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Ireland

INTEGRATED POLLUTION PREVENTION & CONTROL LICENCE

Proposed Determination

Licence Register Number:	P0778-01
Applicant:	Centocor Biologics (Ireland) Limited
Location of Installation:	Barnahely, Ringaskiddy, County Cork

INTRODUCTION

This introduction is not part of the licence and does not purport to be a legal interpretation of the licence.

The Centocor Biologics (Ireland) Limited installation at Barnahely, Ringaskiddy, County Cork will manufacture proteins and antibodies, used in the treatment of Arthritis, Crohn's Disease, MS, Cancer and Auto-immune diseases, by means of a Biotechnology Process. This process is aqueous based and involves the breeding of Genetically Modified Micro-organisms (GMM) mammalian cells in bioreactors and then harvesting the proteins and antibodies manufactured by these cells. This bulk product will then be purified and prepared for shipment to other facilities for use as a pharmaceutical ingredient. Excess purification will allow the installation to also purify and package additional proteins and antibodies from other Centocor facilities. The GMM used in the manufacturing process cannot survive outside the environment of the bioreactor and is subject to a separate use of Genetically Modified Organism (Contained Use) licence. Any residues or effluents from the bioreactors or off-specification product will undergo heat inactivation to ensure that no GMMs survive or enter the natural environment. Given the biotechnology process to be used at the installation there will be very limited use of solvents or other potentially polluting chemicals. The only significant emissions from the plant will be boiler emissions and emissions to sewer. The proposed boilers and possible future Combined Heat & Power (CHP) plant will be energy efficient and modelling has shown they will not have a significant impact on air quality. Effluent will be treated on-site before entering the sewer for discharge at Dognose Bank. Comprehensive emergency planning and environmental measures will be in place to ensure that there are no significant environmental impacts from the operation of the installation.

This licence sets out in detail the conditions under which Centocor Biologics (Ireland) Limited will operate and manage this installation.

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Glossary of Terms

All terms in this licence should be interpreted in accordance with the definitions in the Environmental Protection Agency Acts 1992 and 2003 / Waste Management Acts 1996 to 2005, unless otherwise defined in this section.

Aerosol	A suspension of solid or liquid particles in a gaseous medium.
Adequate lighting	20 lux measured at ground level.
AER	Annual Environmental Report.
Agreement	Agreement in writing.
Annually	At approximately twelve monthly intervals.
Attachment	Any reference to Attachments in this licence refers to attachments submitted as part of this licence application.
Application	The application by the licensee for this licence.
Appropriate facility	A waste management facility, duly authorised under relevant law and technically suitable.
BAT	Best Available Techniques.
Bi-annually	All or part of a period of six consecutive months.
Biennially	Once every two years.
BOD	5 day Biochemical Oxygen Demand.
CEN	Comité Européen De Normalisation – European Committee for Standardisation.
COD	Chemical Oxygen Demand.
Construction and Demolition Waste	Wastes that arise from construction, renovation and demolition activities: Chapter 17 of the EWC or as otherwise may be agreed.
Containment boom	A boom which can contain spillages and prevent them from entering drains or watercourses or from further contaminating watercourses.
Daily	During all days of plant operation, and in the case of emissions, when emissions are taking place; with at least one measurement on any one day.
Day	Any 24 hour period.
Daytime	0800 hrs to 2200 hrs.
dB(A)	Decibels (A weighted).
DO	Dissolved Oxygen.
Documentation	Any report, record, result, data, drawing, proposal, interpretation or other document in written or electronic form which is required by this licence.

Drawing	Any reference to a drawing or drawing number means a drawing or drawing number contained in the application, unless otherwise specified in this licence.
EMP	Environmental Management Programme.
Emission Limits	Those limits, including concentration limits and deposition rates established in *Schedule B* of this licence.
Environmental Damage	Has the meaning given it in Directive 2004/35/EC.
EPA	Environmental Protection Agency.
European Waste Catalogue (EWC)	A harmonised, non-exhaustive list of wastes drawn up by the European Commission and published as Commission Decision 2000/532/EC and any subsequent amendment published in the Official Journal of the European Community.
Facility	Any site or premises used for the purposes of the recovery or disposal of waste.
Fortnightly	A minimum of 24 times per year, at approximately two week intervals.
GC/MS	Gas Chromatography/Mass Spectroscopy.
GMO/GMM	Genetically Modified Organism/Genetically Modified Micro-organism.
Green waste	Waste wood (excluding timber), plant matter such as grass cuttings, and other vegetation.
Heavy Metals	This term is to be interpreted as set out in "Parameters of Water Quality, Interpretation and Standards" published by the Agency in 2001. ISBN 1-84095-015-3.
HFO	Heavy Fuel Oil.
Hours of Operation	The hours during which the installation is authorised to be operational.
ICP	Inductively Coupled Plasma Spectroscopy.
Incident	The following shall constitute an incident for the purposes of this licence: (i) an emergency; (ii) any emission which does not comply with the requirements of this licence; (iii) any trigger level specified in this licence which is attained or exceeded; and, (iv) any indication that environmental pollution has, or may have, taken place.
Industrial Waste	As defined in Section 5(1) of the Waste Management Acts 1996 to 2005.
Installation	A stationary technical unit or plant where the activity concerned referred to in the First Schedule of EPA Acts 1992 and 2003 is or will be carried on, and shall be deemed to include any directly associated activity, which has a technical connection with the activity and is carried out on the site of the activity.

IPPC	Integrated Pollution Prevention & Control.
K	Kelvin.
kPa	Kilo Pascals.
Leq	Equivalent continuous sound level.
Licensee	Centocor Biologics (Ireland) Limited, Barnahely, Ringaskiddy, County Cork.
Liquid Waste	Any waste in liquid form and containing less than 2% dry matter.
List I	As listed in the EC Directives 76/464/EEC and 80/68/EEC and amendments.
List II	As listed in the EC Directives 76/464/EEC and 80/68/EEC and amendments.
Local Authority	Cork County Council.
Maintain	Keep in a fit state, including such regular inspection, servicing, calibration and repair as may be necessary to adequately perform its function.
Mass Flow Limit	An Emission Limit Value which is expressed as the maximum mass of a substance which can be emitted per unit time.
Mass Flow Threshold	A mass flow rate, above which, a concentration limit applies.
Monthly	A minimum of 12 times per year, at approximately monthly intervals.
Night-time	2200 hrs to 0800 hrs.
Noise Sensitive Location (NSL)	Any dwelling house, hotel or hostel, health building, educational establishment, place of worship or entertainment, or any other installation or area of high amenity which for its proper enjoyment requires the absence of noise at nuisance levels.
Oil Separator	Device installed according to the International Standard I.S.EN 858-2:2003 (Separator systems for light liquids, (e.g., oil and petrol)-Part 2:Selection of nominal size, installation, operation and maintenance.
PER	Pollution Emission Register.
Quarterly	All or part of a period of three consecutive months beginning on the first day of January, April, July or October.
Regional Fisheries Board	South Western Regional Fisheries Board.
Sanitary Authority	Cork County Council.
Sanitary Effluent	Waste water from installation toilet, washroom and canteen facilities.
Sample(s)	Unless the context of this licence indicates to the contrary, samples shall include measurements by electronic instruments.
SOP	Standard Operating Procedure.

