management program, history, type of utilities, energy consumption, performance figures, etc.)
- Energy management system in Ringaskiddy (discussion of previous audit results, planned / ongoing energy projects)
- Site tour 1, utility systems (boilers, chillers, cooling towers, CA compressors, HVAC systems, solvent recovery unit, waste water treatment)

Day 2

- Site tour 2, production area (production building, warehouse)
- Detailed discussions on utility & HVAC systems
- Site tour 3, solid waste incineration

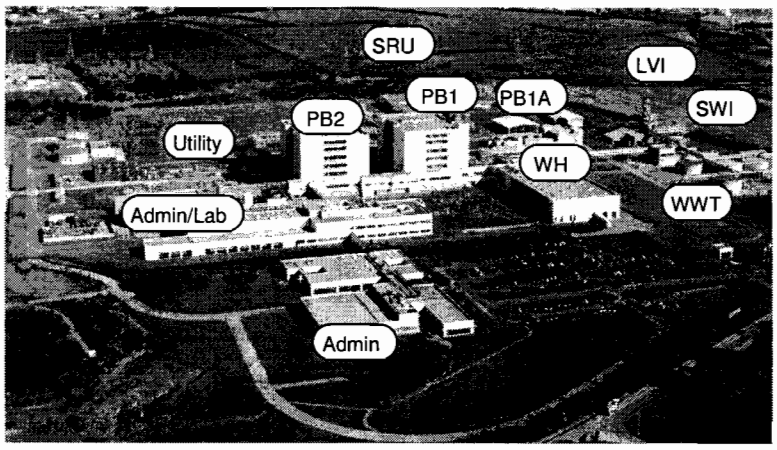
Day 3

- Review and analysis of preliminary results
- Discussion of a site energy strategy → road map
- Wrap-up meeting: Presentation of preliminary audit results to site management

5 Results of audit

5.1 Rough characterization of site

The site consists of two main production buildings for dedicated (PB2) and multipurpose (PB1) production as well as an annex (PB1A) for low temperature reactions. The site has a large solvent recovery unit (SRU), a liquid and vapor incineration plant (LVI) and a solid waste incineration (SWI). Besides some administration and lab buildings there are several different warehouses and a waste water treatment plant (WWT).



The total site land area is roughly 532'000 m^2, building footprint is ~26'000 m^2. About 445 people are working at PH Ringaskiddy.

5.2 Characterization of site energy management

An **energy management** system has been successfully developed and introduced as requested by the CHSE guideline 13.

The function of a **site energy manager** is established with the allocation of required resources and responsibilities. He has ~20% of his time available for energy management related tasks. This is sufficient and adequate considering the fact that the initial effort in establishing the energy management structure is mostly completed but still several areas for technical and organizational optimization are present.

The energy management at NRL comprises activities like

- Creating awareness among employees (e.g. lighting reduction, PC standby program, NRL newsletter, etc.)
- Optimization of electricity and gas supply contracts (hedging of gas, long term contract for electricity)
- Data monitoring & analysis, conducted where possible, e.g. where metering is possible. A comprehensive metering concept was included already during the construction phase of the site which from today's perspective must be considered visionary.
- Performing role in CAR approval
- Performing energy challenging on new projects. Div/Energy management is currently developing a tool for facilitating systematic energy challenging which will be helpful for the site.

The site established an **energy committee** consisting of the site energy manager and representatives of HSE, finance, IT and engineering. This committee is meeting on a monthly base.

The site set up an **energy policy** which has been signed by the site head.

The site filled in the **energy management fitness index** (CHSE GN13.2) which allows a rough assessment of compliance with CHSE standards. Out of a total maximum of 46 points, NRL reached the following score

- 2006 / 2007: 39 pts. (85%)
- September'09: 45 pts. (98%)

45 points is an excellent result, further improvement is neither required nor feasible. Emphasis should be on maintaining this high level.

The current **information and update of site management on energy related topics** on a regular base is considered as a very valuable activity which is to be continued. Possible topics could be: results of energy saving projects, results of KPI monitoring, site and staff energy awareness, development of energy carrier prices (power, gas, water), tendencies on a national level (legislation, requirements, energy tax) etc.

In the situation where the energy management system is well established and low hanging fruits are vastly taken, it should be a main task for site energy management to develop a **long term holistic site energy strategy**. Such a strategy should not only consider technical constraints but also future development of site (e.g. expected change in production, R&D etc.) and legal constraints (e.g. CO_2 emissions, water consumption etc.). Thus, the focus of such a strategy could for example be on CO_2 intensity of production, the thermal supply system or low exergetic heating etc. Such a strategy may be developed by the site alone but might very likely require input and support from site and divisional management, GPE and possibly local authorities.

Compliance with CHSE 13

- energy management is fully compliant with CHSE guideline 13

Compliance with CHSE 14

- CHSE GN 14.1: Climate correction factor for NRL is 0.6.
- CHSE GN 14.2 is fully considered and followed for new projects. Existing building elements partly seem to be not compliant, e.g. windows, and door elements where U values are likely too high (no incompliance as existing elements).
- CHSE GN 14.3: use of refrigerant materials is not compliant. R22 is used in five existing chiller systems (2 x HVAC, 2 x Glycol, cold room) and must be changed by end of 2014. The site is aware of this and a phase out is planned for 2010/2011.

5.3 Characterization of site engineering and system design

Economically feasible **energy saving potentials** are being identified by the site (energy manager & site engineering) continuously. Some low-cost energy saving measures ('low hanging fruits') have been identified during the audit and are recommended for immediate realization (see list below).

Generally, **'good engineering practice'** is conducted at the site. The focus of site engineering is on maintaining and improving existing systems. Nevertheless, in certain areas concerns about efficient system operation were raised. The following table lists some of the identified issues from an operational but also from a design point of view.

System	operational issues	design issues
Boiler	o High steam system pressure: 9 barg. Effectively required temperatures should be assessed (production demand <145°C, only SRU might need higher temperature). See also comment on boiler system below	o Boiler flue gas temperature was observed to be ~120°C. A further reduction is not feasible with the current configuration with de-aerator achieving 107°C boiler supply temperature. (Partly) preheating of the condensate prior the de-aerator could reduce flue gas temperature and increase fuel efficiency.[1] o Only steam, no hot water production at boiler and economizer.
Compr. Air	o Very low dew point of -77°C observed at the adsorption dryers. This issue will be addressed in the framework of a compressor replacement including hot air regenerated adsorption dryers. The set point for dehumidification should be adjusted anyway.	o The compressor installation consists of two equal sized and one smaller units in parallel. A modular concept with different compressor capacities would have allowed covering the varying CA demand more efficiently. The site has addressed this; a project for a new VFD compressor is ongoing.
Chiller	o Glycol chillers are generating -25°C. Only few reactors / units really require this low temperature. An increase to -15°C is aspired by site engineering (eventually with local booster units). This requires of course substantial convincing of all	o The ice bank is loaded by the glycol system (-25°C). This is relatively inefficient (low COP). In the light of HVAC chiller replacement an option for generation of e.g. -5°C glycol to load the ice bank during night might be evaluated (normal HVAC chilling at 5-10°C).

Comments by site:
[1] As 25% of the condensate is returning hotter than 107°C this is unlikely to be economical. Rather, a low temperature heat sink should be supplied, e.g. direct generation of 60°C hot water in a dedicated economizer or supply of condensate heat to 60°C in order to 'cool' condensate prior to entry into the existing economizer.
[2] Dehumidification is not the driver for chilled water temperature rather it is production cooling process. This should be challenged to try to get an operation window of up to 10°C in order to allow temperature to modulate in this band based on dehumidification requirements.

	involved parties. o HVAC chillers generate +5°C chilled water[2]. More relaxed HVAC humidity control might allow increasing chilled water supply to 7-10°C.	
CTW	Very low ΔT between supply and return flow (1-2 K) and very high flow rate and pressure of pump are observed (6 bar). Flow rate is close to hydraulic limit. A reduction of this flow rate is aspired by engineering (e.g. by condenser temperature set-point control) and could partly be achieved, already. The concept for local booster pumps for dedicated consumers was discussed (see below).	

Comment on steam system:

The thermal heat supply for the whole site is provided by the steam generators in the utility building and the LVI from which steam at 9 barg is distributed. Steam is used directly in the SRU and the production buildings (for hot glycol loops). The medium pressure steam condensate is flashed to generate 3.5 barg steam which is used for humidification (HVAC) and for heating in some air handling units. Most of this steam is transformed into hot water (60°C) inside the different buildings for HVAC and static heating.

A large number of HVAC heating coils are supplied by hot water already today. With a corresponding re-design of some further steam-based heating coils (direct steam heating in some AHU) the effective HVAC steam demand of the site would be limited to humidification, only.

Such a re-design would allow for an alternative heat supply concept: instead of 3.5 barg steam[3] a low temperature hot water system (e.g. 50-60°C) would be sufficient to operate the whole site HVAC heating (except humidification). Such a system could be fed by different low exergy sources, e.g. waste heat recoveries[4].

System capacities:

The capacities of the utility systems were discussed during the audit. The following table lists some main utility systems with their capacity and their annual mean load. Note, this annual mean load corresponds to the annual energy consumption (or production) equally distributed over the whole year, thus not accounting for any peak loads. The load percentage is given as per single unit or per system with and without redundancy (n or n-1 units), where applicable.

[3] Most of this steam is produced by pressure reduction, only a small proportion is from flashed condensate.
[4] Site engineering was suggesting that a pre feasibility study should be conducted to evaluate the overall concept, i.e. calculate low exergy demand in each building and try to match with low exergy heat sources with rough implementation costs developed.

Utility	**Installed capacity**	**Annual mean load**	**Load percentage**		
			per unit	redundant system (n-1 unit)	full system (all n units)
Compressed Air	2 x 2'073 + 1'300 = 5446 Nm^3/h	3'300 Nm^3/h	~160%	~98%	~61%
Chillers – HVAC	2 x ~1 MW_{th}	0.7 MW_{th}	70%	70%	35%
Chillers – Glycol	2 x 2 MW_{th}	0.9 MW_{th}	45%	76%	23%
Boilers	2 x 15 MW_{th}	5-7 MW_{th}	33-47%	33-47%	17-23%
Transformers 2 x 38/10 kV	2 x 10 MVA	5.7 MVA	57%	57%	29% (all site)
Transformers 18 x 10/0.38 kV	27 MVA (total)	5.7 MVA	dedicated building supply, redundancy only per building		21% (all site)

In principal, there is overcapacity regarding the two 38/10 kV transformers. However, they're used as redundancy as they're both supplied by different grid areas.

No reactive power has to be paid at NRL. The overall site reactive power compensation is achieving a reasonable value of cos φ ~ 0.95 – 0.97.

Energy monitoring and benchmarking:

A large number of metering units for electricity, steam, flow rates etc. have been installed at different locations in order to monitor the local consumption. Thus, the overall energy consumption of the main consumers is well known. So far, only minor **benchmarking of single equipment efficiency** has been conducted. This has been identified as an area for improvement. The following KPI are recommended for evaluation and some of them could be evaluated preliminary during the audit. Others will have to be assessed in future work.

- Overall site efficiency (these KPI will be established by GPE directly)
  - related to interior gross floor area: $GJ/(m^2\ y)$ *
  - related to production: GJ/(t y) *
- Utility system efficiencies:
  - CA: compressor energy efficiency[5]: 0.129 kWh/m^3_{CA} *
    This KPI is recommended to evaluate dependent on CA production in order to optimize system operation point. The site should assess this benchmark in future.
  - CW: chiller efficiency COP[6]: kWh_{CW} / $kWh_{electricity}$ *

[5] Based on report "Compressed Air System Upgrade " by Eirdata Environmental Services Ltd, 2009
[6] Based on report "Assessment of site cooling options " by Eirdata Environmental Services Ltd, 2009

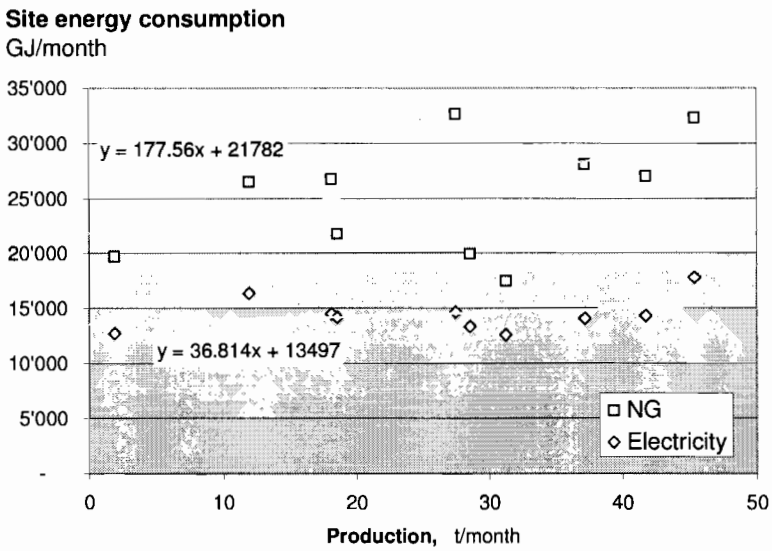
Glycol COP ~ 1.91 (without pumps), ~ 1.47 incl. pumps and condenser fans
CHW COP ~ 2.62 (without pumps), ~ 2.06 incl. pumps and condenser fans

- CTW: cooling tower efficiency, COP: kWh_{CTW} / $kWh_{electricity}$
  COP ~40 (pump and fans)

- Production efficiencies
  - washing: specific water consumption: liter / containment washed
  - rectification: specific energy consumption: MJ / kg solvent recovered
  - etc.

Those KPIs recommended for assessment and continuous monitoring by site energy management or engineering are indicated by an asterisk.

Evaluating the overall site KPI as a function of e.g. production allows insight into base load consumption of the site. This is shown for electricity and natural gas consumption in the figure below (based on DMS data 2008)[7]. It has been the declared goal of site engineering and the site energy manager for the last years to reduce this base line consumption further.



Energy related projects currently evaluated, ongoing or soon to be started:

- Optimization of CTW distribution
- Optimization of leakages in CA distribution and CA production

[7] As most site energy is used by HVAC and buildings it is not to be expected that production will be the major driver (see also energy flow diagram below).

- Reduction of electricity & steam base load consumption (over Christmas)
- Awareness campaign regarding PC standby consumption
- Increase of Glycol -25°C temperature
- LVI capacity extension with third incinerator (see also below)

5.4 Characterization of HVAC system

The following concepts are applied in the NRL HVAC systems:

- Production areas are predominantly classified zone E (general production area) with product specific areas classified D or 2 according to the Novartis implementation guideline N6.2.2.
- Nominal room conditions at NRL are

	Temperature	r.H.	ACR
zone D	22°C±5°C	45%±15%	5-30 h^{-1} (min 5)
zone 2	22°C±6°C	50%±20%[8]	5-30 h^{-1} (min 5)
zone E			reduced to 3 h^{-1}

- Production areas are mainly operated with 100% fresh air (no recirculation due to safety aspects, e.g. solvent vapors). No heat recovery on the fresh air handling units is possible as the exhaust air is vented out on the lateral building walls; no ducting of exhaust air is installed.
- All non hazardous areas on site (including admin) use recirculation of air, there are no full fresh air units in non hazardous areas.
- Dehumidification is performed with chilled water (supply temperature ~5.0°C). Nominal target for dehumidification is 8.5 g/kg, 9.5°C for zone D conditioning. These values can be shifted by the control system in order to reduce chiller load in summer. This regulation system allows exploiting of room tolerances (temperature and r.H.). Considering the wide tolerances, cooling water supply temperature is rather low (see also chiller saving potentials below).
- Humidification is done with flash steam in the laboratory building, only. All other buildings use 9 barg steam reduced to 3.5 barg and then to 1 barg.
- For areas with 100% fresh air supply re-heating coils are located in the main ducts. These are all operated with hot water, there are no steam reheats. Steam is used for frost coils primarily and for space heating in preheat coils in many process areas.
- Filter pressure drop is measured and used as indicator for filter replacement. Alarm values are set with the goal of minimized total cost (energy, maintenance, filter material). The filter concept is based on H13 at the clean room entrance and exit. Fresh air is treated by G4

[8] >35% r.h. for ex areas in zone 3

and F8 type filters.

- Air change rates (ACR) have been minimized throughout the whole site. Generally in production areas, ACR is reduced to as low as 3 h^{-1}. This is considered to be probably a 'best practice' value.
- Where possible AHUs stop during non-occupancy hours, otherwise there is a night setback for temperature and in some areas ACR.

Comment on warehouse operation

- Warehouse areas are not ventilated.
- It was observed that the temperature distribution within the warehouse is considered in the choice of storage place: temperature sensitive material is stored in the lowest shelves; less sensitive goods are stored in higher levels. The SAP system managing the different warehouses (material storage and logistic) was adjusted accordingly.

Conclusions on HVAC systems
HVAC systems at NRL are well optimized already; ACR reduction and control routines are advanced. Current focus of optimization efforts of energy manager and site engineering should be in other areas beyond HVAC.

5.5 Energy Balance of Site

An energy balance of the site was established according to known and calculated energy consumption of the year 2008 as well as based on estimates and assumptions. From this energy balance, the following sankey diagram was drawn.

It should be noted that the energy consumption of the SRU, the chemical production and the HVAC demand was based on calculations as well as existing measurements where available (metering).

Basis for this energy balance was as follows:

- Input to site: known annual consumption data 2008 of gas and electricity as well as known outside air conditions (hourly average values) together with fresh air consumption (design case).
- Output of site: known chiller COP values (indicated by site) and estimates on unit efficiencies and heat losses of installed equipment (estimates by BMG).