Specified Emissions	Those emissions listed in *Schedule B: Emission Limits* of this licence.
Standard Method	A National, European or internationally recognised procedure (eg, I.S. EN, ISO, CEN, BS or equivalent), as an in-house documented procedure based on the above references, a procedure as detailed in the current edition of "Standard Methods for the Examination of Water and Wastewater", (prepared and published jointly by A.P.H.A., A.W.W.A & W.E.F), American Public Health Association, 1015 Fifteenth Street, N.W., Washington DC 20005, USA; or, an alternative method as may be agreed by the Agency.
Storm Water	Rain water run-off from roof and non-process areas.
The Agency	Environmental Protection Agency.
TA Luft	Technical Instructions on Air Quality Control - TA Luft in accordance with art. 48 of the Federal Immission Control Law (BImSchG) dated 15 March 1974 (BGBI. I p.721). Federal Ministry for Environment, Bonn 1986, including the amendment for Classification of Organic Substances according to section 3.1.7 TA.Luft, published in July 1997.
TOC	Total Organic Carbon.
Trade Effluent	Trade Effluent has the meaning given in the Water Pollution Acts 1977 and 1990.
Trigger Level	A parameter value, the achievement or exceedance of which requires certain actions to be taken by the licensee.
Weekly	During all weeks of plant operation, and in the case of emissions, when emissions are taking place; with at least one measurement in any one week.
WWTP	Waste Water Treatment Plant.

Decision & Reasons for the Decisions

The Agency is satisfied, on the basis of the information available, that subject to compliance with the conditions of this licence, any emissions from the activity will comply with and will not contravene any of the requirements of Section 83(5) of the Environmental Protection Agency Acts 1992 and 2003.

In reaching this decision the Environmental Protection Agency has considered the application and supporting documentation received from the applicant, any submissions received from other parties and the report of its inspector.

Part I Schedule of Activities Licensed

In pursuance of the powers conferred on it by the Environmental Protection Agency Acts 1992 and 2003, the Agency proposes to grant this Integrated Pollution Prevention & Control licence to:

Centocor Biologics (Ireland) Limited, Barnahely, Ringaskiddy, Co. Cork

under Section 83(1) of the said Acts to carry on the following activity:

:- The use of a chemical or biological process for the production of basic pharmaceutical products.

at, Barnahely, Ringaskiddy, Co. Cork subject to the following twelve Conditions, with the reasons therefor and associated schedules attached thereto.

Part II Schedule of Activities Refused

None of the proposed activities as set out in the licence application have been refused.

Part III Conditions

Condition 1. Scope

1.1 Activities at this installation shall be limited as set out in *Schedule A: Limitations*, of this licence.

1.2 The installation shall be controlled, operated, and maintained and emissions shall take place as set out in this licence. All programmes required to be carried out under the terms of this licence, become part of this licence.

1.3 For the purposes of this licence, the installation authorised by this licence, is the area of land outlined in solid red line on "Figure A.1.2 – Site Plan" of the Licence Application P0778-01. Any reference in this licence to "installation" shall mean the area thus outlined in solid red line on "Figure A.1.2 – Site Plan" of the Licence Application P0778-01. The licensed activity shall be the carried on only within the area outlined.

1.4 No alteration to, or reconstruction in respect of, the activity or any part thereof which would, or is likely to, result in

(i) a material change or increase in:

- The nature or quantity of any emission,
- The abatement/treatment or recovery systems,
- The range of processes to be carried out,
- The fuels, raw materials, intermediates, products or wastes generated, or

(ii) any changes in:

- Site management infrastructure or control with adverse environmental significance,

shall be carried out or commenced without prior notice to, and without the agreement of, the Agency.

1.5 This licence is for the purposes of IPPC licensing under the EPA Acts 1992 and 2003 only and nothing in this licence shall be construed as negating the licensee's statutory obligations or requirements under any other enactments or regulations.

1.6 Having regard to the nature of the activity and arrangements necessary to be made or made in connection with the carrying on of the activity, the specified period for the purposes of Section 92(1) of the EPA Acts 1992 and 2003 is 5 years.

Reason: To clarify the scope of this licence.

Condition 2. Management of the Installation

2.1 Installation Management

2.1.1 The licensee shall employ a suitably qualified and experienced installation manager who shall be designated as the person in charge. The installation manager or a nominated, suitably qualified and experienced, deputy shall be present on the installation at all times during its operation or as otherwise required by the Agency.

2.1.2 The licensee shall ensure that personnel performing specifically assigned tasks shall be qualified on the basis of appropriate education, training and

experience, as required and shall be aware of the requirements of this licence.

2.2 Environmental Management System (EMS)

2.2.1 The licensee shall establish and maintain an Environmental Management System (EMS) at least four months prior to the commencement of the activity. The EMS shall be updated on an annual basis.

2.2.2 The EMS shall include as a minimum the following elements:

2.2.2.1 Management and Reporting Structure.

2.2.2.2 Schedule of Environmental Objectives and Targets.

The licensee shall prepare and maintain a Schedule of Environmental Objectives and Targets. The schedule shall as a minimum provide for a review of all operations and processes, including an evaluation of practicable options, for energy and resource efficiency, the use of cleaner technology, cleaner production, and the prevention, reduction and minimisation of waste, and shall include waste reduction targets. The schedule shall include time frames for the achievement of set targets and shall address a five year period as a minimum. The schedule shall be reviewed annually and amendments thereto notified to the Agency for agreement as part of the Annual Environmental Report (AER).

2.2.2.3 Environmental Management Programme (EMP)

The licensee shall, at least four months prior to the commencement of the activity submit to the Agency for agreement an EMP, including a time schedule, for achieving the Environmental Objectives and Targets prepared under Condition 2.2.2.2. Once agreed the EMP shall be established and maintained by the licensee. It shall include:

(i) designation of responsibility for targets;

(ii) the means by which they may be achieved;

(iii) the time within which they may be achieved.

The EMP shall be reviewed annually and amendments thereto notified to the Agency for agreement as part of the Annual Environmental Report (AER) (Condition 11.9).

A report on the programme, including the success in meeting agreed targets, shall be prepared and submitted to the Agency as part of the AER. Such reports shall be retained on-site for a period of not less than seven years and shall be available for inspection by authorised persons of the Agency.

2.2.2.4 Documentation

(i) The licensee shall establish and maintain an environmental management documentation system which shall be to the satisfaction of the Agency.

(ii) The licensee shall issue a copy of this licence to all relevant personnel whose duties relate to any condition of this licence.

2.2.2.5 Corrective Action

The licensee shall establish procedures to ensure that corrective action is taken should the specified requirements of this licence not be fulfilled. The responsibility and authority for initiating further investigation and corrective action in the event of a reported non-conformity with this licence shall be defined.

2.2.2.6 Awareness and Training

The licensee shall establish and maintain procedures for identifying training needs, and for providing appropriate training, for all personnel whose work can have a significant effect upon the environment. Appropriate records of training shall be maintained.

2.2.2.7 Communications Programme

The licensee shall establish and maintain a Public Awareness and Communications Programme to ensure that members of the public are informed, and can obtain information at the installation, at all reasonable times, concerning the environmental performance of the installation.

2.2.2.8 Maintenance Programme

The licensee shall establish and maintain a programme for maintenance of all plant and equipment based on the instructions issued by the manufacturer/supplier or installer of the equipment. Appropriate record keeping and diagnostic testing shall support this maintenance programme. The licensee shall clearly allocate responsibility for the planning, management and execution of all aspects of this programme to appropriate personnel (see Condition 2.1 above).

2.2.2.9 Efficient Process Control

The licensee shall establish and maintain a programme to ensure there is adequate control of processes under all modes of operation. The programme shall identify the key indicator parameters for process control performance, as well as identifying methods for measuring and controlling these parameters. Abnormal process operating conditions shall be documented, and analysed to identify any necessary corrective action.

Reason: *To make provision for management of the activity on a planned basis having regard to the desirability of ongoing assessment, recording and reporting of matters affecting the environment.*

Condition 3. Infrastructure and Operation

3.1 The licensee shall establish all infrastructure referred to in this licence in advance, of the commencement of the licensed activities or as required by the conditions of this licence.

3.2 Installation Notice Board

3.2.1 At least three months prior to the commencement of the activity, the licensee shall provide and maintain an Installation Notice Board on the installation so that it is legible to persons outside the main entrance to the installation. The minimum dimensions of the board shall be 1200 mm by 750 mm.

3.2.2 The board shall clearly show:-

(i) the name and telephone number of the installation;

(ii) the normal hours of opening;

(iii) the name of the licence holder;

(iv) an emergency out of hours contact telephone number;

(v) the licence reference number; and

(vi) where environmental information relating to the installation can be obtained.

3.3 The licensee shall install on all emission points such sampling points or equipment, including any data-logging or other electronic communication equipment, as may be required by the Agency. All such equipment shall be consistent with the safe operation of all sampling and monitoring systems.

3.4 In the case of composite sampling of aqueous emissions from the operation of the installation a separate composite sample or homogeneous sub-sample (of sufficient volume as advised) should be refrigerated immediately after collection and retained as required for EPA use.

3.5 The licensee shall clearly label and provide safe and permanent access to all on-site sampling and monitoring points and to off-site points as required by the Agency.

3.6 Tank, Container and Drum Storage Areas

3.6.1 All tank, container and drum storage areas shall be rendered impervious to the materials stored therein. Bunds should be designed having regard to Agency guidelines 'Storage and Transfer of Materials for Scheduled Activities' (2004).

3.6.2 All tank and drum storage areas shall, as a minimum, be bunded, either locally or remotely, to a volume not less than the greater of the following:-

(i) 110% of the capacity of the largest tank or drum within the bunded area; or

(ii) 25% of the total volume of substance which could be stored within the bunded area.

3.6.3 All drainage from bunded areas shall be treated as hazardous waste unless it can be demonstrated to be otherwise. All drainage from bunded areas shall be diverted for collection and safe disposal.

3.6.4 All inlets, outlets, vent pipes, valves and gauges must be within the bunded area.

3.6.5 All tanks, containers and drums shall be labelled to clearly indicate their contents.

3.7 The licensee shall have in storage an adequate supply of containment booms and/or suitable absorbent material to contain and absorb any spillage at the installation. Once used the absorbent material shall be disposed of at an appropriate facility.

3.8 Silt Traps and Oil Separators

The licensee shall install and maintain silt traps and oil separator at the installation to ensure that all storm water discharges from the installation pass through a silt trap and oil separator in advance, of discharge. The separator shall be a Class I full retention separator and the silt traps and separator shall be in accordance with I.S. EN 858-2:2003 (separator systems for light liquids).

3.9 All pump sumps, storage tanks, lagoons or other treatment plant chambers from which spillage of environmentally significant materials might occur in such quantities as are likely to breach local or remote containment or separator, shall be fitted with high liquid level alarms (or oil detectors as appropriate) prior to the date of commencement of the activity.

3.10 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.

3.11 All wellheads, whose locations are shown on Drawing No. ENV-S0100001, attachment F.2 of the licence application shall be adequately protected to prevent contamination or physical damage from the date of grant of this licence. Any historical boreholes not in use for monitoring as detailed in Section I.5.1 of the application shall be adequately protected to prevent contamination or physical damage from the date of grant of this licence. Any boreholes onsite, which are or become unusable will shall be decommissioned by an appropriate contractor.

3.12 The licensee shall, from the date of grant of this licence, install and maintain in a prominent location on the site a wind sock, or other wind direction indicator, which shall be visible from the public roadway outside the site.

3.13 The licensee shall provide and maintain a Wastewater Treatment plant at the installation for the treatment of trade and sanitary effluent arising on-site.

Reason: To provide for appropriate operation of the installation to ensure protection of the environment.

Condition 4. Interpretation

4.1 Emission limit values for emissions to atmosphere in this licence shall be interpreted in the following way:

4.1.1 Continuous Monitoring:

(i) No 24 hour mean value shall exceed the emission limit value.

(ii) 97% of all 30 minute mean values taken continuously over an annual period shall not exceed 1.2 times the emission limit value.

(iii) No 30 minute mean value shall exceed twice the emission limit value.