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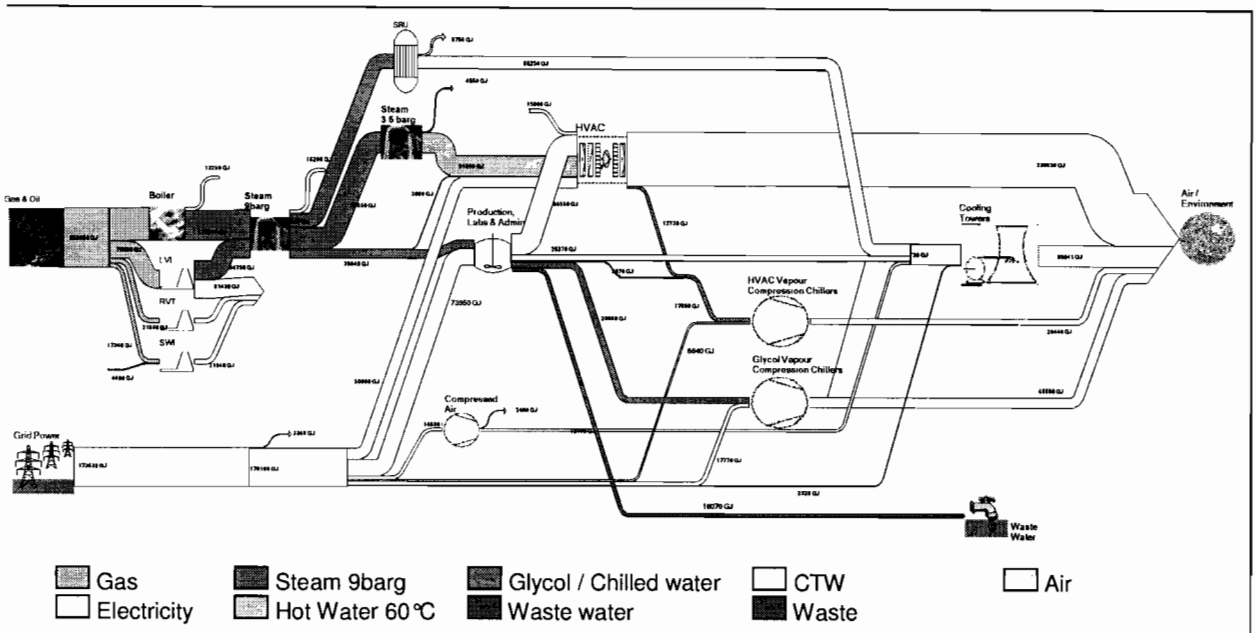


The following conclusions were drawn from this diagram and discussed on site in detail:

- The energy flow diagram reveals the fact that the HVAC system is consuming more thermal energy than the actual production. The cooling and dehumidification demand of the site is not very energy intensive as air change rates have already been reduced and climate conditions as well as requirements are not very demanding.
- Also shown in the energy flow diagram above is the relatively low electricity demand for compressed dry air production even though this system is considered as running relatively inefficient.

Based on this energy flow diagram the following alternative concepts for site energy supply were discussed: waste heat recovery, solvent incineration, combined heat & power generation. The latter two concepts have been investigated by the site itself but need to be briefly mentioned here as they all interfere with each other. These concepts might also be applied in parallel but eventually with limited extend.

A. Possibilities for waste heat recovery were identified and roughly evaluated (see saving potentials below).
    - A high potential for heat recovery lies in the chiller waste heat, either on the level of condensation of the refrigeration material (~30°C) or – preferably – at a higher level suitable to supply an existing or modified supply temperature level. Such a temperature level could be reached by either a heat pump or by making use of the super heating of the refrigeration material (~60°C) prior to entering the condenser.
    - Improved waste heat recovery from boiler flue gas
    - Waste heat recovery at the compressed air compressors

- Waste heat recovery from CTW return, e.g. from SRU
- Waste heat recovery from WWT effluent
- Waste heat recovery from SWI
- The following table summarizes these waste energy streams together with their associated monetary value regarding a substitution of natural gas as well as the CO_2 emissions associated with them.

Waste heat streams - feasibility of low exergetic heating	**waste energy flow**	**Related CO2 emission**	**equivalent gas cost (range)**
Source of waste heat	**GJ/y**	**kt/y**	**k$/y**
Chillers, ~30°C	72'000	4.0	700 - 1'400
Air compressors, ~60°C	12'000	0.7	120 - 220
Boiler flue gas, ~80°C	11'000	0.6	110 - 200
SWI, ~150°C	11'000	0.6	110 - 210
SRU, ~25°C - 50°C	55'000	3.1	570 - 1'060
LVI scrubber, ~60°C	n.a.	n.a.	n.a.
Waste water plant, ~25°C	16'000	0.9	170 - 310
Total available waste heat	**177'000**	**9.9**	**1'800 - 3'400**
Required energy for heating applications	**96'000**	**5.4**	**1'000 - 1'800**

As the table above shows, about 96 TJ of heat with a corresponding natural gas equivalent value of ~1'400 k$/y would have to be supplied by a selection or combination of the available waste heat streams which overall account for ~180 TJ. The required and available temperature levels need to be considered resulting in either a direct heat recovery an option (heat pump).

Such a heat recovery system could consist of a site wide loop to which all kinds of heat sources could dispose their waste heat in and where heat sinks would be supplied from. But also a much smaller heat recovery system is possible, where only a few local sources and sinks are matched, thus not having ultimate flexibility but smaller investment cost. As mentioned above, the overall holistic site energy strategy would help deciding which way to go.

It should be mentioned that the current need for chiller system replacement / modification due to refrigeration material restriction by 2014 is offering a unique situation in the sense of allowing possible waste heat integration of chillers combined with chiller upgrade. A stand-alone retrofit into an existing chiller plant would be technically as well as economically much less feasible. Thus, it is the right moment to evaluate possible heat recovery in the light of the planned chiller modifications.

B. Solvent incineration: The site operates an incineration plant for liquid and gaseous waste (LVI). Due to limitations on capacity and hazardousness of waste to be treated, a large amount of the liquid waste produced in NRL has to be shipped to a thermal treatment plant

in Europe.

A project is under evaluation/approval to incinerate virtually all of the waste produced on site. The concept would foresee producing high pressure steam to run a steam turbine and supplying the low pressure steam into the existing steam system (9 barg). Further, it is foreseen to drive an absorption chiller with surplus steam which would reduce chiller electricity demand.

This project would reduce substantially operating cost (less external transportation and disposal, highly reduced demand of NG, reduced demand of electricity from gird). On the other hand, net site energy consumption (in terms of GJ, including energy from waste) and GHG emissions would increase due to this project. This means **nominally reduced site energy efficiency and increased GHG emissions**, which clearly is against the intention of CHSE.

However, this is **true only for scope 1&2 GHG reporting**, in a scope 3 reporting the situation would be entirely different: local waste incineration in conjunction with high energetic yield regarding heat recovery would be rated beneficiary compared to off-site incineration requiring transportation (energy demand, risk). Site energy efficiency currently is measured as GJ consumed per ton of product whereas electricity, fossil fuels and waste all count equally, e.g. **no exergetic assessment** of these energy carriers is applied.

This conflicting situation between the definition of site energy efficiency and GHG emission reporting vs. economic and ecological value of this project has been discussed on site. A consensus will need to be achieved aligning ecological and economical goals and reporting mechanisms e.g. between GPE and CHSE.

C. Cogen: In 2005, the site investigated the feasibility of a combined heat and power generation plant (Cogen) for NRL. Based on energy carrier cost rates at the time being, various systems in the range of 4.4 – 5.2 MW_{el} turned out to be economically unattractive (pay-back time ~5-9 years). Moreover, the feasibility of a Cogen is only given if the heat produced by the turbine / engine can be absorbed by the site (most likely in the form of process heat, e.g. steam). This was found to be the case only if no additional incineration of waste would take place at NRL. It was agreed to re-evaluate a Cogen plant if no additional waste incineration would take place on site.

5.6 Comments and quantification of identified saving potentials (selection)

Saving potential	*Comments & Quantification*
CTW: replace make-up water by e.g. rain water	The evaporation of water in the cooling towers is made up by city water. A replacement of this city water by any other source of water is recommended for evaluation. Such source might be e.g. rain water or RO blow down. Based on meteorological data the annual amount of precipitation on site is 1050 mm/y. Collecting rain water from ~25% of the total site would be sufficient to cover the cooling tower make up demand (17'500 m^3/y according to estimate by site engineering). Currently, a large amount of rain water is already collected in the fire water basin from which it could be easily pumped

	to the cooling towers. The cost saving potential is roughly 64 k$/y (based on city water unit price of 3.7 $/m^3).
CTW: decreased supply pressure	Cooling tower water is supplied at 6 barg to the site loop; hydraulic flow limit is ~2200 m^3/h, in average the system was estimated to be run at ~1500 m^3/h. The return flow is at ~ambient pressure; virtually all hydraulic work is dissipated at the consumer. The high supply pressure is required solely for supplying the topmost condensers of the SRU, the highest point of the site. It was proposed to have a dedicated booster pump to supply the SRU (and any other critical user). This would allow reducing the loop supply pressure to e.g. 4-5 barg. Based on estimated cooling loads and flow rates, a booster pump of ~20-30 kW would be sufficient to lift the pressure at the SRU from 5 to 6 barg, again. A reduction to 5 barg corresponds to a saving of electricity of roughly 2.3 TJ/y or 120 k$/y, respectively (taking into account the electricity demand of the booster pump), a reduction to 4.5 barg would represent savings of roughly 170 k$/y. This potential is highly recommended for further evaluation.
CTW: change to closed loop design	If the cooling water loop was hydraulically closed, the supply pressure could be reduced to only cover pressure drops over point of use, typically 2 bar. This would result in a far lower electricity consumption of the pump. To realize a closed loop design, the cooling towers would need to be operated by a secondary loop which would in turn cool the closed loop by a large heat exchanger. Having the cooling water as a closed loop might also have operational advantages. Electricity savings would be in the range of 6.6 TJ/y or 350 k$/y, including electricity consumption of pump for secondary cooling tower loop (. But the required investments are rated substantially (e.g. two 15 MW plate heat exchanger in parallel for redundancy, etc.) and the option with a booster pump is favored for its technical simplicity. [9]
Flue gas heat recovery at boiler (steam generation) and condensate use	The temperature of the boiler flue gas at the exit of the steam generator is reduced by an economizer supplying heat to condensate return (~107°C after de-aerator). After the economizer the fume gas temperature is ~120°C. Currently, no further reduction of the flue gas (and consequent reduction of boiler losses) is feasible as the condensate is already at 107°C after the de-aerator. In the de-aerator the condensate is heated with steam. Thus, a

[9] Due to the larger saving potential site engineering favors a closed loop design. This saving potential needs to be analyzed in more detail in a second phase. Besides payback also other aspects must be attractive when considering such an option (i.e. practicability).

	preheating of the condensate return in a secondary economizer could reduce fume gas temperature to e.g. 90-100°C and reduce de-aerator steam demand. The corresponding increase in boiler efficiency is expected to be in the range of 2-3% resulting in annual energy and cost savings of roughly 3 TJ/y or 43 k$/y, respectively. The construction of such a secondary economizer is technically challenging resulting in relatively high investment cost. This saving potential is considered as secondary priority.
Steam system: pressure reduction	Steam system at NRL is operated at 9 barg. This pressure is required solely to drive some of the distillation units of the SRU. The remaining heat demand is limited at ~140°C (~5 barg, 152°C) for hot glycol loops in production buildings and 60°C for HVAC application. The current steam system is expected to have overall losses of ~15% (transmission, radiation, steam traps, etc.). It was proposed to decouple the SRU steam demand from the rest of the steam system with a dedicated steam generation by the LVI. Such a concept was regarded as feasible by site engineering as LVI and SRU are located close by and only minor changes would required to the steam system. Reducing the pressure and thus the temperature of the steam system to e.g. 5 barg will reduce transmission losses of the piping by roughly 13% (see table below) and also boiler efficiency will be increased (given that the economizer can exploit the potential reduction in stack gases). Reduction of steam pressure reduces transmission losses to the environment: **current** / **reduced** Steam pressure, barg: 9 / 5 Saturation temp., °C: 180 / 159 delta T (to 15°C): 165 / 144 Relative transmission losses: 100% / 87% An overall improved efficiency of 12-15% is expected for the steam consumed by process and HVAC (not SRU!) resulting in annual energy and cost savings of roughly 3.5 TJ/y or 51 k$/y, respectively.
SWI: steam generation	Currently, no heat recovery is available at the solid waste incineration plant (SWI). In principal, a steam generator could be introduced in or after the quench zone of the hot fume gases. Based on estimated and indicated waste treatment (20'000 drums per year, 10 kg/drum, 23 MJ/kg) and natural gas consumed (17.3 TJ/y) a conservative estimate of possible steam generation of only 20% of the available heat (due to quenching requirement) yields roughly 33 TJ/y of steam generation corresponding to 490 k$/y natural gas equivalent cost. Supply to the nearby passing steam piping would be rather simple. But a steam generator installed near the quenching zone is expected to be subject to major corrosion issues. A dedicated cleaning mechanism would need to be

	incorporated (e.g. steam cleaning of heat exchanger). Thus, the overall investment costs are considered substantial. Again, this saving potential has to be considered in the framework of the overall site strategy: if enough (or more than enough) steam will be available from the LVI extension project, a SWI steam generation might not be adequate anymore.
CA: Adjustment of compressor load management or compressor size	The compressed air production installation consists of two identical and one smaller oil free compressors (Atlas Copco ZR4-52 2 x 2'073 + ZR145 1'300 = 5446 m^3/h). The average consumption of CA is in the range of 3300 m^3/h, peak demand is around 4'100 m^3/h. With this configuration the varying demand of site will reduce in subsequent start/stop mode (or load/unload mode, respectively) with short cycle times while one compressor operates at full power. It is expected that a smaller compressor unit might address this problem. Replacing one of the 270 kW units with an e.g. 150 kW full VFD engine (35-100%) the load pattern could well be followed. Calculating the energy saving potential based on the known efficiency at given work profile (~0.129 kWh/m^3) compared to reasonable benchmark (~0.110 kWh/m^3) yields about 2 TJ and 100 k$/y. It is recommended to consider the effect of major reduction of air leakages throughout the site on the CA demand profile and to design the new VFD compressor accordingly (e.g. rather smaller than based on today's data).
CA: heat recovery at compressors	The compressors are water cooled. The type of compressor could be retrofitted with a water based heat recovery which does allow producing hot water at e.g. 70°C. This heat could be directly used for the hot water system. As the compressor load varies the installation on all three units would be required to gain maximum energy savings. At current CA consumption (~3300 Nm^3/h) the gas equivalent saving by heat recovery is calculated to be 11 TJ or 166 k$/y. Of course, this amount is proportional to the effective CA consumption which might decrease after leakage repair. The new compressors to be evaluated shall be equipped with internal air dryer. A certain amount of the possible waste heat is used for desiccant recovery. As was mentioned during the audit new compressor models allowing for both desiccant drying plus heat recovery will be available next year.

CA: air leakage management and leakage detection & repair	The site has just analyzed the CA distribution system for leakages in some areas. Leakages in PB1 were found to be ~50%, site wide leakage is estimated ~30%. Some of these losses could be fixed by initiating a leakage repair program bringing base consumption from ~3'300 to 2'700 m^3/h. This corresponds to a reduction from an estimated 30-40% to ~15-20%. With the continuation of a rigorous leakage repair program the leakage rate might be reduced to about 10-15%. Moreover, it is considered as good maintenance practice to repair any leakage that is perceptible by ear. Thus, the associated saving potential is expected to be ~ 500 GJ/y or about 24 k$/y.
CA: Reduction of supply pressure	The reduction of the supply system pressure from currently 6.8 barg[10] towards 6 – 6.5 barg is representing an energy saving potential. It is required to identify minimum pressure demand, especially identifying most critical units. If only a minor number of units require higher pressure it is recommended to evaluate a replacement of such units (if small, e.g. valve etc.) or to install local pressure booster. However, if a large number of units would have to be modified pressure reduction might not be feasible. At current consumption of compressed air, the energy saving potential is about 600 GJ/y or 31 k$/y. If consumption decreased due to reduced leakage losses this saving potential will decrease accordingly.
CA: Reduction of dew point in compressed dry air production	The current dew point for compressed dry air (CA) production is set to -70°C to -80°C. These values are considered very low as production only requests a dew point of -20°C. As the drying of CDA is accomplished by electrically heated adsorption dryers (hot regeneration at ~200°C) a relevant energy and cost saving potential is associated with an increase of the dew point. According to ISO 8573-1, dew points are given at -40°C for class 2 and -20°C for class 3 compressed air qualities. A reduction to class 3 (-20°C) seems feasible. This reduction is resulting in roughly 60% less frequent desorption cycles at the compressed air dryers. The energy and cost saving potential is estimated to be ~280 GJ/y electricity (reduced resistor heating at dryer) corresponding to ~14 k$/y. This saving may be small, but there is virtually no investment cost associated with this measure. Any new compressor will have its dryer integrated, thus the existing desiccant dryer will be a standby and redundancy equipment[11].
Chiller replacement	Cold water production at the site (5/11°C) is based on two chillers operating with R22. Both are air cooled. These chillers will have to be replaced by 2014 (out of operation) due to refrigeration material restriction (CHSE GN 14.3). A replacement is scheduled for 2010/2011.

[10] The pressure used to be 6.2 barg in the past.
[11] Site engineering will pursue this option. Eventually a new EPROM is required.

	A replacement with state of the art chillers will also highly increase the COP value of the cold water production from the current low value of 2.62 to roughly 5.0. For the generation of the same amount of chilled water (17.8 TJ/y in 2008) a new chiller would consume roughly 3.6 TJ/y or 185 k$/y less electricity. Glycol production at the site (-25/-20°C) is based on two chillers operating with R22, one has a water cooled condenser and the other an evaporative condenser. It is foreseen to replace the R22 by ammonia at one chiller and keep the second unit as standby until 2014. Later, also the second unit will be retrofitted to ammonia. In the light of these replacements and retrofits the possibility for heat recovery opportunities and general system optimizations (e.g. seasonal condensation control, higher supply temperature) should be analyzed.
Chillers: Heat recovery at chilled water and glycol production	As the sankey diagram above shows, an annual amount of 73 TJ/y is disposed to the environment at a temperature level of ~30°C. A mayor energy saving potential consist in the recovery of some of this energy for low temperature demand (e.g. hot water) by three options o Direct application of this waste heat: this would require modifications at the point of use (replacement of heat exchange surface area capable of operating with 30°C heat). Given the large number of coils to modify this is not feasible. o Supply of chiller waste heat to a heat pump raising the temperature to a useful level, which is already available at the site, e.g. 60°C. Thus, no investment at the point of use but of course the relatively large investment in a central heat pump combined with infrastructure cost would be required. A heat pump lifting temperature from ~30°C to 70°C (incl. 10 K for heat transfer) would achieve a COP of ~4-5. Exploiting 67% of the available chiller waste heat would allow providing 100% of the hot water demand of the site by such a heat pump concept. This would save natural gas (63 TJ/y, 930 k$/y) but of course use more electricity (-14 TJ/y, -720 k$/y). Thus the net profit would be 210 k$/y. This net saving is highly depending on unit gas and electricity price. Compared to other countries, NRL is experiencing relatively high electricity and low gas price (ratio electricity/gas ~3.5). If this should change in future (e.g. <3.0) such a heat pump concept will be even more economically viable. o Direct heat recovery from the superheated refrigerant materials at the exit of the last compressor stage (prior to entry into condenser). Only about 7-9% of the total chiller waste heat could be recovered from the superheated gas. Still, a temperature of 45-55°C could be achieved (calculation of chiller cycle yields hottest gas temperature >60°C). Recovery of superheated gas from all compressors would yield ~5 TJ/y

	which could substitute the same amount of natural gas. This corresponds to ~8% of site energy demand in the 60°C hot water system. The cost saving potential is roughly 76 k$/y.
Chiller: Increasing chiller efficiency	Chiller efficiency can be increased by raising the supply temperature of cold water or Glycol, respectively. Chilled water is mainly used for HVAC purposes but also to a minor extent for process cooling. Given the wide tolerances of the HVAC specifications a chilled water supply temperature of roughly 9-10° would be sufficient. It is the lower fraction of process demand (estimated ~20-30%) which requires a supply temperature of 5°C. Increasing chilled water supply from currently 5°C to e.g. 6°C would increase chiller efficiency by roughly 3%. The associated energy and cost saving potential per degree of temperature increase was calculated to be roughly 260 GJ/y or 13 k$/y, respectively. It is recommended to evaluate whether a separation of this process demand by e.g. a transfer to the glycol system or a local booster chiller is feasible and thus an increase of chilled water supply temperature could be envisioned. This should be evaluated in the light of the planned chiller replacement. Increasing glycol supply from currently -25°C to -15°C (as intended by a long term project of the energy manager) would increase chiller efficiency by roughly 25%. The associated energy and cost saving potential was calculated to be roughly 4.5 TJ/y or 235 k$/y, respectively. This is considered as a long term strategy for the site which will require the involvement of all production aspects.
Chiller: Seasonal reduction of condensation temperature of chillers according to ambient temperature.	The condensation temperature of the air cooled chillers (both, chilled water and glycol) can be lowered substantially during winter (outside air temperature < 10°C) from the observed value of ~35°C to e.g. 20-25°C. As only the glycol system has high load also during winter this concept cannot be applied to the chilled water system. Such a reduced condensation pressure and temperature corresponds to an increase of COP by ~30% for the glycol system. Calculating the net electricity savings based on estimated annual operating hours (2900 h at reduced condensation, rest of year design operation) results in the order of 5.5 TJ/y amounting to roughly 282 k$/y. An advanced option would be to control the condensation pressure and temperature based on a wet bulb temperature measurement of the ambient air. The feasibility of such a measure has to be checked with the chiller supplier[12]. Furthermore, such a reduction would also influence the saving potential of a possible heat recovery. Again, this shows that not all of the identified saving potentials are additive.

[12] Especially in the case of the relatively old and standardized HVAC chillers.

Lighting: T5 as standard	Replacing current T8 fluorescent tubes generally with T5 type would reduce electricity consumption for lighting. Such replacement has been pursued and realized at selective locations but T5 is not yet the site standard. Based on expected non-justifiable investment cost a conceptual change to T5 is not recommended but is likely to be feasible in the framework of normal maintenance. It might be viable for older areas with 24 hour lighting requirements.
Comment	All cost saving potentials have been calculated with the following current cost rates: o Electricity: 127 €/MWh ~ 187 $/MWh o Gas: 36 €/MWh ~ 53 $/MWh These values represent the current estimates by site engineering regarding existing and future contracts. The calculated cost saving potentials are to be taken as rough estimates, as the effective cost rates may differ from the above values (spot market prices, peak load prices etc) and as some assumptions had to be made.

6 Conclusions

The energy audit revealed several energy saving potentials. Some of these potentials have been quantified based on consumption data but also based on estimates. These quantifications are given with ±30% accuracy. Thus, in a next step it is recommended to evaluate these potentials in more detail in order to establish an accurate cost/benefit statement. The following table summarizes these potentials.
The different energy and cost saving potentials have been prioritized together with the site in the form of a simple ranking (see column 9 in table below):

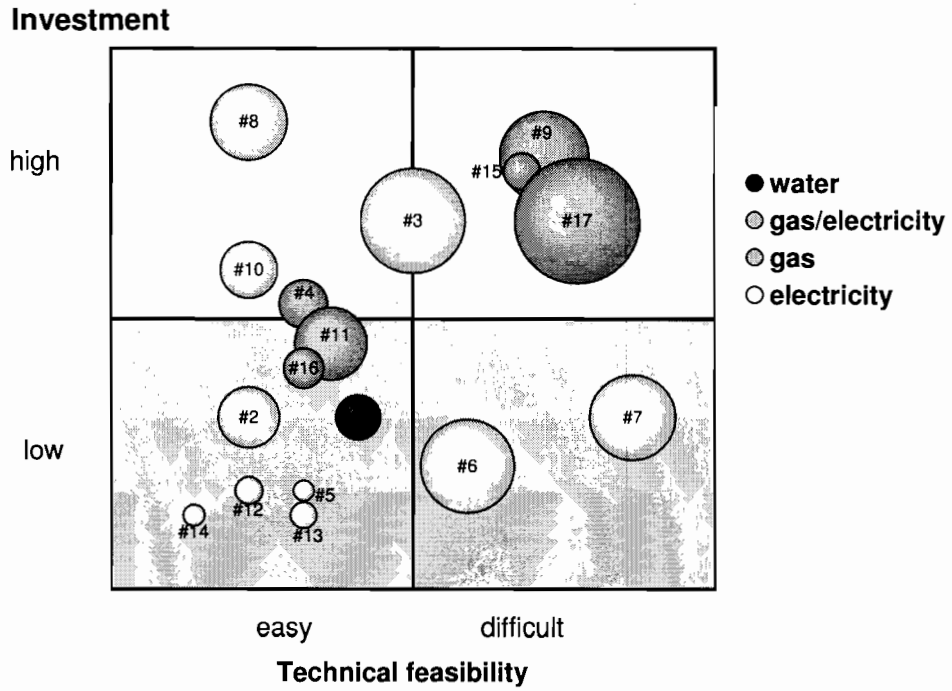
- Three stars *** 1st priority project; interesting saving potential, technically feasible, investment moderate
- Two stars ** 2nd priority: interesting saving potential, but technically challenging or investment rather high
- One star * 3rd priority: small saving potential or technically hardly feasibly or very expensive

As not all potentials are strictly additive (column 6) only the most interesting saving potentials which the site will pursue in near future have been summed up.
Several of the *** potentials have not been cumulated as they need to be evaluated in the light of the overall site energy strategy as mentioned above. However, they represent an additional value of roughly 900-1600 k$/y equivalent cost.

Report of Energy Audit Novartis Pharma Ringaskiddy
Subject

Nr.	Utility	subject	energy saving GJ/y	CO2 mitigation to/y	cost saving range t$/y	rough evaluation of investment	technical feasibility	priori-tization	cost savings of top priority measures t$/y
1	CTW	replace make-up water (alt. source)	n.a.	n.a.	45 - 84	low-med	rather easy	***	45 - 83
2	CTW	decr. supply pressue (booster pumps)	2'296	331	80 - 150	low-med	easy	***	80 - 150
3	CTW	closed loop design	6'644	957	240 - 450	med-high	can be done	*	
4	CHW+Gly	Chiller direct heat recovery	117	7	52 - 97	med	rather easy	***	strategy dependent
5	CHW	temp. increase, per °C	259	37	9 - 17	low	rather easy	***	9 - 17
6	Gly	saisonal condensation control	5'309	765	190 - 360	low	can be done	***	190 - 360
7	Gly	reduce to -15°C	4'414	636	160 - 300	low-med	difficult	**	
8	CHW	HVAC chiller replacment	3'560	513	130 - 240	high	easy	***	130 - 240
9	Gly	indirect heat recovery (heat pump)	16'818	1'846	180 - 330	med-high	rather difficult	**	strategy dependent
10	CA	new compressor, VFD	1'964	283	70 - 130	med	easy	***	70 - 130
11	CA	compressor heat recovery	11'313	632	120 - 220	low-med	rather easy	***	strategy dependent
12	CA	leakage management	465	67	17 - 31	low	easy	***	17 - 31
13	CA	pressure reduction (6bar)	424	61	15 - 29	low	rather easy	***	15 - 29
14	CA	dew point reduction	275	40	10 - 19	low	easy	***	10 - 18
15	Steam	optimized economizer use	2'944	164	30 - 56	med-high	rather difficult	**	strategy dependent
16	Steam	pressure reduction (6bar)	3'458	193	36 - 66	low-med	rather easy	***	36 - 66
17	SWI	steam generation	33'235	1'856	340 - 640	med-high	rather difficult	**	strategy dependent
	Total		**93'495**	**8'385**					**610 - 1'130**

A graphical representation of theses saving potentials is given in the portfolio chart below. Criteria considered are technical feasibility (related to the site constraints) and expected investment cost (rough qualitative estimates). The annual cost saving potential for the two main energy carriers on site (gas and electricity, or combined effects) is represented by the area of the circle. The circle labeling corresponds to the number of the saving potential in the table above.



Based on these saving potentials a road map was set up and discussed in order to define and schedule the further procedure on site. This road map covers the most relevant saving potentials (based on the audit results; see list above) and consists of the following main steps:

1. Short term: immediately start re-evaluation and possible realization of **'low hanging fruits'** in the lower left corner of the above diagram, e.g. CA dew point adjustment, CTW booster pump, CTW make up replacement etc.
2. Mid term: Reassess and rework the overall **site energy concept** including integration of options for LVI extension, various options for waste heat recovery, chiller replacement and combined heat and power. This strategy will define how to proceed with the chiller system, how to optimize the thermal supply (steam, hot water) and how to integrate any source of waste heat in a technically and economically feasible way. Also pursue the steam de-segregation from LVI.
3. Long term: Evaluate and possibly realize results from above energy concept, e.g. low exergetic heating, solvent incineration etc.

Note:

- Some of the discussed measures require discussion / coordination with engineering. It is recommended that these discussions are supported by GPE in the sense of know-how transfer from other sites or from external companies.
- On demand: further support by BMG Engineering is possible for NRL site. Support in the fields of evaluation of energy strategies, energy challenging or evaluation of measures (technical, economical) is possible.

7 Next steps	*- see below*
o Audit report	*BMG, asap*
o Detailed evaluation of saving potentials & prioritization, development of projects with support of GPE (where required)	*NRL, GPE 2009*

General comment:

This study has been performed based on a limited set of data and has to be considered a first rough analysis. Therefore, the saving potentials have to be evaluated in more depth and the corresponding cost savings have to be regarded as order of magnitude. Some saving potentials are not independent from other measures and thus the saving potentials are not strictly additive.

For the protocol,

Dr. Reto Müller

Zurich, Switzerland, October 6, 2009

Attachments		*- no action*
Slides of Kick-off meeting: (attached PDF)	Slides Kick-Off Meeting	
Slides of Wrap-up meeting & updated results: (attached PDF)	Slides Wrap-up Meeting & Results	
Filled Energy Management Fitness Index (attached PDF)	Energy Mgmt Fitness Index CHSE GL 13	

Novartis Ringaskiddy Limited

Effluent Toxicity Report 2009

IPPCL Register Number P0006-03

Schedule C.3.2 of IPPCL Register Number P0006-03 requires that the toxicity of emissions to sewer be monitored on an annual basis.

The company carried its annual toxicity testing, using the Shannon Aquatic Toxicity Laboratory of Enterprise Ireland, during March of 2009. Data from this round of testing is presented in the following attachment. The attached report was prepared on a twenty-four hour flow proportionate composite sample of 690 m^3, sampled between 08:00, Sunday, 01-Mar-2009, and 08:00, Monday, 02-Mar-2009. The sample was couriered directly to Enterprise Ireland following completion of sampling.

The following is a summary of the report's findings:

Test Species	Test Parameter	Number of Toxic Units
Psetta maxima (turbot)	96 hour LC_{50}	< 3.1
Tisbe battagliai (marine copepod)	48 hour LC_{50}	< 3.1
Vibrio fischeri (mictotox test)	5 minute EC_{50}	2.4
Vibrio fischeri (mictotox test)	15 minute EC_{50}	2.8

All tests were compliant with the emission limit value of 10 toxic units specified in Schedule B.3 of IPPCL Register Number P0006-03.

ATTACHMENT I

Shannon Town Centre, Shannon, Co.Clare, Ireland
Croí Bhaile na Sionna, Sionainn, Co an Chláir, Éire

t:+353. 61. 718 300 f:+353. 61. 361 979

ENTERPRISE IRELAND

CONFIDENTIAL REPORT
SHANNON AQUATIC TOXICITY LABORATORY

Front Cover Report Sheet

Dept. Toxicity
Sheet no. 1 of 4 sheets

Tox F020 Ver. 2.2

Customer Novartis Ringaskiddy Ltd Ringaskiddy Co. Cork Attn: Mr. Vincent Boyton	Title Toxicological analysis of an effluent sample
Report reference: 09T012	Order no.: 95367
	Report by: Kathleen O' Rourke Robert Hernan
Date received: 02.03.09	Approved by: Jim Clancy Head of Department
Copies to: R.6. Files	Date of issue: 10.03.09

Standard Terms & Conditions for Testing and Consultancy Assignments

1. Reports issued by the Shannon Aquatic Toxicity Laboratory of Enterprise Ireland are copyright to Enterprise Ireland and shall not be used, either in whole or in part, for the purpose of advertising, publicity or litigation without the written consent of the Chief Executive or his nominee.
2. Reports shall only be reproduced in full.
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4. Payment for work carried out shall be in accordance with the terms stated on Enterprise Ireland's invoices
5. No action or legal proceeding shall be taken (except in the case of wilful neglect or default) against Enterprise Ireland or the Board or any member of the Board or any committee appointed by the Board or any officer or servant of Enterprise Ireland by reason of or arising out of the carrying out of research, investigation, test or analysis or the publication of the results thereof in the name of Enterprise Ireland.
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7. This contract is governed by the laws of Ireland whose courts shall have exclusive jurisdiction.

Test report relates only to the sample(s) tested

SHANNON AQUATIC TOXICITY LABORATORY

ENTERPRISE IRELAND

TOXICOLOGICAL ANALYSIS REPORT

Form No.: ToxF035-2 Ver 2.2

TEST RESULTS

Customer: Novartis Ringaskiddy Ltd

Customer sample description: Treated effluent, 1-2.03.09, Sample No.: 089100006176

Tox. Ref. No.: 09T012-1

Test Date: 02.03.09 – *Psetta maxima*
04.03.09 – *Tisbe battagliai, Vibrio fischeri*

Test Parameter	Test Results		95% Confidence Limits % vol./vol.	Method of Calculation
	Concentration % vol./vol.	Toxic Units		
96 h LC_{50} to *Psetta maxima*	>32	<3.1	n/a	n/a
48 h LC_{50} to *Tisbe battagliai*	>32	<3.1	n/a	n/a
5 min EC_{50} to *Vibrio fischeri*	41.4	2.4	37.2-46.1	Microtox
15 min EC_{50} to *Vibrio fischeri*	35.9	2.8	32.1-40.2	Microtox

Comments:

96 h LC_{50} to *Psetta maxima*
No mortality occurred at 32% vol./vol.

48 h LC_{50} to *Tisbe battagliai*
No mortality occurred at 32% vol./vol.

5,15 min EC_{50} to *Vibrio fischeri*
Vibrio test report is presented on the next page.

Test Method(s): (see Appendix on back of page 4)
Method 7: *Psetta maxima* (turbot)
Method 3: *Tisbe battagliai*
Method 2: *Vibrio fischeri*

SHANNON AQUATIC TOXICITY LABORATORY

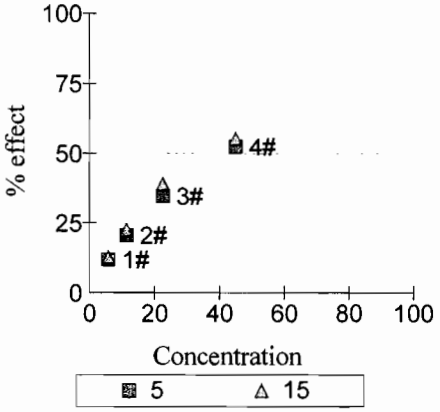
Vibrio Test Report

ENTERPRISE IRELAND

Date: - -

Test Protocol: Basic-type Test
Sample: 09T012-1
Toxicant:
Reagent Lot no.:
Test description: -
Data File: 09T012-1.K5; 09T012-1.K15;

Plot of %Effect vs Concentration



			5 Mins Data:			15 Mins Data:		
Sample	Conc	Io	It	Gamma	% effect	It	Gamma	% effect
Control	0.000	81.14	67.64	0.8336 #		64.17	0.7909 #	
1	5.625	81.59	59.88	0.1359 #	11.96%	56.29	0.1463 #	12.76%
2	11.25	80.80	53.50	0.2590 #	20.57%	49.45	0.2922 #	22.61%
3	22.50	73.36	39.89	0.5331 #	34.77%	35.34	0.6417 #	39.09%
4	45.00	67.29	26.64	1.106 #	52.51%	23.77	1.239 #	55.33%

- used in calculation; * - invalid data; D - deleted from calcs.