4.1.2 For Non-Continuous Monitoring

(i) For any parameter where, due to sampling/analytical limitations, a 30 minute sample is inappropriate, a suitable sampling period should be employed and the value obtained therein shall not exceed the emission limit value.

(ii) For flow, no hourly or daily mean value, calculated on the basis of appropriate spot readings, shall exceed the relevant limit value.

(iii) For all other parameters, no 30 minute mean value shall exceed the emission limit value.

(iv) Mass flow thresholds refer to a rate of discharge expressed in units of kg/h, above which the concentration emission limit value applies. Mass flow threshold rates shall be determined on the basis of a single 30 minute measurement (i.e. the concentration determined as a 30 minute average shall be multiplied by an appropriate measurement of flow and the result shall be expressed in units of kg/h).

(v) Mass flow limits shall be calculated on the basis of the concentration, determined as an average over the specified period, multiplied by an appropriate measurement of flow. No value, so determined, shall exceed the mass flow limit value.

4.2 The concentration and volume flow limits for emissions to atmosphere specified in this licence shall be achieved without the introduction of dilution air and shall be based on gas volumes under standard conditions of:-

4.2.1 In the case of non-combustion gases:

Temperature 273K, Pressure 101.3 kPa (no correction for oxygen or water content).

4.2.2 In the case of combustion gases:

Temperature 273K, Pressure 101.3 kPa, dry gas; 3% oxygen for liquid and gas fuels; 6% oxygen for solid fuels.

4.3 Emission limit values for emissions to sewer/waters in this licence shall be interpreted in the following way:-

4.3.1 Continuous monitoring:

(i) No flow value shall exceed the specified limit.

(ii) No pH value shall deviate from the specified range.

(iii) No temperature value shall exceed the limit value.

4.3.2 Composite Sampling:

(i) No pH value shall deviate from the specified range.

(ii) For parameters other than pH and flow, eight out of ten consecutive composite results, based on flow proportional composite sampling, shall not exceed the emission limit value. No individual result similarly calculated shall exceed 1.2 times the emission limit value.

4.3.3 Discrete Sampling

For parameters other than pH and temperature, no grab sample value shall exceed 1.2 times the emission limit value.

4.4 Where the ability to measure a parameter is affected by mixing before emission, then, with agreement from the Agency, the parameter may be assessed before mixing takes place.

4.5 Noise

Noise from the installation shall not give rise to sound pressure levels (Leq,T) measured at the site boundary which exceed the limit value(s).

Reason: *To clarify the interpretation of limit values fixed under the licence and to provide for the requirements of the Sanitary Authority in accordance with Section 99E of the EPA Acts 1992 and 2003.*

Condition 5. Emissions

5.1 No specified emission from the installation shall exceed the emission limit values set out in *Schedule B: Emission Limits* of this licence. There shall be no other emissions of environmental significance.

5.2 No emissions, including odours, from the activities carried on at the site shall result in an impairment of, or an interference with amenities or the environment beyond the facility boundary or any other legitimate uses of the environment beyond the installation boundary.

5.3 No substance shall be discharged in a manner, or at a concentration that, following initial dilution, causes tainting of fish or shellfish.

5.4 Natural gas or biodiesel meeting CEN standard EN14214 shall be used in the boilers or Combined Heat & Power plant on site. In the event of an interruption to the supply of natural gas or biodiesel, an alternative fuel such as gas oil (sulphur content

not exceeding 0.2% by mass until 31st December 2007 and not exceeding 0.1% by mass thereafter) may be used with the prior written agreement of the Agency.

5.5 All boilers and CHP plant at the installation shall be maintained, in accordance with the instructions issued by the manufacturer/supplier or installer, with flue gases monitored on an annual basis as per Schedule C.

5.6 The licensee shall at no time discharge or permit to be discharged in to the sewer any liquid matter or thing that is or may be liable to set or congeal at average sewer temperature or is capable of giving off any inflammable or explosive gas or any acid, alkali or other substance in sufficient concentration to cause corrosion to sewer pipes, penstock and sewer fittings or the general integrity of the sewer.

5.7 The licensee shall permit authorised persons of the Agency and Sanitary Authority to inspect, examine and test, at all reasonable times, any works and apparatus installed in connection with the process effluent and to take samples of the process effluent.

Reason: To provide for the protection of the environment by way of control and limitation of emissions and to provide for the requirements of the Sanitary Authority in accordance with Section 99E of the EPA Acts 1992 and 2003.

Condition 6. Control and Monitoring

6.1 The licensee shall carry out such sampling, analyses, measurements, examinations, maintenance and calibrations as set out below and as in accordance with Schedule C of this licence:

6.1.1 Analysis shall be undertaken by competent staff in accordance with documented operating procedures.

6.1.2 Such procedures shall be assessed for their suitability for the test matrix and performance characteristics determined.

6.1.3 Such procedures shall be subject to a programme of Analytical Quality Control using control standards with evaluation of test responses.

6.1.4 Where analysis is sub-contracted it shall be to a competent laboratory.

6.2 Sampling and analysis of all pollutants as well as reference measurement methods to calibrate automated measurement systems shall be carried out in accordance with CEN-standards. If CEN standards are not available, ISO, national or international standards which will ensure the provision of data of an equivalent scientific quality shall apply.

6.3 All automatic monitors and samplers shall be functioning at all times (except during maintenance and calibration) when the activity is being carried on unless alternative sampling or monitoring has been agreed in writing by the Agency for a limited period. In the event of the malfunction of any continuous monitor, the licensee shall contact the Agency as soon as practicable, and alternative sampling and monitoring facilities shall be put in place. Agreement for the use of alternative equipment, other than in emergency situations, shall be obtained from the Agency.

6.4 Monitoring and analysis equipment shall be operated and maintained as necessary so that monitoring accurately reflects the emission or discharge.

6.5 The licensee shall ensure that groundwater monitoring well sampling equipment is available/installed on-site and is fit for purpose at all times. The sampling equipment shall be to Agency specifications.

6.6 All treatment/abatement and emission control equipment shall be calibrated and maintained, in accordance with the instructions issued by the manufacturer/supplier or installer.

6.7 The frequency, methods and scope of monitoring, sampling and analyses, as set out in this licence, may be amended with the agreement of the Agency following evaluation of test results.

6.8 The licensee shall prepare a programme, to the satisfaction of the Agency, for the identification and reduction of fugitive emissions. This programme shall be included in the Environmental Management Programme.