Calculations on 5 Mins data:
EC50 Concentration:41.43% (95% confidence range: 37.22 to 46.12)
95% Confidence Factor: 1.113
Estimating Equation:LOG C =0.9878 x LOG G +1.617
Coeff. of Determination (R^2):0.9992
Slope: 1.012
Correction Factor: 0.8336

Calculations on 15 Mins data:
EC50 Concentration:35.89% (95% confidence range: 32.09 to 40.15)
95% Confidence Factor: 1.119
Estimating Equation:LOG C =0.9623 x LOG G +1.555
Coeff. of Determination (R^2):0.9989
Slope: 1.038
Correction Factor: 0.7909

Signature:_____

SHANNON AQUATIC TOXICITY LABORATORY

ENTERPRISE IRELAND

TOXICOLOGICAL ANALYSIS REPORT

Form No.: ToxF035-2 Ver 2.2

SAMPLE INFORMATION

	SATL	Customer	Other
Sampled by:		✓	
Collected by:		✓	

Tox Ref. No.	09T012-1
Sampling procedure	n/a
Date of analysis	02.03.09
Storage conditions (°C)	3±3
Temperature (°C)	14.0
pH (at 14.3 °C)	7.3
Dissolved oxygen (mg/l)	1.9
Dissolved oxygen (% saturation)	19
Conductivity (mS/cm at 25°C)	2.2
Salinity (ppt at 20°C)	1.0

Toxicity Test Methods and Procedures

1. Freshwater Crustacean
Method 6.1 based on ISO 6341:1996/Cor.1:1998: 'Water quality – Determination of the inhibition of the mobility of *Daphnia magna* Straus (Cladocera, Crustacea) – Acute toxicity test'

2. Marine Bacterium
Method 6.2 based on BS EN ISO 11348-3:1999: 'Water quality - Determination of the inhibitory effect of water samples on the light emission of *Vibrio fischeri* (Luminescent bacteria test) – Part 3: Method using freeze-dried bacteria'

3. Marine Copepod
Method 6.3 based on ISO 14669:1999: 'Water quality – Determination of acute lethal toxicity to marine copepods (*Copepoda, Crustacea*)'

4. Marine Algae
Method 6.4 based on ISO 10253:2006: 'Water quality - Marine algal growth inhibition test with *Skeletonema costatum* and *Phaeodactylum tricornutum'*

5. Freshwater Algae
Method 6.5 based on ISO 8692:2004 : 'Water quality – Freshwater algal growth inhibition test with unicellular green algae' [*Pseudokirchneriella subcapitata*]

6. Freshwater Plant
Method 6.6 based on ISO 20079:2005: 'Water quality – Determination of the toxic effect of water constituents and waste water to duckweed (*Lemna minor*) – Duckweed growth inhibition test'

7. Marine Fish
Method 6.7 based on OECD 1992: Guideline 203: - 'Fish, acute toxicity test'

8. Freshwater Fish
Method 6.8 based on OECD 1992: Guideline 203: - 'Fish, acute toxicity test'

9. Estuarine Crustacean
Method 6.9 based on MAFF SOP No. BEG/030:1996: 'Brown Shrimp (*Crangon crangon*) 96 h acute toxicity for liquid effluents and wastes'

10. Marine Amphipod
Method 6.10 based on ICES, No. 28, 2001: 'Biological effects of contaminants: *Corophium* sp. sediment bioassay and toxicity test'

11. Eluate Generation
Procedure 4.7.8. "Eluate Generation" based on DIN 38 414 part 4, 1984: – 'Sludge and Sediments (Group S) – Determination of leachability by water (S4)'

Novartis Ringaskiddy Limited

Environmental Liability Risk Assessment (Update)

IPPCL Register Number P0006-03

The following pages contain the company's Environmental Liability Risk Assessment (ELRA), which was updated at the start of 2010. It outlines the measures taken and/or adopted at the site in relation to the prevention of environmental damage. Also enclosed is a letter of guarantee making financial provision to cover any of the liabilities identified in the ELRA.

Note that the company completed two large capital projects during the course of 2008 and 2009 with a view to reducing previously identified potential liabilities. These are described in the thirteenth revision to the company's Environmental Management Programme (EMP), which was also submitted as part of the 2008 AER. The projects are reproduced here:

4.5.3.11 Provision of Secondary Containment for Lift Station (from Rev 11 – Item complete)

Reason for modification:

The Wastewater Treatment Plant Lift Station was identified as a potential source of groundwater contamination in the company's 2006 Environmental Liability Risk Assessment. To-date there has been no evidence of groundwater contamination. This modification is of a precautionary nature. A capital allocation of the order of €500,000 was made for this work and the work described in sub-section 4.5.3.12 below.

Anticipated results from modification:

Significantly reduced risk of groundwater contamination from the Wastewater Treatment Plant Lift Station. This work was completed during the latter half of 2009.

4.5.3.12 Provision of Secondary Containment for Neutralisation Basin (from Rev 11 – Item complete)

Reason for modification:

The Wastewater Treatment Plant Neutralisation Basin was identified as a potential source of groundwater contamination in the company's 2006 Environmental Liability Risk Assessment. To-date there has been no evidence of groundwater contamination. This modification is of a precautionary nature. A capital allocation of the order of €500,000 was made for this work and the work described in sub-section 4.5.3.11 above.

Anticipated results from modification:

Significantly reduced risk of groundwater contamination from the Wastewater Treatment Plant Neutralisation Basin. This work was completed during the latter half of 2009.

4.5.3.13 Provision of Additional Groundwater Monitoring Well (from Rev 11 – on-going)

Reason for modification:

The Wastewater Treatment Plant Lift Station and Neutralisation Basin were identified as a potential source of groundwater contamination in the company's 2006 Environmental Liability Risk Assessment. To-date there has been no evidence of groundwater contamination. This modification is to enable additional groundwater monitoring to be undertaken in the vicinity of the Wastewater Treatment Plant if required.

Anticipated results from modification:

Significantly reduced risk of groundwater contamination from the Wastewater Treatment Plant Lift Station. Additional groundwater monitoring point available in the vicinity of the Wastewater Treatment Plant. This work was not undertaken during 2009 as the focus was on completing the more challenging work described in sub-sections 4.5.3.11 and 4.5.3.12 above. It will now be undertaken during the course of the current EMP.

Novartis Ringaskiddy

Environmental Liabilities Risk Assessment Report 2010

DOCUMENT CONTROL SHEET

Client	Novartis Ringaskiddy Limited					
Project Title	Novartis Ringaskiddy Limited Environmental Liabilities Risk Assessment (ELRA) 2010					
Document Title	Environmental Liabilities Risk Assessment Report 2010					
Document No.	MDE0970Rp0001					
This Document Comprises	DCS	TOC	Text	List of Tables	List of Figures	No. of Appendices
	1	1	39	1	1	3

Rev.	Status	Author(s)	Reviewed By	Approved By	Office of Origin	Issue Date
D01	Draft	Martin Doherty	Paul Chadwick	Shane Herlihy	West Pier	22nd March 2010
F01	Final				West Pier	24th March 2010

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1 INTRODUCTION

Novartis Ringaskiddy Limited is a pharmaceutical manufacturing company operating in Ringaskiddy, Co. Cork. The site is licensed by the Environmental Protection Agency (EPA) to carry out the following activities:

'the use of a chemical or biological process for the production of basic pharmaceutical products,

and the recovery or disposal of waste in a facility, within the meaning of the Act of 1996, which facility is connected or associated with another activity specified in this Schedule in respect of which a licence under the said Part is or will be required'

In October 2005, Novartis Ringaskiddy Limited updated their Integrated Pollution Control Licence (IPC Licence) on request of the Environmental Protection Agency (EPA) to an Integrated Pollution Prevention and Control Licence (IPPC), Register Number: **P0006-03.** This was undertaken in order to meet the requirements of the European Incineration of Waste Directive 2000/76/EC and the IPPC directive (96/61/EC) which was transposed into Irish Law in 2003 with the enactment of the Protection of the Environment Act (PoE) 2003.

A major part of the licensing upgrade focuses on the requirement of companies to assess their risks to the environment and set aside adequate financial provisions to account for all environmental liabilities.

Condition 12.3 of licence P006-03 specifically makes reference to these requirements. The conditions are quoted below:

Condition 12.3 Environmental Liabilities

12.3.2 *'The licensee shall arrange for the completion, by an independent and appropriately qualified consultant, of a comprehensive and fully costed Environmental Liabilities Risk Assessment (ELRA), which addresses the liabilities from past and present activities. The assessment shall include those liabilities and costs identified in Condition 10 for execution of the RMP…*

12.3.3 *'As part of the measures identified in Condition 12.3.1, the licensee shall, to the satisfaction for the Agency, make financial provision to cover any liabilities identified in Condition 12.3.2….'*

2 METHODOLOGY

The methodology for the development of the ELRA and subsequent reviews follows the EPA Guidance on Environmental Liability Risk Assessment, Residuals Management Plans and Financial Provision, 2006. The 2010 review of the Environmental Liabilities Risk Assessment (ELRA) was undertaken during a site visit by RPS to the Novartis Ringaskiddy Limited facility on 10th February 2010.

The review consisted of discussion of operational conditions on site with regard to 2009. There are no significant alterations to manufacturing operations since the previous ELRA.

The project risk register for 2009 was reviewed in detail. Each hazard was examined and any changes to mitigation measures/operating conditions were assessed. Where mitigation measures have been implemented successfully, the revised risk score for the hazard is applied. Where mitigation is in development stage, no change to the risk score is applied. Only on completion of mitigation measures will the revised risk scores be applied.

Where mitigation measures have been fully implemented resulting in a reduction in risk score for a hazard, the financial liabilities were recalculated using the updated risk score.

3 RISK IDENTIFICATION

3.1 METHODOLOGY

Risk identification was initially undertaken during the Risk Management Workshop in 2007 with the environmental and production managers. The risk identification process involved:

- The identification of potential environmental receptors at the site.
- The identification of production processes that posed potential hazards to the environment.
- The identification and quantification of the risks using a Failure Mode Effect Analysis (FMEA) worksheet.

3.2 IDENTIFICATION OF ENVIRONMENTAL RECEPTORS

The term 'environmental receptors' describes those parts of the surroundings likely to be affected by the processes that are ongoing at the Novartis Ringaskiddy Limited site. The significant environmental receptors are listed below. These receptors are used as a starting point to ensure that all significant hazards are identified and all major aspects of the environment are taken into account.

Environmental Receptors:

- Groundwater
- Surface water
- Human Beings
- Air Quality

3.2.1 Groundwater

As part of the site's IPPC licence, emissions to groundwater are monitored on a bi-annual basis at four groundwater monitoring wells (MW-1, MW-2, MW-3 and AW-6) all located within the grounds of the facility. The locations of the wells have been chosen to represent the most vulnerable areas down gradient of groundwater flowing throughout the site.

Monitoring parameters are as per Schedule C6 of the licence. The quality of groundwater is assessed in terms of the drift in quality between ambient baseline determined before the facility commenced operation. Monitoring to date at these wells up to 2009 has not resulted in any change in quality when compared to baseline quality levels when manufacturing activities commenced at the facility. This indicates that there has been no observed impact to groundwater quality from the facilities operation.

3.2.2 Surface Water

Surface water is collected through a series of storm water drain networks around the site from building roofs, roads and all hard standing areas. The storm water drains flow directly via a buried gravity sewer into the storm water retention pond located in the south west of the site and out to the Cork

County Council storm water sewer. Water flowing into the retention pond is monitored using a continual water chemical monitoring system to check compliance with water quality levels suitable for discharge into the storm water sewer. The system checks levels of pH and Total Organic Carbon (TOC) the levels of which are fed back to the Environmental Controls Department (ECD). Monitoring results discharging from the surface water point have shown full compliance from Annual Environmental Reports (AER) to date.

3.2.3 Emissions to Sewer

Novartis Ringaskiddy Limited operates an enclosed wastewater treatment plant (WWTP) that is used to treat lightly contaminated water that is used in processing activities, in addition to sanitary wastewater. The effluent is treated by a mixture of physical and biological treatment before being discharged to the Local Authority's (Cork County Council) marine outfall pipeline. This pipeline services a number of local towns and industries and discharges in deep water in the outer section of Cork Harbour.

3.2.4 Air Quality

Emissions to atmosphere are from four main emission points on the site. These are the solid waste and liquid waste incinerators and the natural gas boilers. On review of the sites AERs from 2005 to 2009, annual emissions to air have shown compliance in the range of 99.96 to 99.99% for all parameters monitored at these emission points.

3.2.5 Human Beings

The location of the Novartis Ringaskiddy Limited site is situated northwest of the village of Ringaskiddy within IDA Industrial estate grounds.

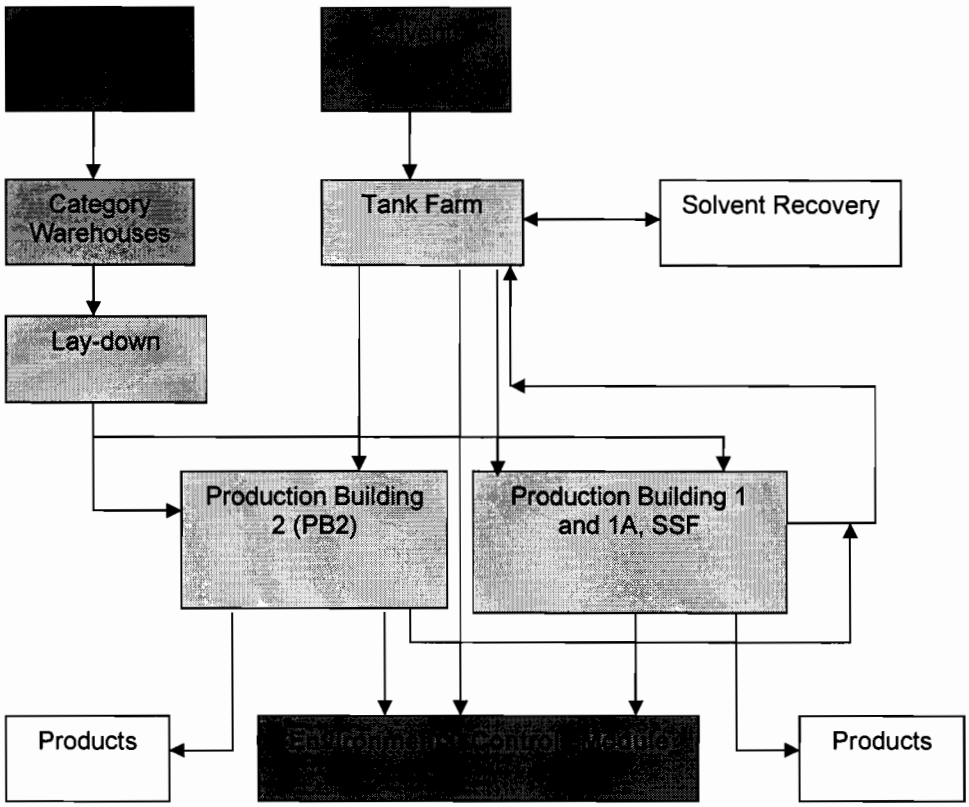
The nearest residential receptors to the site boundary are located adjacent to the western site boundary. The distance between site buildings and activities however are approximately 200-300m from the nearest properties.

The operation of the site will be most noticeable in terms of noise emissions and potentially from odours. Noise levels are monitored as part of the sites IPPC licence on an annual basis. This includes measurements at the sites boundary and at the nearest noise sensitive locations. The facility must comply with noise emission limits of 55dB L_{Aeq} during day time hours and 45dB L_{Aeq} during night time periods. The operation of the Novartis Ringaskiddy Limited site has shown full compliance with these day and night time licence limits to date. Odours are controlled through ventilation systems on the WWTP and enclosed venting systems leaving the production buildings to the liquid vapour incinerator.

3.3 IDENTIFICATION OF PROCESSES

The various processes undertaken at the Novartis Ringaskiddy Limited site were identified during the course of the workshop. In order to gain an overview of the flow of materials, processes on site and the relationship between each working area, Figure 3.1 below summarises the various flow of materials raw materials to finished product.

Figure 3.1 Overview of Materials Flow on site:



Each of the identified areas has inherent environmental risks associated with them. A brief description of each of the areas and a summary of their processes are included below.

3.3.1 Production Buildings

There are three main production buildings on the Novartis Ringaskiddy Limited site, which perform a variety of operations required for the manufacture of bulk pharmaceutical actives, a summary of the processes undertaken within the production buildings are outlined below and summarised in Figure 3.2.

A new Small Scale facility (SSF) production plant was built and commissioned in 2008. The process undertaken is 'low volume, high value'. The process is integrated into the existing effluent treatment and air abatement systems and there are no significant additional emissions or hazards associated with the new building.

Production Building 1 (PB1): This is a seven story process building which contains a variety of multi-purpose equipment ranging from reactors, crystallisers and separators, solid/liquid separators, driers, evaporators and a range of auxiliary equipment which flow from top floor down. The production lines can be configured for different production trains as required and the plant is capable of coping with all standard processes required to produce fine chemicals.

Production Building 2 (PB2): This is a seven story process building which contains a variety of equipment such as separators, reactors, crystallisers, dissolvers or various sizes, solid/liquid

separators, driers, evaporators and a range of auxiliary equipment from top floor down. Equipment within this building is used predominately for the same family of products, predominately Diovan and Cyclosporine. The equipment is capable of being configured for different production trains however, this occurs on a less frequent basis.

Production Building 1A (PB1A): This is a five story building used for process steps where a higher degree of safety and environmental protection is required. Water reactive chemical substances, hydrogenation, and low temperature reactions are all included in this building. Much of the equipment housed in this building is similar to that contained in PB1 and PB2.

The three buildings have been designed in order to contain any releases of substances within the manufacturing process, in addition procedures are set down in order to minimise the potential for environmental risks, and these include:

- Process floor drains throughout the buildings flow directly into process drains. These drains flow into the site's WWTP lift station, but can alternatively be diverted into Spill Basin 1 in the event of a large spillage or release of liquids with high solvent concentrations.

- All production trains in the production buildings are linked to the Liquid Vapour Incinerator (LVI).

- HVAC system in production buildings circulate air exchange, filters are replaced on regular basis by dedicated team.

- Containment suites are used for high category substances.

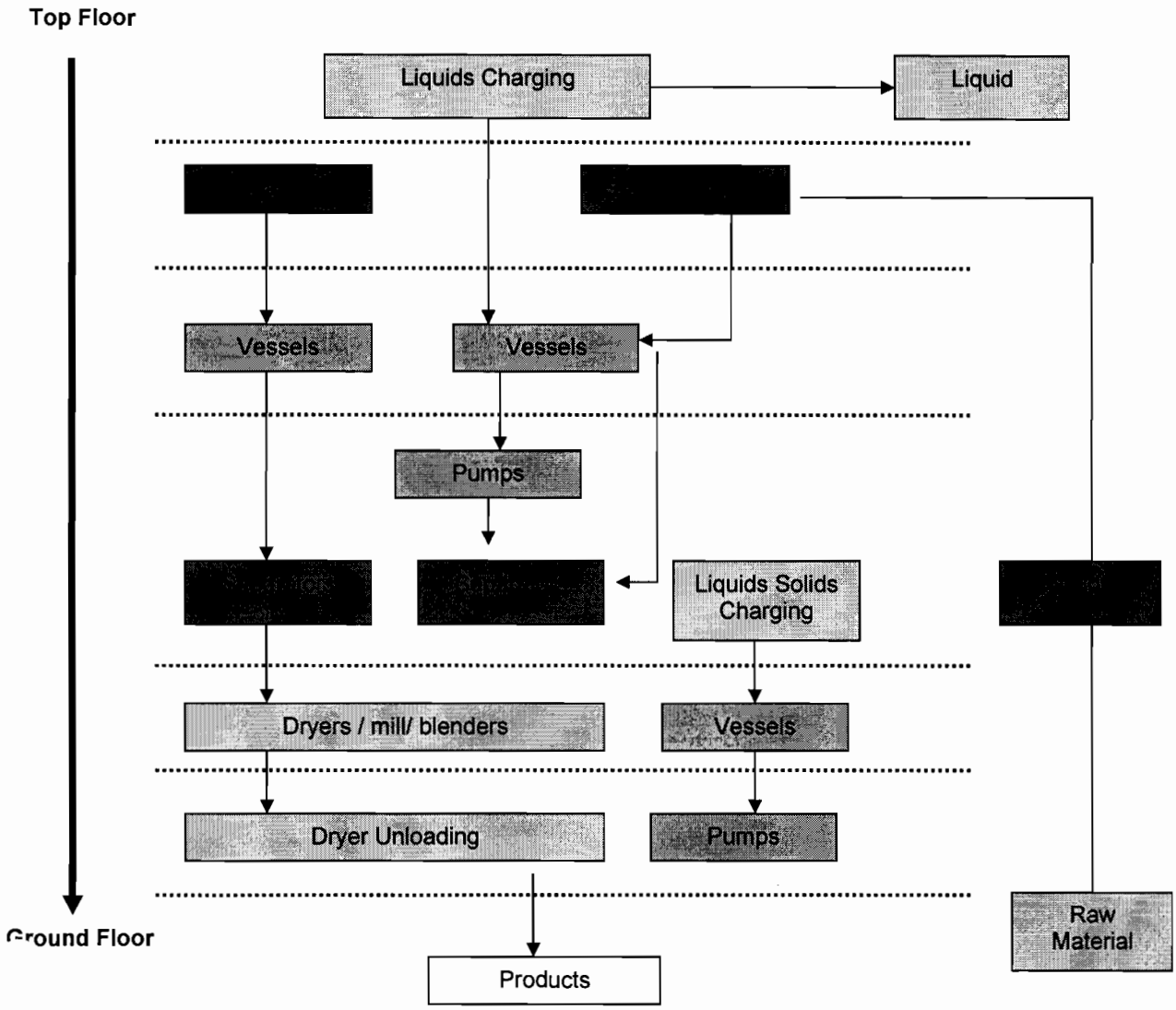
- Raw materials are brought in on a strict requirement basis to avoid stockpiling within production buildings

- Full clean down of vessels and equipment on regular basis

- Figure 3.2 overleaf, provides an outline of the vertical processes within a typical production building from top floor material input to ground floor product out.

The **Small Scale facility (SSF) plant** is located north of Production Building 1A. The SSF was commissioned during 2008/09 and is now used for the manufacture of certain 'low volume high value' It is a relatively small two-storey building of modular design that will allow incorporation of additional modules as required.

Figure 3.2 Flow Diagram of Material Flow Through Production Buildings



3.3.2 Tank Farm

This area is located to the north of the site and is used for the bulk storage of liquids, principally solvents, which are directed into production buildings via overhead pipelines. Un-reusable and un-recyclable waste solvent and process liquids awaiting incineration are stored in this area also. The Tank Farm consists of 100 tank compartments with capacities ranging between 25 to 100 m^3 with a total storage capacity of 3,200 m^3. The tank farm is bunded to contain any spillages and incompatible liquids are bunded separately. The capacity of each bund is not less than 110% of the largest tank. All bunded areas or containment tanks are directly linked to the process flow drains, which flow directly into a designated spill basin.

Process drains linked to containment basins 1 to 4, flow directly into Spill Basin 1, while process drains linked to containment basins 5-9 flow directly into Spill Basin 2. Pipes are stainless steel and flow underground between these areas.

3.3.3 Solvent Recovery Unit

This area is located to the north east of the site and is involved in the recovery by distillation of solvents from the processes. The unit consists of 15 distillation columns with still pots of varying capacity. Solvents awaiting recovery and recovered solvents are stored in the main Tank Farm.

The recovery unit is bunded to contain any spillages. The capacity of each bund is not less than 110% of the largest tank. All bunded areas or containment tanks are directly linked to the process flow drains, which flow directly into a designated spill basin.

3.3.4 Warehouses

A variety of storage warehouses are located within the Novartis Ringaskiddy Limited grounds, mostly towards the east of the site. These are used for separate storage of raw materials, products and intermediates. Each warehouse contains substances classified by their 'storage category' using the Novartis Corporate HSE warehouse guidelines. These segregate goods on their physical, ecological and toxicological properties and their combustion properties. The design of each warehouse inclusive of the layout, density of stock, fire control and other specific contingency arrangements are related to the nature of the stored goods.

Any spillages from warehouse areas are captured within floor drains which flow into the process drains which flow directly into Spill Basin 1 at the WWTP.

3.3.5 Storm Water Retention Pond

The storm water retention pond is located to the south west of the site, within the lowest gradient area of the site. This consists of two separated lined holding lagoons with a combined storage capacity of 5,000m^3. The pond is used to avoid the possible discharge of contaminated surface water arising from a spill and/or fire incident or other accident involving contaminated water flowing into the storm water drain system. All water flowing into this system is continuously monitored with a system in place for retaining any contaminated water in the event of exceedance of foul sewer water quality limits which can be pumped directly back to the WWTP for treatment prior to discharge.

The system delivers a warning alarm and an automatic shut off mechanism of the valve between the storm ponds and the discharge outlet when levels of pH and/or TOC are at the 'warning emission levels', set by Novartis Ringaskiddy Limited. The alarm alerts the Environmental Controls Department

(ECD) that there is a drift in the storm water quality. A second alarm is activated when storm water levels are at 'action emission levels'. This system ensures that no contaminated water in breach of the sites IPPC Emission Limit Values (ELV's) occurs.

Following from the study undertaken by Novartis in 2009, the report 'Surface Water Drainage and Fire Water Retention Pond Assessment, Arup Consulting Engineers, 07-Aug-2009, retention capacity at the Storm Water Retention Ponds was increased to 9,000m^3. To ensure that maximum capacity is available at all times, a Low Flow Transfer Station (LFTS) with TOC monitor was installed on inflow, which can automatically divert small volume, high TOC water to the WWTP during normal operations.

3.3.6 Waste Water Treatment Plant (WWTP)

This area is located to the east of the site and is used to treat all process water and sewer water prior to discharge from the site.

As a direct result of the potential hazards identified during the ELRA procedure in 2007, Novartis implemented major works at the WWTP in 2008. The process water lift station was removed and a new tank installed above ground. The old tank (concrete) was inspected during removal and was observed to be in good condition with no evidence of leakage. The new tank is visible and of stainless steel construction.

Work was also undertaken on the neutralisation basin to provide additional protection through the installation of a stainless steel tank. The neutralisation basin is now contained in a 'bund within a bund'.

Novartis invested heavily in this mitigation project with total costs in excess of €500,000 for the WWTP works. The system is now comprised of the modules outlined in Table 3.1

Table 3.1 Modules contained in WWTP system prior to 2008

Module	Original Construction	Source of Water	Function	Controls
Process Water lift station	Sealed/lined concrete tank, gases vented to Liquid Vapour Incinerator (LVI) Since major works in 2008, the entire structure is now visible	Production and utility buildings, floor drains	Pumping Station	All monitoring and control functions are controlled by Distributed Control Systems (DCS)
Sanitary Lift Station	Underground, concrete tank	Sanitary effluent	Pumping Station	
Spill Basin	Underground, lined concrete tank	Tank farm/solvent recovery/liquid vapour incinerator bunds	Pumping Station	
Equalisation Tank	Overground, lined concrete tank, fitted with monitoring system, covered and vented to LVI	Process Lift Station	Primary Treatment	
Neutralisation Basin	Above ground, free standing tank lined concrete, vented to LVI	Equalisation Tank by gravity	Primary Treatment	
Aeration Basin	Overground, lined concrete tank covered and vented to LVI	Pumped from Neutralization Basin	Secondary Treatment	
Clarifier	Overground, permaglass tank	Fed by gravity from Aeration basin	Secondary Treatment	
Digester	Overground, lined concrete tank, covered and vented to LVI	Discharged from Clarifier	Sludge Handling	
Belt Filter Press	Mechanical Press Filter, bunded in building	Pumped from Digester	Sludge Handling	

3.3.7 Liquid Vapour Incinerator (LVI)

The LVI is located to the east of the site boundary in the 'environmental controls' area of the site. This system is used for the destruction of non-recoverable solvents, process wastes and process vapours in addition to the recovery of heat for steam generation and energy conservation. The system consists of 5 liquid feed tanks, a vapour intake system, a burning chamber, a heat recovery unit, a scrubber and a stack with plume suppression. Air emissions are monitored on a continual basis using the Continuous Emissions Monitoring System (CEMs), which compares emissions against the requirements of the European Waste incineration Directive. The unit has an automatic shut down system in place in the event of temperature drop, and/or emission limit value exceedance.

All liquids tanks are held in the bunded areas, which flow into the process drains, which are fed into the WWTP.

3.3.8 Solid Waste Incinerator (S WI)

The SWI is located to the east of the site boundary in the 'environmental controls' area of the site. This incinerator is a much smaller system than that of the liquid vapour. It is used for the destruction of contaminated packaging and other combustible wastes. The system consists of a multiple chamber fired with natural gas and a flue gas cleaning system. Air emissions are monitored on a continual basis using the Continuous Emissions Monitoring System (CEMS), which compares emissions against the requirements of the European Waste Incineration Directive. Environmental controls include automatic lock out of additional waste allowed into chambers if any of the control parameters are outside optimal operating ranges, predominately temperature ranges or exceedences in ELV's which are continually monitored.

3.3.9 Utility Building and Service Yard

This area of the facility is located within the mid west area of the site and houses the heating systems consisting of two gas fired boilers with oil as backup, air compressors, water softening plant and chillers. External to the building, the services yard contains a cooling tower and bunded fuel oil and glycol storage area. The building is laid over underground floor drains, which in the event of accident or spill would drain into the process drains. Any contamination therefore flows into the lift station for treatment in the WWTP. Any chemicals or dangerous substances are held in contained bunds within this area of the building.

3.3.10 Technical Services Building

This building is used for the maintenance and repair of plant and equipment, a workshop and also houses the in-house fire brigade.

3.4 IDENTIFICATION OF HAZARDS

As part of the original ELRA in 2007, a facilitated workshop was undertaken on site to systematically identify the risks at the site. A total of 42 risks were identified which are summarised in **Table 3.2** and ranked in order in **Table 4.3**.

Table 3.2 Project Risk Register

Risk	Area/Issue	Potential Failure Mode / Risk	Principle Impacted Receptors
Production Buildings 1 and 2			
1	Manifold Connections	Minor Spillages Solvents - Manifold Connections	Groundwater/Soils
2	Manifold Management	Backfill of materials resulting in overfill of tanks	Groundwater/Soils
3	Hydrogenator in PB1	Explosion of Hydrogenator	
4	Plant equipment	Potential Failure of reaction vessels	Groundwater/Soils
5	Dryer in Cyclosporine process in PB1	Seal failure in cyclosporine dryer	Groundwater/Soils
6	Production Floor	Spillages of solvents- bio-degradable	Groundwater/Soils
7	Production Floor	Spillages of solvents- non bio-degradable	Groundwater/Soils
8	HVAC	Failure of HVAC filter systems	Air Quality/ Human Beings Properties
Production Building 1A			
9	Hydrogenator	Explosion of Hydrogenator	Air Quality/Residential Properties/ Groundwater/Soils
10	Plant equipment PB1	Solid/powder spill	Groundwater/Soils
11	Production Floor	General spillages in process non-biodegradable material (up to 300Kg's)	Groundwater/Soils
12	Water sensitive Materials	Explosion of reacting materials if exposed to water	Air Quality/ Human Beings /Groundwater/Soils
Warehouse			
13	Spillage of Substances	Spillage of Materials from storage vessels	Groundwater/Soils
Tank Farm			
14	Delivery of Solvents	Overturned tanker	Groundwater/Soils
15	Catchment Basins 6-9	Failure of tanks over catchment basins	Groundwater/Soils
16	Catchment Basins 1-5	Failure of tanks over catchment basins	Groundwater/Soils
17	Tanks	Manual leaks due to sampling points	Groundwater/Soils
18	Tanks	Leaks from failure of flange (gasket failing) valves breaking	Groundwater/Soils
19	Overhead lines (Solvent)	Failure of overhead lines/leaks in lines	Groundwater/Soils
20	Loading Bay	Leaking between tanker and tanks	Groundwater/Soils
Liquid Vapour Incinerator			
21	Loading area	Overfill of tankers to rear of incinerator	Groundwater/Soils
Solid Waste Incinerator			
22	Burning of material	Burning of unauthorised material in	Air Quality/Human Beings

Risk	Area/Issue	Potential Failure Mode / Risk	Principle Impacted Receptors
		incinerator	
23	Release to Atmosphere	Exceedences in ELV's of Dioxins	Human Beings
24	Transport of waste ash/liquid waste	Accident from haulage vehicle transporting waste ash & liquid waste	Human Beings
Waste (general)			
25	Metal Waste Drum Decontamination	Potential for contaminated drums being exported for recycling	Human Beings
26	Waste Oil in Process Buildings	Potential for spillages/leaks of waste oil in process areas	Groundwater/Soils
Solvent Recovery unit			
27	Purging process	Build up for solid residue in still pot	Groundwater/Soils
Storm Water Retention Pond			
28	Pond Capacity	Overflow of retention pond due to inadequate capacity (worst case scenario)	Groundwater/Soils
29	Pond Lining	Leakage from liner	Groundwater/Soils
Process Drains			
30	Line Integrity	Stainless steel lines	Groundwater/Soils
31	Line Integrity	Double containment lines	Groundwater/Soils
32	Spill basin 1	Potential leaks	Groundwater/Soils
33	Spill basin 2	Potential leaks	Groundwater/Soils
34	Storm drains	Potential degradation of concrete lines	Groundwater/Soils
35	WWTP tanks (overground)	Potential leakage from tanks	Groundwater/Soils
36	WWTP underground tanks - lift station	Potential leaks to underground	Groundwater/Soils
37	WWTP underground tanks- neutralisation tank	Potential leaks to underground	Groundwater/Soils
External Storage Areas			
38	Fuel Oil	Risks from leaking of fuel oil tank (into bund)	Groundwater/Soils
39	Fuel Oil	Filling of tanks	Groundwater/Soils
40	Fuel Oil	Filling of Vehicles	Groundwater/Soils
41	Glycol storage	Potential leakage	Groundwater/Soils
42	Solvent usage for cleaning tools in Workshop	Potential for contamination of degreasing materials for tool cleaning.	Groundwater/Soils

3.4.1 Summary of Hazards Identified on Site

The hazards identified in **Table 3.2** are a general overview of potential hazards within each area of the Novartis Ringaskiddy Limited site. The severity and likelihood of occurrence for each hazard will depend greatly upon the control measures in place in the site's operation.

As a general overview of the facilities activities and control measures in place, many of the hazards identified do not pose a significant risk due to the safeguards already in place at the facility. A large majority of the hazards identified relate to potential spillages/leaks and risks to ground and water contamination. These potential hazards rely heavily on the integrity of the various bunds, catchment areas, spill basins and process and solvent drains. These control measures are therefore the 'weakest link' in the risk chain and have been therefore given high priority as part of the assessment. All underground pipes/lines and tanks similarly are automatically at a higher risk due to the potential for undetected leaks occurring from these structures containing potentially contaminated substances.

4 ASSESSMENT OF RISKS

4.1 METHODOLOGY

The hazards identified during the workshop are listed in **Table 3.2**. These hazards were assessed against the risk classification tables (RCT) in **Tables 4.1 and 4.2**. The risk classification tables were designed to reflect the levels of risk appropriate to the Novartis Ringaskiddy Limited facility.