6.9 The integrity and water tightness of all underground pipes, tanks, bunding structures and containers and their resistance to penetration by water or other materials carried or stored therein shall be tested and demonstrated by the licensee prior to use. This testing shall be carried out by the licensee at least once every three years thereafter and reported to the Agency on each occasion. This testing shall be carried out in accordance with any guidance published by the Agency. A written record of all integrity tests and any maintenance or remedial work arising from them shall be maintained by the licensee.

6.10 The drainage system, bunds, silt traps and oil separators shall be inspected weekly, desludged as necessary and properly maintained at all times. All sludge and drainage from these operations shall be collected for safe disposal.

6.11 Process Effluent

A representative sample of effluent from the Wastewater Treatment plant shall be screened for the presence of organic compounds. Such screening shall be repeated on an annual basis or as requested by the Agency thereafter.

6.12 Storm water

A visual examination of the storm water discharge shall be carried out daily. A log of such inspections shall be maintained. The licensee shall within twelve months of the commencement of the activity submit warning and action levels for stormwater at SEMP2 and SEMP3 in accordance with Schedule C.2.3.

6.13 Noise

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.

6.14 Pollutant Release and Transfer Register (PRTR)

The licensee shall prepare and report a PRTR for the site. The substances and/or waste to be included in the PRTR shall be agreed by the Agency each year by reference to EC Regulation No.166/2006 concerning the establishment of the European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC. The PRTR shall be prepared in accordance with any relevant guidelines issued by the Agency and shall be submitted electronically in specified format and as part of the AER.

6.15 Test Programme

6.15.1 The licensee shall prepare, to the satisfaction of the Agency, a test programme for any abatement equipment installed. This programme shall be submitted to the Agency in advance of implementation.

6.15.2 This programme, following agreement with the Agency, shall be completed prior to the commencement of operation of the abatement equipment.

6.15.3 The criteria for the operation of the abatement equipment as determined by the test programme, shall be incorporated into the standard operating procedures.

6.16 The test programme, referred to in condition 6.15, shall include as a minimum, the following:

6.16.1 Establish all criteria for operation, control and management of the abatement equipment to ensure compliance with the emission limit values specified in this licence.

6.16.2 Assess the performance of any monitors on the abatement system and establish a maintenance and calibration programme for each monitor.

6.16.3 A report on the test programme shall be submitted to the Agency within one month of completion.

6.17 The licensee shall, at least four months prior to the date of commencement of the activity, develop and establish a Data Management System for collation, archiving, assessing and graphically presenting the environmental monitoring data generated as a result of this licence.

6.18 The licensee shall within six months of the commencement of the activity prepare an odour audit of the installation to include: the Waste Water Treatment Plant; the autoclaves; and vents from the thermal inactivation process area. The report of the audit shall contain proposals for any additional measures required to comply with Condition 5.2.

Reason: To provide for the protection of the environment by way of treatment and monitoring of emissions and to provide for the requirements of the Sanitary Authority in accordance with Section 99E of the EPA Acts 1992 and 2003.

Condition 7. Resource Use and Energy Efficiency

7.1 The licensee shall carry out an audit of the energy efficiency of the site within twelve months of the commencement of the activity. The audit shall be carried out in accordance with the guidance published by the Agency; "Guidance Note on Energy Efficiency Auditing". The energy efficiency audit shall be repeated at intervals as required by the Agency.

7.2 The audit shall identify all opportunities for energy use reduction and efficiency and the recommendations of the audit will be incorporated into the Schedule of Environmental Objectives and Targets under Condition 2 above.

7.3 The licensee shall identify opportunities for reduction in the quantity of water used on site including recycling and reuse initiatives, wherever possible. Reductions in water usage shall be incorporated into Schedule of Environmental Objectives and Targets.

7.4 The licensee shall undertake an assessment of the efficiency of use of raw materials in all processes, having particular regard to the reduction in waste generated. The assessment should take account of best international practice for this type of activity. Where improvements are identified, these shall be incorporated into the Schedule of Environmental Objectives and Targets.

Reason: To provide for the efficient use of resources and energy in all site operations.

Condition 8. Materials Handling

8.1 Disposal or recovery of waste on-site shall only take place in accordance with the conditions of this licence and in accordance with the appropriate National and European legislation and protocols.

8.2 Waste sent off-site for recovery or disposal shall be transported only by an authorised waste contractor. The waste shall be transported only from the site of the activity to the site of recovery/disposal in a manner that will not adversely affect the environment and in accordance with the appropriate National and European legislation and protocols.

8.3 The licensee shall ensure that waste in advance, of transfer to another person shall be classified packaged and labelled in accordance with National, European and any other standards which are in force in relation to such labelling.

8.4 The loading and unloading of materials shall be carried out in designated areas protected against spillage and leachate run – off.

8.5 Waste shall be stored in designated areas, protected as may be appropriate, against spillage and leachate run-off. The waste is to be clearly labelled and appropriately segregated.

8.6 No waste classified as green list waste in accordance with the EU Transfrontier Shipment of Waste Regulations (Council Regulation EEC No.259/1993, as amended) shall be consigned for recovery without the agreement of the Agency.

8.7 Waste for disposal/recovery off-site shall be analysed in accordance with *Schedule C4: Waste Monitoring* of this licence.

8.8 Unless approved in writing by the Agency the licensee is prohibited from mixing a hazardous waste of one category with a hazardous waste of another category or with any other non-hazardous waste.

Reason: *To provide for the appropriate handling of materials and the protection of the environment.*

Condition 9. Accident Prevention and Emergency Response

9.1 The licensee shall at least four months prior to the commencement of the activity ensure that a documented Accident Prevention Policy is in place, which will address the hazards on-site, particularly in relation to the prevention of accidents with a possible impact on the environment. This procedure shall be reviewed annually and updated as necessary.

9.2 The licensee shall, at least four months prior to the commencement of the activity, ensure that a documented Emergency Response Procedure is in place, which shall address any emergency situation which may originate on-site. This procedure shall include provision for minimising the effects of any emergency on the environment. This procedure shall be reviewed annually and updated as necessary.

9.3 Incidents

9.3.1 In the event of an incident the licensee shall immediately:-

(i) carry out an investigation to identify the nature, source and cause of the incident and any emission arising therefrom;

(ii) isolate the source of any such emission;

(iii) evaluate the environmental pollution, if any, caused by the incident;

(iv) identify and execute measures to minimise the emissions/malfunction and the effects thereof;

(v) identify the date, time and place of the incident;

(vi) notify the Agency and other relevant authorities.

9.3.2 The licensee shall provide a proposal to the Agency for its agreement within one month of the incident occurring or as otherwise agreed by the Agency to:-

(i) identify and put in place measures to avoid reoccurrence of the incident; and

(ii) identify and put in place any other appropriate remedial action.

Reason: To provide for the protection of the environment.

Condition 10. Decommissioning & Residuals Management

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

10.2 Residuals Management Plan:

10.2.1 The licensee shall prepare, to the satisfaction of the Agency, a fully detailed and costed plan for the decommissioning or closure of the site or part thereof. This plan shall be submitted as part of the first AER submitted to the Agency as outlined Condition 11.9.

10.2.2 The plan shall be reviewed annually and proposed amendments thereto notified to the Agency for agreement as part of the AER. No amendments may be implemented without the agreement of the Agency.

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

10.3.1 A scope statement for the plan.

10.3.2 The criteria which define the successful decommissioning of the activity or part thereof, which ensures minimum impact on the environment.

10.3.3 A programme to achieve the stated criteria.

10.3.4 Where relevant, a test programme to demonstrate the successful implementation of the decommissioning plan.

10.3.5 Details of the costings for the plan and the financial provisions to underwrite those costs.

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

Reason: To make provision for the proper closure of the activity ensuring protection of the environment.

Condition 11. Notifications, Records and Reports

11.1 The licensee shall notify the Agency, in writing, four months in advance, of the intended date of commencement of the Scheduled Activity.

11.2 The licensee shall notify the Agency by both telephone and either facsimile or electronic mail, if available, to the Office of Environmental Enforcement, South Western Region, EPA, Inniscarra, County Cork, or to such other Agency office as may be specified by the Agency, as soon as practicable after the occurrence of any of the following:

(i) Any release of environmental significance to atmosphere from any potential emission point including bypasses.

(ii) Any emission which does not comply with the requirements of this licence.

(iii) Any malfunction or breakdown of key control equipment or monitoring equipment set out in S*chedule C: Control & Monitoring* which is likely to lead to loss of control of the abatement system.

(iv) Any incident with the potential for environmental contamination of surface water or groundwater, or posing an environmental threat to air or land, or requiring an emergency response by the Local Authority.

The licensee shall include as part of the notification, date and time of the incident, summary details of the occurrence, and where available, the steps taken to minimise any emissions.

11.3 In the event of any incident which relates to discharges to sewer, having taken place, the licensee shall notify the Local and Sanitary Authority as soon as practicable, after such an incident.

11.4 In the case of any incident which relates to discharges to water, the licensee shall notify the Local Authority and the South Western Regional Fisheries Board as soon as practicable after such an incident.

11.5 The licensee shall make a record of any incident. This record shall include details of the nature, extent, and impact of, and circumstances giving rise to, the incident. The record shall include all corrective actions taken to; manage the incident, minimise wastes generated and the effect on the environment, and avoid recurrence. The licensee shall as soon as practicable following incident notification, submit to the Agency the incident record.

11.6 The licensee shall record all complaints of an environmental nature related to the operation of the activity. Each such record shall give details of the date and time of the complaint, the name of the complainant and give details of the nature of the complaint. A record shall also be kept of the response made in the case of each complaint.

11.7 The licensee shall record all sampling, analyses, measurements, examinations, calibrations and maintenance carried out in accordance with the requirements of this licence and all other such monitoring which relates to the environmental performance of the installation.

11.8 The licensee shall as a minimum keep the following documents at the site:-

(i) the licences relating to the installation;

(ii) the current EMS for the installation;

(iii) the previous year's AER for the installation;

(iv) records of all sampling, analyses, measurements, examinations, calibrations and maintenance carried out in accordance with the requirements of this licence and all other such monitoring which relates to the environmental performance of the installation;

(v) relevant correspondence with the Agency;

(vi) up to date site drawings/plans showing the location of key process and environmental infrastructure, including monitoring locations and emission points;

(vii) up to date Standard Operational Procedures for all processes, plant and equipment necessary to give effect to this licence or otherwise to ensure that standard operation of such processes, plant or equipment does not result in unauthorised emissions to the environment;

and this documentation shall be available to the Agency for inspection at all reasonable times.

11.9 The licensee shall submit to the Agency, by the 31st March of each year, an AER covering the previous calendar year. This report, which shall be to the satisfaction of the Agency, shall include as a minimum the information specified in *Schedule D: Annual Environmental Report* of this licence and shall be prepared in accordance with any relevant guidelines issued by the Agency.

11.10 A full record, which shall be open to inspection by authorised persons of the Agency at all times, shall be kept by the licensee on matters relating to the waste management operations and practices at this site. This record shall be maintained on a monthly basis and shall as a minimum contain details of the following:

(i) The tonnages and EWC Code for the waste materials imported and/or sent off-site for disposal/recovery.

(ii) The names of the agent and carrier of the waste, and their waste collection permit details, if required (to include issuing authority and vehicle registration number).

(iii) Details of the ultimate disposal/recovery destination facility for the waste and its appropriateness to accept the consigned waste stream, to include its permit/licence details and issuing authority, if required.

(iv) Written confirmation of the acceptance and disposal/recovery of any hazardous waste consignments sent off-site.

(v) Details of all wastes consigned abroad for Recovery and classified as 'Green' in accordance with the EU Transfrontier Shipment of Waste Regulations (Council Regulation EEC No. 259/1993, as amended). The rationale for the classification must form part of the record.

(vi) Details of any rejected consignments.

(vii) Details of any approved waste mixing.

(viii) The results of any waste analyses required under *Schedule C: Control & Monitoring,* of this licence.

(ix) The tonnages and EWC Code for the waste materials recovered/disposed on-site.

(x) Details and quantities of any off-specification GMM materials or wastes sent for thermal inactivation and treatment in the WWTP.

11.11 The licencee shall at least four months prior to the date of commencement of the activity submit to the Agency an appropriately scaled A3 map showing all environmental monitoring points specified in the licence.

Reason: To provide for the collection and reporting of adequate information on the activity.

Condition 12. Financial Charges and Provisions

12.1 Agency Charges

12.1.1 The licensee shall pay to the Agency an annual contribution of €20,572, or such sum as the Agency from time to time determines, having regard to variations in the extent of reporting, auditing, inspection, sampling and analysis or other functions carried out by the Agency, towards the cost of monitoring the activity as the Agency considers necessary for the performance of its functions under the Environmental Protection Agency Acts 1992 and 2003. The first payment shall be a pro-rata amount for the period from the date of commencement of enforcement to the 31st day of December, and shall be paid to the Agency within one month from the date of the licence. In subsequent years the licensee shall pay to the Agency such revised annual contribution as the Agency shall from time to time consider necessary to enable performance by the Agency of its relevant functions under the Environmental Protection Agency Acts 1992 and 2003, and all such payments shall be made within one month of the date upon which demanded by the Agency.