Ratings, taken from a risk classification table, were applied to the severity and likelihood of occurrence of each hazard. A risk score was calculated for each hazard using the ratings. The hazards were then ranked and compared based on the risk scores.

The hazards were placed in a risk matrix to illustrate the ranking of each hazard, and allow the risk to be visually prioritised. The risk matrix is a particularly useful tool for tracking changes in risk levels over time.

Risk management measures were identified for selected hazards during the workshop and included in the worksheets. These measures are presented in Section 5.

4.2 RISK CLASSIFICATION TABLE

The Risk Classification Tables (Tables 4.1 and 4.2) has been designed to reflect the critical levels of risk appropriate to the Novartis Ringaskiddy Limited site. The RCT provides probability and severity for the risk ranking of hazards. The cost ranges in Table 4.2 are those considered by Novartis Ringaskiddy Limited management to represent likely costs of environmental remediation. These are included in **4.2** below.

Table 4.1 Risk Classification Table (Occurrence)

Rating	Occurrence		
	Category	Probability (%)	Description
1	Very Low	0 – 5	Very low chance (0-5%) of hazard occurring in 30 yr period
2	Low	5 – 10	Low chance (5-10%) of hazard occurring in 30 yr period
3	Medium	10 – 20	Medium chance (10-20%) chance of hazard occurring in 30 yr period
4	High	20 – 50	High chance (20-50%) chance of hazard occurring in 30 yr period
5	Very High	> 50	Very high chance (>50%) chance of hazard occurring in 30 yr period

Table 4.2 Risk Classification Table (Severity)

Rating	Severity		
	Category	Cost of Remediation	Description
1	Trivial	€0-10,000	No damage or negligible change to the environment
2	Minor	€10,000- 100k	Minor/localised impact or nuisance
3	Moderate	€100k - 1m	Moderate damage to the environment
4	Major	€1m – 5m	Severe damage to the environment
5	Massive	>€5 million	Massive damage to a large area, irreversible in the medium term

The risks are identified in **Table 4.3** and a description of each heading of the table is given below:

- Risk ID – Provides a unique identifier for each hazard.
- Processes carried out on site – Lists the sites process which gives rise to the potential hazard.
- Potential failure mode / risk – Identifies the potential failure mode that could result in the hazard occurring.
- Potential causes – Identifies what events could cause the potential failure mode to occur.
- Current controls – Identifies the current controls in place to prevent the hazard event from occurring.
- Occurrence – Rates the likelihood of the potential hazard occurring given the current controls. The occurrence rating is ranked against the Risk Classification Table (RCT) as provided in **Table 4.1.**
- Basis for occurrence rating – Identifies the basis for the selected occurrence rating.
- Severity – Rates the environmental impact and potential costs due to the hazard event occurring given the current controls. The cost reflects the expense that may be incurred in

managing and rectifying the hazard event. This may include: costs in managing or controlling hazard incidents (e.g. fires, spillages etc.).

- Basis for severity rating – Identifies the basis for the selected severity rating.
- Risk score – Provides a risk score to allow the ranking of each hazard. The risk score is based on the product of the severity rating and the occurrence rating for the hazard.

Table 4.3 Original Project Risk Register – Ranked by Risk Score

Risk ID	Process	Potential Hazards	Occurrence Rating	Basis of Occurrence	Severity	Basis of Severity	Risk Score
36	WWTP underground tanks	Potential leaks to soils/ groundwater/ from lift station	4	High volume of solids containing acids left in sump, leading to corrosion. Problems for testing, patches in lining required to be replaced. 10m underground	4	Underground tanks leaking may go undetected and lead to high investigation and clean up costs	16
37	WWTP underground tanks	Potential leaks to soils/groundwater from neutralisation tank	4	Most vulnerable structure for reaction due to various substances in vessel, lining of polymer, have had problems with integrity in lining	4	Underground tanks leaking may go undetected and lead to high investigation and clean up costs	16
33	Spill Basin 2	Potential leaks	3	Testing undertaken every 3 years for integrity, regular checks for visual inspection, less frequent emptying allowing higher head of liquid in tank and higher chance of potential leaking	4	Underground structure leaking may go undetected and lead to high investigation and clean up costs	12
28	Storm water retention pond	Overflow of retention pond due to inadequate capacity (worst case scenario)	2	Calibration of probes TOC- every 2 weeks, pH once/month. During calibration one of the retention ponds is held full. Potential instance for spillage area washed down into storm drain filling 2nd lagoon in addition to a fire event on-site	5	Overflow can lead to flow into river estuary outfall causing potential for high environmental costs	10
39	Filling of mobile tanks from fuel oil tank	Potential leakage/spillage to ground	5	Occurs on regular basis during normal operation	2	Spillages are caught in concrete plinth external to bund, potential for waste oil to seep into ground below, area not subject to test. Potential clean up and investigation costs not included in sites current controls	10
40	Filling of vehicles from fuel oil tank	Potential leakage/spillage to ground	5	Occurs on regular basis during normal operation	2	Spillages are caught in concrete plinth external to bund, potential for waste oil to seep into ground below, area not subject to test. Potential clean up and investigation costs	10
30	Solvent drains- from tank farm/solvent recovery	Loss of integrity of stainless steel lines resulting in ground contamination	2	Stainless steel lines from tank farms inspected every 3 yrs including CCTV, visual inspections of manholes, bund tests line tests etc. Small potential for hairline fractures in line with minor leakages going to ground	4	Undetected leaking to ground if undetected between 3 year surveys can lead to high clean up costs and ground investigation costs	8
24	Transport of waste ash/liquid waste	Accident from haulage vehicle transporting waste ash & liquid waste	2	Potential for accidents on haul route	4	Major severity if accident occurred, cost high, 24 hr staff from Novartis Ringaskiddy Limited on call trained in accident/emergency procedures	8

Risk ID	Process	Potential Hazards	Occurrence Rating	Basis of Occurrence	Severity	Basis of Severity	Risk Score
32	Spill Basin 1	Potential leaks	2	Testing undertaken every 3 years for integrity, regular checks for visual inspection, single containment basin with potential of mixed solvents held in tank	4	Underground structure, leaks may go undetected and lead to high investigation and clean up costs	8
2	Manifold Management	Misconnections of lines resulting in overflow of tanks as a result of backfilling	3	Manifold lines can be misconnected and result in product filling back to tanker, has happened previously	2	Overspill is caught in control system, may potentially result in contamination of tanker with mixing of solvents, additional cost of incineration. Underground structures are considered to pose highest severity in terms of potential ground contamination and clean up costs	6
7	Production Floor	Spillages of solvents- non bio-degradable	3	PB2 contains highest volume of non-biodegradable substances, potential for spillages during non-routine operations	2	Any spillages caught in process drains which flow into WWTP system. Potential for some leaking between source and holding area leading to potential minor impacts	6
11	Production Floor of PB1A	Spillage In process non-biodegradable material (up to 300Kg's)	3	Minor spillages have occurred in past most likely to occur during non-routine operations. Manual intervention, opening closed system	2	All spillages flow into process drains, material could result in blockages, may precipitate out in WWTP or be taken off site- taken off for incineration if occurs	6
1	Manifold Connections	Minor Spillages Solvents	5	Connections from Manifolds part of daily processes, leaks likely to occur on a very high frequency	1	Spillages caught in floor drains of building and into contained treatment system. No major cost for clean up	5
17	Tank Farm	Manual leaks from tanks sampling points	5	Leak from sample points occurs on a regular basis (sample frequency 2-4 times per day) due to non correct closure of lids, overfilling of tanker	1	Tank containment basins flow into spill basin, and treated on site	5
18	Tank Farm	Leaks from failure of flange on tanks (gasket failing) valves breaking	5	Flange (gasket breaking) valve may fail (failure to close). Has happened to date on site	1	Any solvents released are caught in control system and treated on site	5
41	Glycol storage	Potential leakage from tank/connections into bund	5	Some Glycol is sent back from PB1 to small tank in bund and into other larger tanks, one in 5 samples from bund (3month period) will be contaminated	1	All liquids in bund are chemically tested prior to discharge. If contaminated, pumped out and treated. Cost absorbed in operating system	5

Risk ID	Process	Potential Hazards	Occurrence Rating	Basis of Occurrence	Severity	Basis of Severity	Risk Score
31	Process drains from production buildings	Line integrity of double contained UPVC lines	1	Inspections every 3 years. Leaks detection tests undertaken periodically. Manholes inspected on site- under 'as need' requirement, if observations made. Double contained lines provide additional safeguard	4	Leakages in lines may result in major costs due to high reliance as a control measure Undetected leaking to ground if undetected between 3 year surveys can lead to high clean up costs and ground investigation costs	4
38	Fuel Oil Tank	Risks from leaking of fuel oil tank (into bund)	4	Potential for tank leakage over 30 yr life span, also potential for leaks in connections	1	Any liquids in contained bunds are chemically tested prior to discharge. If contaminated, liquids are pumped to WWTP for treatment. Controlled in system	4
6	Production Floors	Spillages of bio-degradable solvents	4	Instructions on proper handling may not be followed leading to incidents. Opening of incorrect values, mis-reading labels etc	1	Fully contained in control system and treated in WWTP	4
22	Solid Waste Incinerator	Burning of unauthorised material in incinerator	4	Has occurred in past, controlled by training in place for staff, tracking system in place for ID, measuring system in place, person responsible for packing can be traced. This has reduced frequency of occurrence	1	Low. No major cost for clean up	4
29	Storm water retention pond	Leakage from liner leading to contamination of ground	2	2003 test of SWRP liner stated liner passed all checks (visually). Tested every 3 yrs. Annual visual checks undertaken- sub contractors required to repair if noted. Over 30 yr period, likelihood of lining to wear and tear is moderate	2	Potential ground and soil contamination if undetected between 3 year checks and contaminated water is held in lagoon for long periods at a time	4
35	WWTP tanks (overground)	potential leakage from tanks	2	tanks are visually inspected as overground, tanks tested twice to date on site, equalisation tank most stress, passed tests for integrity	2	Any large leaks would be detected as overground	4
3	Hydrogenator PB2	Explosion of Hydrogenator in PB2	1	Hasn't occurred to date on plant. Strict controls in place in accordance with BAT guidance	3	Emergency receiver on site, drop down doors as response, located at side of building to explode outwards. Majority of content would be contained in event of explosion, in process drains, vapour drains, etc. Potential release to external area- low	3

Risk ID	Process	Potential Hazards	Occurrence Rating	Basis of Occurrence	Severity	Basis of Severity	Risk Score
10	Plant equipment PB 1&2	Solid/powder spillage	3	No dispensing, offload all in contained system comes in as raw material in drums- Contained system with PTS, control is to sweep up and avoid where possible going down drain, if drain- washed with water in drains (<1kg)	1	Spillages all contained in control system and treated accordingly. Worst case - 10kg spillage	3
14	Delivery of Solvents to Tank Farm	Overturned tanker	1	Tanks are designed to withstand impact in case of accident. Traffic management controls, speed limits on site, low congestion on site. No incident in sites history to date	3	Potential impact to groundwater from non-paved or non bunded areas	3
34	Storm drains	Degradation of concrete lines leading to potential ground contamination	3	Not tested as part of environmental management-. Concrete underground pipes, likelihood of leaking over 30 year periods, medium	1	Large dilution washed down drain from rainwater and dilution of any spills. Severity of contamination low	3
42	Solvent usage for cleaning tools	Potential for contaminated of solvents to warehouse floor	3	Degreasing agents used on site, waste degreaser is stored and held in tanks and removed off site	1	Small amounts used over long time period, all containers are within contained bunds, floor drains flow into WWTP. Process sewer flows into oil interceptor	3
4	Plant equipment PB 1&2	Potential Failure of reaction vessels leading to spillage of product	2	Regular inspection of system, computerised maintenance system in place as control measure	1	Any release from vessel caught in process drains, vapour is removed via vapour hoods, some solvent can potentially drain into storm water system, fed back to WWTP due to containment in lagoon and detection method in system. Cost of clean up will not be major due to systems of control already in place	2
5	Dryer in Cyclosporine process PB2	Seal failure in cyclosporine dryer, leading to release of product	2	Release of powder/slurry from dryer, rare occurrence, never happened in production, happened once during cleaning of drum. Cleaning occurs 4 times per year on 4 dryers	1	Fully contained, treated in WWTP, all products in PB2 are fully bio-degradable	2

Risk ID	Process	Potential Hazards	Occurrence Rating	Basis of Occurrence	Severity	Basis of Severity	Risk Score
9	Hydrogenator in Annex 1	Risk of explosion	1	System designed to BAT and safety guidelines. No history to date of failure or faults	2	Annex building designed for hydrogen reaction safety including vessels in contained room, detectors in building and dedicated H2 vents etc ejected materials inside and outside building, emergency system will have controlled severity. Release of solvent and debris- flow into process drains (potential into storm drains- contained in Lagoons - redirected to WWTP). Costs of external clean up and small soil/ground testing required to sign off as clean up	2
12	PB1A Production areas	Potential for reaction of water sensitive materials leading to explosion	1	Held in contained and segregated areas, control systems in place. No such instances have occurred to date	2	Predominant damage contained inside, potential damage to lines and building. If exploded outside, potential for contamination of small grassed area- ground water and soil in non-paved and non bunded areas external to plant	2
15	Catchment Basins 6-9 in Tank Farm	Failure of tanks over catchment basins, leading to ground contamination	1	No tank failure or ruption of tanks in site history, history of damage of tank (rusting), tap leaking to date. Probability of full rupture very low	2	LEL detection from spill basin 2, tank contains rainwater which is not emptied regularly, potential for overflow into surface water drains and into SWRT. Considered minor- contained in either spill pits or SWTP and sent back to WWTP for treatment or pumped out	2
16	Catchment Basins 1-5 in Tank Farm	Failure of tanks over catchment basins	1	No tank failure or ruption of tanks in site history, history of damage of tank (rusting), tap leaking to date. Probability of full rupture very low	2	Spillage diverts towards spill pit 1 and pumped out for treatment	2
19	Overhead lines (Solvent)	Failure of overhead lines/leaks in lines, leading to ground contamination	1	Stainless steel welded lines, with exception of flange areas. For non-routine applications lines tested prior and after production. For routine areas, no checks of lines. Would be detected in storm monitoring system. No failure to date in 13 yr period	2	Over paved areas, going to storm drains and detected in storm detection system. Can be contained. Pump feeding line would continue to run unless manually switched off. Detection sys in storm water retention would trigger	2
25	Metal Waste Drum Decontamination	Potential for contaminated drums being exported for recycling	2	Drums washed in production area, visually and LEL (gas) checked and recorded. Manually labelled - not tracked, labels are kept on drums. Most hazardous materials are dry and lined in drum. Some double/tripled lined	1	Potential for contamination at end waste receiver	2

Risk ID	Process	Potential Hazards	Occurrence Rating	Basis of Occurrence	Severity	Basis of Severity	Risk Score
27	Solvent Recovery Unit	Build up for solid residue in still pot resulting in exothermic reaction	1	Exothermic decomposition- unlikely to occur due to purging process, process risk assessment has identified such risks. Filter on incoming feed & automated system- leads to emergency cooling and disables production process	2	Control measures in place reduce severity of risk. May lead to explosion, can lead to fracturing of line and potential spray onto non-hard surfaces	2
8	HVAC	Failure of HVAC filter systems resulting in potential release of lightly contaminated air emissions	1	Low, regular inspection of filters visually and of pressure differential changes etc. Dedicated team of staff for all HVAC systems involved in maintenance checking	1	Low, internal building has containment measures for all high risk category substances	1
13	Warehouse	Spillage of Materials from storage vessels	1	Low, no spillage occurrence during life span of Plant, control measures in place. Tanks are designed to withstand impact in case of accident	1	Low, materials are segregated according to substance and category type. All areas connected to process drains and treatment areas	1
20	Loading Bay	Leaking/spillages between tanker and tanks	1	Tankers are double valved; tankers are chalked and charged during filling. Overfilling of tank unlikely due to switch off mechanism when full. Flow rates are slow due to gravity filling. Occurrence very low- never happened to date	1	Tanker filling area in hard-standing area, any spillages from leaking are contained in process drains flowing into spill basin	1
21	Liquid Vapour Incinerator	Overfill of tankers to rear of incinerator in loading area	1	Low, automatic filling system with alarm system in place, no history of overfill in life span of site	1	Low all spillages caught in process flow drains/spill basin	1
23	Solid Waste Incinerator	Exceedance in Dioxins ELV's	1	Monitoring of SWI has resulted typically full compliance, through independent and EPA monitoring. Use of system does not allow burning to occur below required temperature, switch off and door lock mechanism in place	1	No major cost to clean up. Any exceedance would be minor and short lived	1
26	Process Buildings	Potential for spillages/leaks of waste oil in process areas	1	Waste Oil contained in IBC's on plastic mobile bunds/pallets. Oil handling study undertaken on site- findings of report all implemented. (9-15 tonnes/year)	1	Held in bunded pallets and flow into process drains if overflowed. Potential problem flowing into storm water pond, clean up would require further cleaning of pond	1

4.3 RISK MATRIX

The Risk Matrix has been developed to allow the risks to be easily displayed and prioritised. The severity and occurrence ratings are used in the matrix, with the level of severity forming the x-axis and the likelihood of occurrence forming the y-axis. This matrix provides a visual tool for regular risk reviews and the success of mitigation can be easily identified. The risk matrix is displayed in **Table 4.4**. The risks have been colour coded in the matrix to provide a broad indication of the critical nature of each risk. The colour code is as follows:

- **Red** – These are hazards with high-level of risks and requiring priority attention. These hazards have the potential to be catastrophic and should be addressed as a priority.
- **Amber / Yellow** – These are hazards with medium to high-level risk requiring action, but are not as critical as a red coded risk.
- **Green** (light and dark green) – These are lowest-level risks and indicate a need for continuing awareness and monitoring on a regular basis. Whilst they are currently low or minor risks, some have the potential to increase to medium or even high-level risks and must therefore be regularly monitored. If cost effective mitigation can be carried out to reduce/mitigate the risk even further this should be pursued.

Figure 4.1 Original Risk Matrix 2007

Occurrence	**V. High**	**5**	1,17,18, 41	39,40			
	High	**4**	38, 6, 22			36,37	
	Medium	**3**	10,34,42	2,7,11		33	
	Low	**2**	4,5,25	29,35		24,32,30	28
	V. Low	**1**	8,13,20,21, 23, 26	9,12,15,16, 19,27	3,14	31	
			Trivial	**Minor**	**Moderate**	**Major**	**Massive**
			1	**2**	**3**	**4**	**5**
			Severity				

The Novartis Ringaskiddy Limited facility is well managed in terms of environmental controls, resulting in a minor number of hazards with both high occurrence and high severity. In cases where hazards were identified as occurring on a regular basis, the severity of environmental damage and remedial cost was generally found to be minor as a result of control measures integrated into daily operations, site design and risk management on site.

Similarly those hazards identified as high severity in terms of environmental damage and cost, generally were identified to occur on a low to infrequent basis as a result of the management and design of the site, thus resulting in an overall low score.

5 IDENTIFICATION AND ASSESSMENT OF MITIGATION ACTIONS

5.1 IDENTIFICATION OF MITIGATION ACTIONS

During the 2010 review of the Environmental Liabilities Risk Assessment (ELRA) each hazard was re-examined and changes to mitigation measures/operating conditions were assessed. Where mitigation measures, which were recommended in 2007, have been implemented successfully, the revised risk score for the hazard is applied. Where mitigation is in development stage, no change to the risk score is applied. Only on completion of mitigation measures will the revised risk scores be applied.

The recommended risk mitigation measures identified and the changes to mitigation measures, during the review, are provided in **Table 5.1.** This Table provides the following information;

- Risk ID – Designated ID number for each hazard
- Processes carried out on site – Lists the process which gives rise to the potential hazard.
- Potential hazards/risks– Identifies the potential failure mode that could result in the hazard occurring.
- Current controls in place on site as a means of preventing or reducing the risk
- Mitigation measures recommended in 2007 – Describes the mitigation actions, which were identified in 2007 to reduce the likelihood of occurrence or severity of the hazard, and hence the risk score. The progress to date of the mitigation measures is included.
- Current Score – This is the risk score prior to mitigation
- 2010 Revised risk score - This is a revised risk score after the mitigation actions have been implemented based on the product of revised occurrence and severity, where applicable, during the 2010 review. The revised risk score is also illustrated on a revised colour matrix as per **Figure 5.2**.

Table 5.1 Impact of Risk Mitigation

Risk ID	Process	Potential Hazards	Current Controls	Additional Mitigation Measures	Original Risk Score	2008 Revised Score	2009 Revised Risk Score	2010 Revised Risk Score
36	WWTP underground tanks - Lift station	Potential leaks to underground	Tank integrity test every 3 years, lining replaced where necessary	Consider installing an internal metal tank into concrete bund to create a 'bund within a bund' with liquid sensor within outer bund. Alternatively consideration can be given to relocating tank to an overground position where defects/cracking etc can be checked easier. Alternatively consideration can be given to installation of groundwater monitoring well adjacent to underground tanks in WWTP **2009 update:** **Capital project fully implemented for remediation of hazard ID 36 and 37. Lift station tank was moved to above ground and of stainless steel fabrication.**	16 (4x4)	No change	2 (1x2) Likelihood of undetected leakage greatly reduced and any leak would be visible	Risk is reduced to acceptable level and can be removed from risk register
37	WWTP underground tanks - neutralisation tank	Potential leaks to underground	Tank integrity test every 3 years, lining replaced where necessary	Consider installing an internal metal tank into concrete bund to create a 'bund within a bund'. Alternatively consideration can be given to relocating tank to an overground position where defects/cracking etc can be checked easier. Alternatively, consideration can be given to installation of groundwater monitoring well adjacent to underground tanks in WWTP **2009 update:** **As described in Risk ID 36 above**	16 (4x4)	No change	2 (1x2) Likelihood of undetected leakage greatly reduced. Potential impact reduced as any leakage will be responded to quickly	Risk is reduced to acceptable level and can be removed from risk register
33	Spill Basin 2	Potential leaks	Testing undertaken every 3 years for integrity, regular checks for visual inspection, less frequent removal allowing higher head of liquid in tank and higher chance of potential leaking	Emptying of spill basin on frequent basis to reduce water head in tank. **2009 update:** **Spill basin 2 is emptied automatically. Plans to increase nominal capacity will be implemented in 2009**	12 (3x4)	No change	No change	2x2 Takes rain water from bunds in Tank farm. Severity of a spillage would be minor so amend severity to 2. Spillages has never occurred so amend occurrence to 2

Risk ID	Process	Potential Hazards	Current Controls	Additional Mitigation Measures	Original Risk Score	2008 Revised Score	2009 Revised Risk Score	2010 Revised Risk Score
28	Storm water retention pond	Overflow of retention pond due to inadequate capacity (worst case scenario)	Two lagoons separate from each other, water level detection system in place. Contaminated water held in lagoon and pumped back to WWTP for treatment	Update of Standard Operating Procedures (SOP) for Storm water Retention System to include for fire control measures and instrument calibration. **2009 update: Programme of work agreed for optimising instrument calibration. Additional work to be undertaken to optimise available SWRP capacity in the event of incident. HSE will continue to assess the scale of incident response in terms of firewater usage**	10 (2x5)	No change	No change	(1x2) Sizing review carried out in 2009 identified potential shortfall in capacity. Capacity increased through capital works in 2009 (complete). The LFTS Low Flow Transfer Station is currently being installed. This will optimise capacity during low flow. 9000m3 capacity will be available at all times once complete. This reduces potential occurrence of an overflow and the use of TOC analyser and interceptor reduces potential severity also
39	Fuel Oil Tank	Filling of tanks	Tap is located on a concrete plinth	Training of staff to ensure tap is filled over concrete plinth. Plinth can be lined to ensure oil is not leaking into ground below. **2009 update: Concrete plinth examined and cleaned and Plinth was lined in May 2007**	10 (5x2)	4 (4x1)	No change	Risk is reduced to acceptable level and can be removed from risk register
40	Fuel Oil Tank	Filling of Vehicles	Tap is located on a concrete plinth	Training of staff to ensure tap is filled over concrete plinth. Plinth can be lined to ensure oil is not leaking into ground below. **2009 update**	10 (5x2)	4 (4x1)	No change	Risk is reduced to acceptable level and can be removed from risk

Risk ID	Process	Potential Hazards	Current Controls	Additional Mitigation Measures	Original Risk Score	2008 Revised Score	2009 Revised Risk Score	2010 Revised Risk Score
				Concrete plinth examined and cleaned and Plinth was lined in May 2007				register
30	Line integrity- tank farm/solvent recovery (solvent drains)	Stainless steel lines	Inspected every 3 yrs including CCTV, visual inspections of manholes, bund tests line tests etc.	Current controls are considered to be adequate **2009 update:** **Line integrity was checked in 2007. No problems identified.**	8 (2x4)	No change	No change	(2 x 2) The severity score appears too high for the hazard. Any spill from lines would be detected quickly. Potential for large scale loss of solvent to ground is low. Severity would be reduced by quick detection
24	Transport of waste ash/liquid waste	Accident from haulage vehicle transporting waste ash & liquid waste	DGSA recommendations, training of vehicle drivers.	Control measures in place are considered adequate. Risk potential lies largely outside the controls of the site. Reinforce speed limit requirements. Review DGSA documentation and update where and when necessary. Further training where required.	8 (2x4)	No change	No change	2x 2 No change. Contamination to storm water pond is worst case. Severity would be minor as contained on-site. Reduce severity score to 2.
32	Spill Basin 1	Potential leaks	Testing undertaken every 3 years for integrity, regular checks for visual inspection, single lined containment	Consider installation of groundwater monitoring well installed adjacent to WWTP underground tanks **2009 update:** **Well installation scheduled for completion in 20010.** **Spill basin integrity was checked as per bund integrity programme in 2007. No issues identified**	8 (2x4)	No change	No change	(2 x 2) Well installation scheduled for April 2010. No significant solvent concentration (as with Spill basin 2), therefore reduced severity to 2
2	Manifold Management	Misconnections of lines resulting in overflow of tanks	Receiving tank LSH automatically shuts off inlet valve, disconnects motor supply to tank. All non-routine line connections are subject to checkout sheet and sign off by supervisor	Training of staff for awareness, consider installation of non-return value on lines between tankers and manifolds	6 (3x2)	No change	No change	No change

Risk ID	Process	Potential Hazards	Current Controls	Additional Mitigation Measures	Original Risk Score	2008 Revised Score	2009 Revised Risk Score	2010 Revised Risk Score
7	Production Buildings-Production Floor	Spillages of liquid solvents-non bio-degradable	All liquid spillages flow into floor drain	Training of staff to prevent occurrence of spillages	6 (3x2)	No change	No change	No change
11	Annex Building (PB 1A)	Spillage of In-process non-biodegradable material (up to 300Kg's)	All spillages flow into floor drain, drains washed down in event of spillage	Training of staff to prevent occurrence of spillages	6 (3x2)	No change	No change	No change
1	Manifold Connections	Minor Spillages Solvents	Spillages are caught in floor drains and treated	Training of staff, regular floor inspections opposed to remote monitoring	5 (5x1)	No change	No change	No change
17	Tank Farm	Manual leaks due to sampling points from tanks	Any solvents released are caught in control system and treated on site	Training of staff on correct closure procedures. Regular testing of solvent lines	5 (5x1)	No change	No change	No change
18	Tank Farm	Leaks from failure of flange (gasket failing) valves breaking	Any solvents released are caught in control system and treated on site	No mitigation measured recommended	5 (5x1)	No change	No change	No change
41	Glycol storage	Potential leakage from tank into bund	All liquids in bund are chemically tested prior to discharge. If contaminated, pumped out and treated. Alarm system in place	Control measures are considered adequate Checked as part of integrity programme	5 (5x1)	No change	No change	No change
31	Process drains	Double containment lines	Inspected every 3 yrs including CCTV, visual inspections of manholes, bund tests line tests etc	Current controls are considered to be adequate Checked as part of integrity programme	4 (1x4)	No change	No change	(1x3) On review severity appears high. All licence conditions are met and good control measures in place. No additional mitigation required.
38	Fuel Oil Tank	Risks from leaking of fuel oil tank (into bund)	Any liquids in contained bunds are chemically tested prior to discharge. If contaminated, liquids are pumped to WWTP for treatment. Controlled in system	Current controls are considered adequate Checked as part of integrity programme	4 (4x1)	No change	No change	No change
6	Production Buildings-production floor	Spillages of solvents- bio-degradable	Fully contained in control system and treated in WWTP	Training of staff on correct closure procedures.	4 (4x1)	No change	No change	No change

Risk ID	Process	Potential Hazards	Current Controls	Additional Mitigation Measures	Original Risk Score	2008 Revised Score	2009 Revised Risk Score	2010 Revised Risk Score
22	Solid Waste Incinerator	Burning of unauthorised material in incinerator	Training in place for staff, tracking system in place for ID, measuring system in place, person responsible for packing is tracked. All recently implemented	Current controls are considered adequate. Strict controls have reduced such instances occurring. Reduction of overall waste being generated to be become part of sites EMS	4 (4x1)	No change	No change	No change
29	Storm Water Retention Pond	Leakage from liner	Tested every 3 yrs. Annual visual checks undertaken- sub contractors required to repair if noted	Maintenance of planting around lagoons on regular basis to allow for easier visual inspections of liner integrity. Visual tests to be performed on annual basis. Consider covering walkway between two lagoons to prevent photo-degeneration of material.	4 (2x2)	No change	No change	No change
35	WWTP tanks (overground)	Potential leakage from tanks	Tanks are visually inspected as overground, tanks tested twice over current operating life span	Systematic inspection of tanks to be documented as part of control procedure on set interval basis	4 (2x2)	No change	No change	No change
3	Hydrogenator PB2	Explosion of Hydrogenator in PB2	Emergency receiver on site, drop down doors as response, located at side of building to explode outwards. Majority of content would be contained in event of explosion, in process drains, vapour drains, etc	Control measures on site are considered to be adequate	3 (1x3)	No change	No change	Risk is at acceptable level and can be removed from risk register
10	Plant equipment PB 1&2	Solid/powder spill	Spillages all contained in control system and treated accordingly	Staff awareness training, inspections of process drains	3 (3x1)	No change	No change	Risk is at acceptable level and can be removed from risk register
14	Tank Farm	Overturned tanker during delivery of solvents	Tanks are designed to withstand impact in case of accident, traffic management controls, speed limits on site, low congestion on site	Control measures are considered adequate	3 (1x3)	No change	No change	Risk is at acceptable level and can be removed from risk register

Risk ID	Process	Potential Hazards	Current Controls	Additional Mitigation Measures	Original Risk Score	2008 Revised Score	2009 Revised Risk Score	2010 Revised Risk Score
42	Solvent usage for cleaning tools	Potential for contamination	All waste put into tank held in bunded areas, process sewer flows into with oil interceptor, waste degreaser in stored and held in tanks and removed off site	Control measures are considered adequate	3 (3x1)	No change	No change	Risk is at acceptable level and can be removed from risk register
34	Storm drains	Potential degradation of concrete lines	Manholes inspected on a 'as need' basis. Any spillages are diluted with water through drains	Consider inclusion of storm drain system as part of 3 year testing programme.	3 (3x1)	No change	No change	Risk is at acceptable level and can be removed from risk register

Figure 5.1 Original Risk Matrix 2007

Occurrence							
	V. High	5	1,17,18, 41	39,40			
	High	4	38, 6, 22			36,37	
	Medium	3	10,34,42	2,7,11		33	
	Low	2	4,5,25	29,35		24,32,30	28
	V. Low	1	8,13,20,21, 23, 26	9,12,15,16, 19,27	3,14	31	
			Trivial	**Minor**	**Moderate**	**Major**	**Massive**
			1	**2**	**3**	**4**	**5**
			Severity				

Figure 5.2 Revised Risk Matrix 2010

Occurrence							
	V. High	5	1, 17, 18, 41				
	High	4	6, 22, 38, 39, 40				
	Medium	3	10, 34, 42	2, 7, 11			
	Low	2		24, 29, 30, 32, 33, 35			
	V. Low	1		*36, 37, 28*	3, 14, 31		
			Trivial	**Minor**	**Moderate**	**Major**	**Massive**
			1	**2**	**3**	**4**	**5**
			Severity				

Note: As stated in EPA 2006, Hazards with risk score ≤2 (italic) will be scoped out and are available in Appendix A

6 RISK MANAGEMENT PROGRAM

6.1 RISK MANAGEMENT REVIEW

Significant mitigation measures identified in the original ELRA were implemented in 2008 and 2009. The result of these capital projects has been a reduction in risk score and potential liability estimates for a number of high score risks associated with the WWTP and Storm Water Retention Ponds. It is evident from the updated risk matrix that Novartis Ringaskiddy Limited has been proactive in mitigating risk at the site and has consistently reduced risk scores since commencement of the ELRA process in 2006/07.

Novartis successfully combines the ELRA with the site EMS and EMP. The site environmental committee meets every 2 months and reviews the established EMP fro the year. Actionable items from ELRA are implemented in EMP and reviewed throughout the year.

Although the operation of the facility is unlikely to see any major changes in operation and controls, there is potential however for processes and conditions to change. This assessment should therefore be considered to be a live document and be reviewed at least annually to ensure that all risks are identified and managed.

7 ENVIRONMENTAL LIABILITIES

7.1 TYPES OF ENVIRONMENTAL LIABILITIES

The purpose of this report is to assess the unknown liabilities (unexpected events) and to quantify them by ELRA assessment as per sections 4 and 5 of this document. Overall the EPA requires potential environmental liabilities to be broken down into two separate sections, the "known" environmental liabilities and "unknown" environmental liabilities. The assessment of "known" environmental liabilities associated with the closure of the facility and decommissioning are dealt with in the CRAMP report. Both known and unknown environmental liabilities are required to be quantified/costed by Novartis Ringaskiddy Limited as per condition 12.3.2 of this IPPC licence. Section 7.2 costs the unknown liabilities by a financial model, whereas the closure report costs the known liabilities by a CRAMP process.

7.2 QUANTIFICATION OF 'UNKNOWN' LIABILITIES

The 'unknown' environmental liabilities at Novartis Ringaskiddy Limited are associated with the environmental hazards at the facility, which may or may not occur. The best-case scenario is that none of the environmental hazards occurs and hence at the end of the assessment period, no additional costs shall be incurred by Novartis Ringaskiddy Limited, due to the environmental risks being zero. Alternatively, should a significant number of the hazards materialise, significant costs could be incurred.

The costs associated with the environmental risks have been estimated for the 'Most Likely (50th percentile)', 'Most likely with Contingency (90th percentile)' and 'Highest Cost' (100th percentile) scenarios.

Table 7.1 summarises the estimated costs for each hazard under each scenario for 2007. This figure represents an indicative cost of liabilities due to unknown environmental risks based on the estimated cost and probability ranges for each hazard. The method cannot give an accurate prediction of the final cost due to the subjective and uncertain nature of the risk data. However, it should be accurate enough to assist making judgements on the appropriate level of financial provision required for unknown environmental liabilities.