12.1.2 In the event that the frequency or extent of monitoring or other functions carried out by the Agency needs to be increased the licensee shall contribute such sums as determined by the Agency to defraying its costs in regard to items not covered by the said annual contribution.

12.2 Sanitary Authority Charges

The licensee shall pay to the Sanitary Authority such sum as may be determined from time to time, having regard to the variations in the cost of providing drainage and the variation in effluent reception and treatment costs. Payment to be made on demand.

12.3 Environmental Liabilities

12.3.1 The licensee shall as part of the AER provide an annual statement as to the measures taken or adopted at the site in relation to the prevention of environmental damage, and the financial provisions in place in relation to the underwriting of costs for remedial actions following anticipated events or accidents/incidents, as may be associated with the carrying on of the activity.

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. A report on this assessment shall be submitted to the Agency for agreement in advance, of the commencement of the activity. The ELRA shall be reviewed as necessary to reflect any significant change on site,

and in any case every three years following initial agreement: review results are to be notified as part of the AER.

12.3.3 In advance, of the commencement of the activity, the licensee shall, to the satisfaction of the Agency, make financial provision to cover any liabilities identified in Condition 12.3.2. The amount of indemnity held shall be reviewed and revised as necessary, but at least annually. Proof of renewal or revision of such financial indemnity shall be included in the annual 'statement of measures' report identified in Condition 12.3.1.

Reason: *To provide for adequate financing for monitoring and financial provisions for measures to protect the environment and to provide for the requirements of the Sanitary Authority in accordance with Section 99E of the EPA Acts 1992 and 2003.*

SCHEDULE A: Limitations

There are no limitations on the installation specified in the Schedule.

SCHEDULE B: Emission Limits

B.1 Emissions to Air

Emission Point Reference No.: A1-1, A1-2, A1-3

Location: Boiler Stack North of CUP building.

Volume to be emitted: Maximum in any one day: 240,000 m^3

Maximum rate per hour: 10,000m^3

Minimum discharge height: 30 m above ground.

Parameter	Emission Limit Value
Nitrogen oxides (as NO_2)	150 mg/m^3
Particulates	50 mg/m^3

Emission Point Reference No.: A1-4

Location: Waste Heat Recovery Boiler/Gas Turbine Stack North of CUP Building.

Volume to be emitted: Maximum in any one day: 576,000 m^3

Maximum rate per hour: 24,000 m^3

Minimum discharge height: 30 m above ground.

Parameter	Emission Limit Value
Nitrogen oxides (as NO_2)	150 mg/m
Particulates	50 mg/m

Emission Point Reference No.: A3-11, A3-12

Location: Dust collector vents in Manufacturing Plant, H-12 (or equivalent filters to 0.5 micron).

Volume to be emitted: 2,000 m^3/hr

Parameter	Emission Limit Value
Total Particulate	20 mg/m^3 (at mass flows > 200 g/hr)

B.2 Emissions to Water

There shall be no Emissions to Water of environmental significance.

B.3 Emission to Sewer

Emission Point Reference No.: SE1

Name of Receiving Waters: Dognose Bank, Cork Harbour.

Location: Outside southeastern corner of site, south of wastewater treatment plant.

Volume to be emitted: Maximum in any one day: 800 m^3

Maximum rate per hour: 100 m^3

Parameter	Emission Limit Value	
Temperature	30°C (max.)	
PH	6.0 – 9.0	
Toxicity	10 Toxic Units	
	mg/l	**kg/day**
BOD	60	48
COD	300	240
Suspended Solids	50	40
Total Nitrogen	80	-
Total Phosphorus (as P)	20	-
Oils, fats and greases	20	-
Sulphate (SO_4)	200	-

B.4. Noise Emissions

Daytime dB(A) L_{Aeq}(30 minutes)	Night-time dB(A) L_{Aeq}(30 minutes)
55 Note 1	45 Note 1

Note 1: There shall be no clearly audible tonal component or impulsive component in the noise emission from the activity at any noise sensitive location.

SCHEDULE C: Control &Monitoring

C.1.1 Control of Emissions to Air

Emission Point Reference No.: A3-23

Description of Treatment: WWTP Odour Abatement Biofilter.

Control Parameter[Note1]	Monitoring	Key Equipment[Note 2]
Inlet and Outlet Gas		
Ammonia	Monthly	Colorimetric Indicator Tubes [Note 1]
Hydrogen sulphide	Monthly	Colorimetric Indicator Tubes [Note 1]
Mercaptans	Monthly	Colorimetric Indicator Tubes [Note 1]
Bed Media		
Odour Assessment	Daily	Subjective Impression
Condition and depth of biofilter [Note 2]	Monthly	Visual Inspection
Moisture content	Monthly	Standard laboratory method [Note 1]
pH	Biannually	-
General		
Sprinkler System	Check operation Daily	Visual Inspection
Fan	Check operation Daily	Visual Inspection
Negative Pressure	Monthly	Air Current Tubes

Note 1: Control parameters to be determined as part of the Test Programme in Condition 6.15.
Note 2: The licensee shall maintain appropriate access to standby and/or spares to ensure the operation of the abatement system.

Emission Point Reference No.: A3-11, A3-12

Description of Treatment: Dust Extraction.

Control Parameter	Monitoring	Key Equipment[Note 1]
Filters	Filter integrity	To be agreed with Agency.

Note 1: The licensee shall maintain appropriate access to standby and/or spares to ensure the operation of the abatement system.

C.1.2 Monitoring of Emissions to Air

Emission Point Reference No.: A1-1, A1-2, A1-3, A1-4

Parameter	Monitoring Frequency	Analysis Method/Technique
NOx	Annually	Flue gas analyser
CO	Annually	Flue gas analyser
Particulates	Annually	Isokinetic/Gravimetric
PM_{10}	Annually	Standard method.

Emission Point Reference No.: A3-11, A3-12,

Parameter	Monitoring Frequency	Analysis Method/Technique
Total Particulate	Annually	Isokinetic/gravimetric
Active Pharmaceutical Particulate	Annually	Isokinetic/gravimetric

C.2.1 Control of Emissions to Water

There shall be no Emissions to Water of environmental significance.

C.2.2 Monitoring of Emissions to Water

There shall be no Emissions to Water of environmental significance.

C.2.3 Monitoring of Storm Water Emission

Emission Point Reference No.: SEMP2 and SEMP3 (Prior to SE2)

Parameter	Monitoring Frequency	Analysis Method/Technique
pH	Continuous	On-line pH electrode/meter with recorder
TOC	Continuous	On-Line TOC meter with recorder
Temperature	Weekly	Thermometer
COD	Weekly	Standard Method
Total Ammonia	Weekly	Standard Method
Total Nitrogen	Weekly	Standard Method
Conductivity	Weekly	Standard Method
Visual Inspection	Weekly	Sample and examine for colour and odour

C.3.1 Control of Emissions to Sewer

Emission Point Reference No.: SE1

Description of Treatment: Waste Water Treatment.

Equipment:

Control Parameter	Monitoring	Key Equipment[Note 1, Note 2.]
Effluent (pH) Neutralisation	Continuous pH output from neutralisation tank	Acid/Sodium Hydroxide dosing.
Temperature	Continuous temperature	Cooling Tower
Agitation	Not applicable	Air Blowers
Equalisation Tank Level	Continuous level	Level Probes
Dissolved Oxygen	Continuous DO	Air Blowers
Mixed Liquor suspended solids	Daily MLSS (Laboratory Test)	None
Sludge Volume Index	Daily SVI (Laboratory Test)	None
F/M Ratio	Daily F/M (Laboratory Test)	None
Final effluent Flow	Continuous flow	Actuated valve recycling pumps
Final effluent pH	Continuous flow	Actuated valve recycling pumps
Final effluent TOC	Continuous flow	Actuated valve recycling pumps
Effluent Transfer	Daily	Lift Pumps
Suspended Solids (primary)	Daily	Agitator Solid removal pumps Skimmed solids pump
Effluent Balancing	Daily	Agitator Feed-forward pump

Note 1: The licensee shall maintain appropriate access to standby and/or spares to ensure the operation of the abatement system.

Note 2: Key equipment may be modified in accordance with Condition 6 of the licence.

C.3.2 Monitoring of Emissions to Sewer

Emission Point Reference No.: SE1/SEMP1

Parameter	Monitoring Frequency	Analysis Method/Technique [Note 1]
Flow	Continuous	On-line flow meter with recorder
Temperature	Continuous	On-line temperature probe with recorder
pH	Continuous	On-Line pH electrode/meter and recorder
Biochemical Oxygen Demand	Monthly	Composite
Chemical Oxygen Demand	Weekly	Composite
Suspended Solids	Weekly [Note 1]	Composite
Total Nitrogen	Monthly	Composite
Total Phosphorus	Quarterly	Composite
Oils, fats & greases	Monthly	Composite
Sulphate	Quarterly	Composite
Toxicity [Note 2]	Annually	Composite

Note 1: All composite samples shall be collected on an appropriate flow proportional composite sampling basis.
Note 2: The number of toxic units (Tu) = 100/x hour EC/LC_{50} in percentage vol/vol so that higher Tu values reflect greater levels of toxicity. For test regimes where species death is not easily detected, immobilisation is considered equivalent to death.

C.4 Waste Monitoring

Waste Class	Frequency	Parameter	Method
Pharmaceutical Wastes [Note 1]	Per consignment	To be agreed with Agency.	To be agreed with Agency.

Note 1: Analytical requirements to be determined on a case by case basis.

C.5 Noise Monitoring

Location[Note 1]	Measurement	Frequency
N1	L(A)eq (15 minutes), $L(A)_{10}$, $L(A)_{90}$	Annually
N2	L(A)eq (15 minutes), $L(A)_{10}$, $L(A)_{90}$	Annually
N3	L(A)eq (15 minutes), $L(A)_{10}$, $L(A)_{90}$	Annually
N4	L(A)eq (15 minutes), $L(A)_{10}$, $L(A)_{90}$	Annually
N5	L(A)eq (15 minutes), $L(A)_{10}$, $L(A)_{90}$	Annually
NS1	L(A)eq (15 minutes), $L(A)_{10}$, $L(A)_{90}$	Annually
NS2	L(A)eq (15 minutes), $L(A)_{10}$, $L(A)_{90}$	Annually

Note 1: Or at other locations as specified by the Agency.

C.6 Ambient Monitoring

Groundwater Monitoring

Location: AGW01, AGW02, AGW03 and AGW04

Parameter	Monitoring Frequency	Analysis Method/Technique
pH	Biannually	pH electrode/meter
Conductivity	Biannually	Standard Method
COD	Biannually	Standard Method
TOC	Biannually	Standard Method
Temperature	Biannually	Standard Method
Major cations & anions [Note 1]	Biannually	Standard Method
Nitrite	Biannually	Standard Method
Nitrate	Biannually	Standard Method
Total Ammonia	Biannually	Standard Method
Total Nitrogen	Biannually	Standard Method
Conductivity	Biannually	Standard Method
Chloride	Biannually	Standard Method
Organohalogens [Note 2]	Biannually	GC-MS

Note 1: An ionic balance shall be presented, with explanation of any significant error.
Note 2: Screening for priority pollutant list substances (such as US EPA volatile and/or semi-volatile compounds).

SCHEDULE D: Annual Environmental Report

Annual Environmental Report Content[Note 1]
Emissions from the installation.
Waste management record.
Resource consumption summary.
Complaints summary.
Schedule of Environmental Objectives and Targets.
Environmental management programme – report for previous year.
Environmental management programme – proposal for current year.
Pollution emission register – report for previous year.
Pollution emission register – proposal for current year.
Noise monitoring report summary.
Ambient monitoring summary.
Tank and pipeline testing and inspection report.
Reported incidents summary.
Energy efficiency audit report summary.
Report on the assessment of the efficiency of use of raw materials in processes and the reduction in waste generated.
Report on progress made and proposals being developed to minimise water demand and the volume of trade effluent discharge.
Development / Infrastructural works summary (completed in previous year or prepared for current year).
Reports on financial provision made under this licence, management and staffing structure of the installation, and a programme for public information.
Review of residuals management plan.
Statement of measures in relation to prevention of environmental damage and remedial actions (Environmental Liabilities).
Environmental Liabilities Risk Assessment Review (every three years or more frequently as dictated by relevant on site change including financial provisions.
Details of Test Programme for Abatement measures.
Any other items specified by the Agency.

Note 1: Content may be revised subject to the agreement of the Agency.

Signed on behalf of the said Agency _____
on the 9th day of November, 2006 Marie O'Connor, **Authorised Person**