Table 7.1 Summary of Potential "Unknown" Environmental Liabilities as calculated in 2007

Risk ID	Occurrence	Severity	Most Likely Scenario – 50% Percentile	Most Likely Scenario with Contingency – 90% Percentile	Highest Cost Scenario
37	4	4	971,389	1,789,837	2,464,739
36	4	4	985,614	1,764,321	2,473,971
28	2	5	542,422	782,832	994,177
33	3	4	428,396	725,079	989,983
30	2	4	217,013	366,188	494,533
32	2	4	220,125	362,638	493,992
24	2	4	213,642	360,032	494,716
31	1	4	64,244	158,971	244,847
39	5	2	40,047	72,171	99,123
40	5	2	39,231	71,838	97,890
14	1	3	11,113	30,915	49,282
3	1	3	11,112	30,386	49,542
11	3	2	7,751	14,289	19,679
2	3	2	7,912	14,210	19,619
7	3	2	7,772	14,171	19,697
29	2	2	4,006	7,193	9,912
41	5	1	3,674	7,105	9,863
35	2	2	3,994	7,056	9,908
18	5	1	3,632	7,045	9,920
1	5	1	3,565	7,014	9,762
17	5	1	3,693	7,001	9,975
6	4	1	1,693	3,406	4,974
22	4	1	1,642	3,379	4,937
38	4	1	1,608	3,331	4,957
42	3	1	734	1,420	1,995
10	3	1	739	1,408	1,989
34	3	1	717	1,390	1,974

Note: Hazards with risk score ≤2 are not included

Table 7.1 presents the calculated costs of environmental liabilities ranked in order of highest financial provisions. The key areas are those related to potential ground contamination from leaking underground tanks and underground pipes and lines. The implemented mitigation options set out in **Table 5.1** lead to revised occurrence and/or severity of risks. Using the updated rating scores in **Table 5.1**, a post-mitigation financial assessment has been calculated for the hazards with reduced risk scores.

Table 7.2 Revised 2008 and 2009 Post Mitigation "Unknown" Environmental Liabilities

Risk ID	Scenario	Occurrence	Severity	Most Likely Scenario – 50% Percentile	Most Likely Scenario with Contingency – 90% Percentile	Highest Cost Scenario
36	Pre-mitigation	4	4	985,614	1,764,321	2,473,971
	Post-mitigation	1	2	1,375	4050	5,000
37	Pre-mitigation	4	4	971,389	1,789,837	2,464,739
	Post-mitigation	1	2	1,375	4050	5,000
39	Pre-mitigation	5	2	40,047	72,171	99,123
	Post-mitigation	4	1	1,742	3,400	4,950
40	Pre-mitigation	5	2	39,231	71,838	97,890
	Post-mitigation	4	1	1,701	3,399	4,957
28	Pre-mitigation	2	5	542,422	782,832	994,177
	Post-mitigation	1	2	1,375	4050	5,000

It is evident that the mitigation measures implemented for the above hazards have resulted in a reduction of the financial provision required for these hazards. This demonstrates that additional mitigation measures are effective in reducing environmental risk and are cost effective.

Table 7.3 Summary of Potential "Unknown" Environmental Liabilities as calculated in 2010

Risk ID	Occurrence	Severity	Most Likely Scenario – 50% Percentile	Most Likely Scenario with Contingency – 90% Percentile	Highest Cost Scenario
37	**1**	**2**	**1,375**	**4050**	**5,000**
36	**1**	**2**	1,375	4050	5,000
28	1	2	1,375	4050	5,000
33	2	2	4,006	7,193	9,912
30	2	2	4,006	7,193	9,912
32	2	2	4,006	7,193	9,912
24	2	2	4,006	7,193	9,912
31	1	3	11,113	30,915	49,282
39	**4**	**1**	**1,742**	**3,400**	**4,950**
40	**4**	**1**	**1,701**	**3,399**	**4,957**
14	1	3	11,113	30,915	49,282
3	1	3	11,112	30,386	49,542
11	3	2	7,751	14,289	19,679
2	3	2	7,912	14,210	19,619
7	3	2	7,772	14,171	19,697
29	2	2	4,006	7,193	9,912
41	5	1	3,674	7,105	9,863
35	2	2	3,994	7,056	9,908
18	5	1	3,632	7,045	9,920
1	5	1	3,565	7,014	9,762
17	5	1	3,693	7,001	9,975
6	4	1	1,693	3,406	4,974
22	4	1	1,642	3,379	4,937
38	4	1	1,608	3,331	4,957
42	3	1	734	1,420	1,995
10	3	1	739	1,408	1,989
34	3	1	717	1,390	1,974

Note: Hazards with risk score ≤2 are not included

8 FINANCIAL PROVISIONS

Novartis Ringaskiddy 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.

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

Novartis AG, in common with many large multinational companies, provides central funds to its operating units through standard financial mechanisms.

Novartis Ringaskiddy operates a significant annual environmental budget. The Environmental Committee meets 6 times per year to review progress on targets set in the annual EMP. The suggested mitigation measures for high-risk hazards identified in 2007 during the ELRA process were incorporated into the objectives and targets for 2008 and 2009.

In 2008 a capital project with a final cost of in excess of €500,000 was implemented at the WWTP. In 2009/10 the major project undertaken at the Surface Water Retention Ponds will have a total cost of €250,000. These are examples of proactive risk and environmental management at Novartis Ringaskiddy. Through managing risk proactively Novartis address potential liabilities on an ongoing basis and through annual budgetary measures.

In 2009 Novartis Ringaskiddy made a capital expenditure of €1,818,000 on environmental protection and a current expenditure of €10,125,000 on environmental protection.

Novartis Ringaskiddy has submitted a Parent Company Guarantee (Appendix B) to the EPA in respect of financial provisions for potential unknown liabilities, taking the outcome of this updated ELRA into account. This guarantee will be reviewed and updated as necessary to reflect changed circumstance or risk profiles on site as identified during the ELRA process.

9 CONCLUSION

The 2010 review of the Environmental Liabilities Risk Assessment (ELRA) was undertaken during a site visit to the Novartis Ringaskiddy Limited facility in order to review the operational conditions and implementation of mitigation measures identified during the Risk Workshop in 2007.

During the workshop the project risk register was reviewed in detail. Each hazard was examined and changes to mitigation measures were assessed. Where mitigation measures, which were recommended in 2007, have been implemented successfully, the revised risk score for the hazard was applied. Where mitigation is in development stage, no change to the risk score is applied. Only on completion of mitigation measures will the revised risk scores be applied.

The financial provision for the hazards with revised scores was calculated using the bands of ratings defined in Risk Classification Tables. This information was used to give an updated estimate of financial provision required for each hazard.

Mitigation measures for two of the highest risk score hazards has been fully implemented, resulting in reduced risk score and financial provision. This demonstrates how Novartis act on the findings of risk assessments and put place measures to reduce risk at the facility.

Further mitigation measures to address other hazards are in the process of being implemented and the risk scores and financial provisions for these will be reviewed on completion.

APPENDIX A

LOW RISK SCORE HAZARDS

Risk ID	Process	Potential Hazards	Current Controls	Additional Mitigation Measures	Original Risk Score	2008 Revised Score	2009 Revised Risk Score	2010 Revised Risk Score
4	Plant equipment PB 1&2	Potential Failure of reaction vessels	Regular inspection of system, computerised maintenance system in place as control measure. Occurrence is part of sites operation- used on a demand basis	Staff awareness training, inspections of process drains	2 (2x1)	No change	No change	
5	Dryer in Cyclosporine process PB2	Seal failure in cyclosporine dryer	Fully contained, treated in WWTP, all products in PB2 are fully bio-degradable	Staff awareness training	2 (2x1)	No change	No change	
9	Hydrogenator in Annex 1	Risk of explosion	Ejected materials inside and outside building, emergency system will have controlled severity. Release of solvent and debris- flow into process drains (potential into storm drains- contained in Lagoons - redirected to WWTP)	Control measures are considered BAT available	2 (1x2)	No change	No change	
12	PB1A Production area	Explosion of water sensitive materials if exposed to water	Control systems in place, predominant damage contained inside, potential damage to lines and building	Containment and control measures considered adequate and best practice	2 (1x2)	No change	No change	
15	Catchment Basins 6-9 in Tank Farm	Failure of tanks over catchment basins	LEL detection from spill basin 2, tank contains rainwater, which is not emptied regularly, potential for overflow into surface water drains and into SWRT. Considered minor- contained in either spill pits or SWTP and sent back to WWTP for treatment or pumped out	Spill basin 2 to be emptied on frequent basis. Line tests between tanks to be tested regularly	2 (1x2)	No change	No change	
16	Catchment Basins 1-5 in Tank Farm	Failure of tanks over catchment basins	Spillage diverts towards spill basin 1 and pumped out for treatment	Testing of solvent lines between catchment tanks and spill basin.	2 (1x2)	No change	No change	

Risk ID	Process	Potential Hazards	Current Controls	Additional Mitigation Measures	Original Risk Score	2008 Revised Score	2009 Revised Risk Score	2010 Revised Risk Score
19	Overhead lines (Solvent)	Failure of overhead lines/leaks in lines	Stainless steel welded lines. Routed over paved areas. For non-routine applications lines tested prior and after production. For routine areas, no checks of lines. Would be detected in storm monitoring system	Control measures considered adequate- overhead lines should be part of visual inspection on specified time frame	2 (1x2)	No change	No change	
25	Metal Waste Drum Decontamination	Potential for contaminated drums being exported for recycling	Drums washed in production area, visually and lel (gas) checked and recorded. Manually labelled - not tracked, labels are kept on drums. Most hazardous materials are dry and lined in drum. Some double/tripled lined	Tracking system to be put in place for all waste drums to ensure complete decontamination. Reduction and reuse of drums to be investigated as part of site's waste reduction measures **2009 Update** **Reuse of drums was investigated as part of site's waste reduction measures. Concluded that it was not viable and existing process is sufficient**	2 (2x1)	No change	No change	
27	Solvent Recovery Unit	Build up for solid residue in still pot	Control measures in place reduce severity of risk. Spillages/residues are all caught in process drains	Control measures in place are considered adequate	2 (1x2)	No change	No change	
8	HVAC	Failure of HVAC filter systems	Low, regular inspection of filters visually and of pressure differential changes etc. Dedicated team of staff for all HVAC systems involved in maintenance checking	Control measures considered adequate	1 (1x1)	No change	No change	
13	Warehouse	Spillage of Materials from storage vessels	Low, no spillage occurrence during life span of Plant, control measures in place. Tanks are designed to withstand impact in case of accident	Control measures for warehouses are considered adequate	1 (1x1)	No change	No change	

Risk ID	Process	Potential Hazards	Current Controls	Additional Mitigation Measures	Original Risk Score	2008 Revised Score	2009 Revised Risk Score	2010 Revised Risk Score
20	*Loading Bay*	*Leaking/spillages between tanker and tanks*	*Tankers are double valved, tankers are chalked and charged during filling. Overfilling of tank unlikely due to switch off mechanism when full. Flow rates are slow due to gravity filling. Occurrence very low- never happened to date*	*Control measures are considered adequate*	*1 (1x1)*	*No change*	No change	
21	*Liquid Vapour Incinerator*	*Overfill of tankers to rear of incinerator*	*Low, automatic filling system with alarm system in place, no history of overfill in life span of site*	*Control measures are considered adequate*	*1 (1x1)*	*No change*	No change	
23	*Solid Waste Incinerator*	*Exceedence in ELV's of Dioxins*	*Monitoring of SWI has resulted in typically <10% of ELV, through independent and EPA monitoring. Use of system safety and environmental controls include automatic lock out of fresh feed if any of control parameters are exceeded.*	*Control measures are considered adequate* ***Update 2008: Annual monitoring results from 2007 indicate that controls are adequate***	*1 (1x1)*	*No change*	No change	
26	*Process Buildings*	*Potential for spillages/leaks of waste oil in process areas*	*Waste Oil contained in IBC's on plastic mobile bunds/pallets. Oil handling study undertaken on site- findings of report all implemented. (9-15 tonnes/year)*	*Control measures are considered adequate*	*1 (1x1)*	*No change*	No change	

APPENDIX B

PARENT COMPANY GUARANTEE

NOVARTIS

Novartis AG
Lichtstrasse 35
CH-4056 Basel
Switzerland

Environmetal Protection Agency
EPA Regional Inspectorate Cork
Inniscarra
County Cork
Ireland

Basel, February 10, 2009

RE: Condition 12.3.3 of IPPCL Register Number P0006-03

Dear Sirs

We confirm that Novartis AG, Lichtstrasse 35, CH-4056 Basel, Switzerland undertakes to guarantee the liabilities of Novartis Ringaskiddy Limited, Ringaskiddy, Ireland amounting to EUR 542'422.- identified in the Environmental Liability Risk Assessment (ELRA) of Novartis Ringaskiddy Limited prepared as a requirement of Condition 12.3.2. of the Integration Pollution Prevention and Control Licence - Register Number P0006-03.

This financial guarantee has been set at EUR 542'422.- for the calendar year 2009.

Yours sincerely,

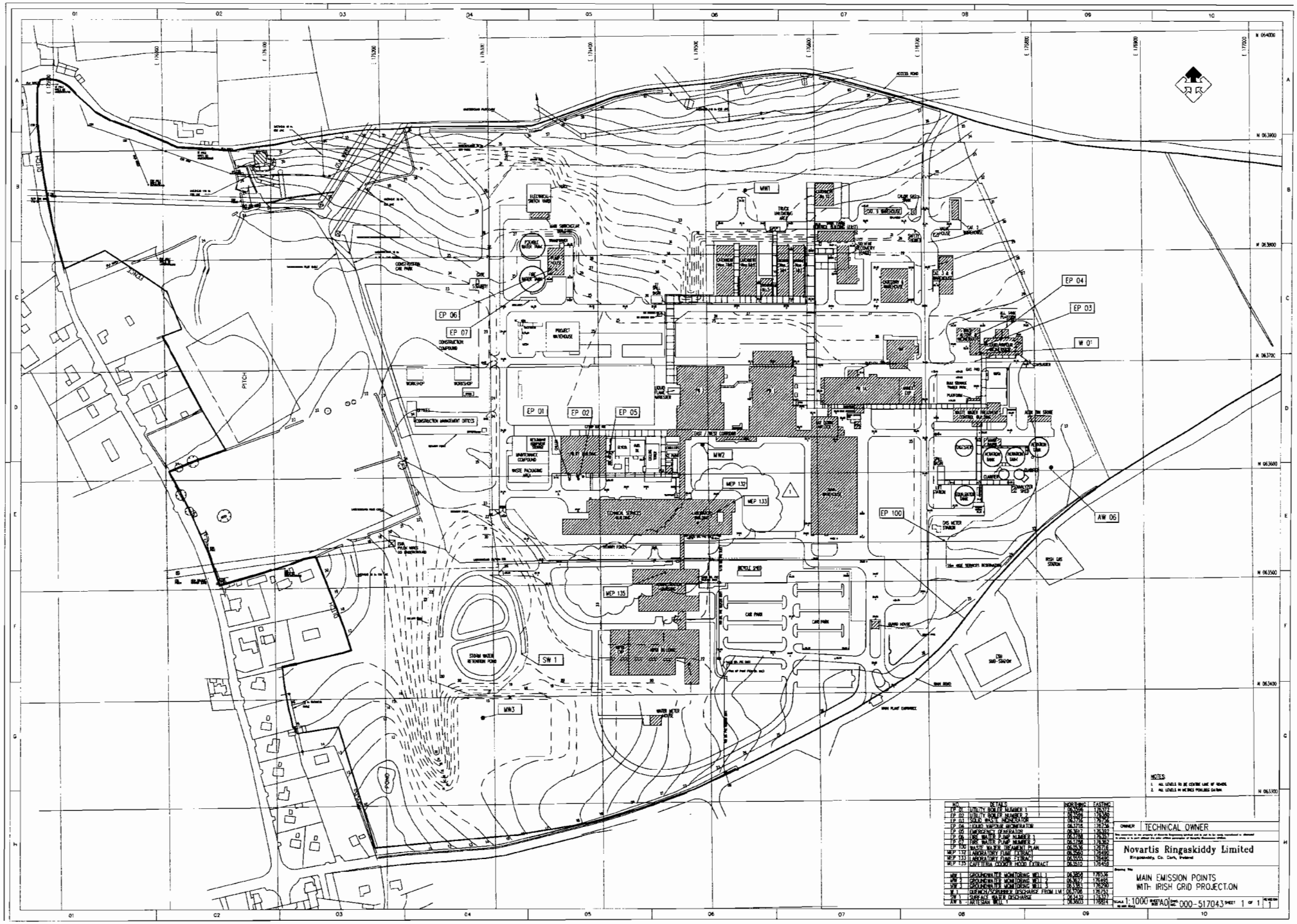
Novartis AG

J. Vierkötter
authorized signatory

F. Eichhorn
authorized signatory

APPENDIX C

SITE PLAN



NO.	DETAILS	NORTHING	EASTING
EP 01	UTILITY BOILER NUMBER 1	063496	176372
EP 02	UTILITY BOILER NUMBER 2	063496	176386
EP 03	SOLID WASTE INCINERATOR	063716	176754
EP 04	LIQUID WASTEWAT INCINERATOR	063716	176746
EP 05	EMERGENCY GENERATOR	063691	176332
EP 06	FIRE WATER PUMP NUMBER 1	063738	176157
EP 07	FIRE WATER PUMP NUMBER 2	063738	176162
EP 100	WASTE WATER TREATMENT PLAN	063535	176716
MEP 132	LABORATORY FUME EXTRACT	063560	176490
MEP 133	LABORATORY FUME EXTRACT	063560	176490
MEP 135	CAFETERIA COOKER HOOD EXTRACT	063510	176459
MW 1	GROUNDWATER MONITORING WELL 1	063850	176536
MW 2	GROUNDWATER MONITORING WELL 2	063697	176495
MW 3	GROUNDWATER MONITORING WELL 3	063581	176290
W 1	CHEMICAL/SCRUBBER DISCHARGE FROM LWT	063700	176151
SW 1	STORM WATER DISCHARGE	063430	176371
AW 6	ARTESIAN WELL 1	063605	176684

OWNER: TECHNICAL OWNER

Novartis Ringaskiddy Limited
Ringaskiddy, Co. Cork, Ireland

Drawing Title:
MAIN EMISSION POINTS
WITH IRISH GRID PROJECT.ON

SCALE 1:1000 (Full size drawing) PAPER SIZE A0 DRAWING NO. 000-517043 SHEET 1 OF 1 REVISION 1