

Section J Attachment

Attachment J: Accident Prevention & Emergency Response
Plan

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Attachment J: Accident Prevention and Emergency Response

The proposed facility is not currently in existence, so a site Accident Prevention and Emergency Response Procedure is not currently in place for the site.

The following measures will be implemented during the operational phase of the proposed facility. Further mitigation measures to deal with known and unknown potential accidents and incidents arising during closure have been identified during the preparation of the site Environmental Liability Risk Assessment; see Section K of this licence application.

J.1 Accidental Emissions Control

Regeneration regards the prevention of accidental emissions from its sites to be an integral part of the efficient production of its high quality products. The prevention of accidental emissions and spills will be facilitated by the correct design of equipment and operations at the site in the following areas.

J.2 Bunding and Collection

Bunding of drums will be provided at the facility where appropriate. Any potential leaks in the building of raw materials or products will be held within portable bunds (if required) or will drain to the process effluent drainage system, thus ensuring that nothing will be released to surface water or groundwater.

J.3 Storage and Transport

Liquids used on site will be stored in accordance with suppliers' requirements and storage will be inspected on an on-going basis for leaks, wear, and deterioration. Process liquids will generally be transported within the facility in sealed containers or via process piping ensuring little potential for accidental spillage. Waste waters will be transported in piped drainage systems.

Individual drums will be transported manually and by forklift within the plant. The quantity of drummed chemicals stored on-site at any one time will be closely monitored and controlled.

J.4 Training

The documentation of production techniques and specifications will ensure a high level of awareness in the handling of equipment and materials. Safety and hazard training will be provided for all new employees on site.

J.5 Procedural Control

Procedures will be created to cover both the avoidance of control loss and the actions to restore control, and to minimise the potential for environmental impact at the installation.

Anticipated standard procedures to be created include:

- Environmental Aspects Identification
- External Communications
- Outside Contractors Initiation
- Emergency Response Procedure
- Malfunction of Equipment
- Tanks, Pipes & Flanges Inspection
- Bund Emptying Work Instruction
- Waste Disposal Work Instruction
- Bulk Chemicals Intake

J.6 Emergency Response

In the event of spillage or accidental emission, a Supervisor/Manager will instigate corrective action as follows:

- Identify the source of emission/spillage
- Shut off emission/spillage
- Detail a team responsible for containment/clean up
- Notify the relevant Authorities
- Investigate the cause of the incident and take corrective action.

The maintenance operatives on site will have access to telephone numbers of plant Supervisors/Managers with instruction to notify in the event of an emergency situation.

The site will have an Emergency Response Policy based on a comprehensive risk assessment of all aspects of the installation as part of a defined Hazard Identification and Hazard Evaluation process.

Arising from this process, facility management will implement a range of measures to prevent and protect against accidental emissions and discharges. These are anticipated to include:

- Permit to work procedures and controls
- Extensive fire detection systems
- Local suppression and quench systems
- Provision of firebreaks
- Use of bunded areas for storage and containment
- Spill response and containment measures
- Extensive emergency equipment resources
- Thorough accident/incident investigation procedures
- Comprehensive guidelines and procedures for dealing with accidental emissions
- Training, e.g. spill response

The Emergency Response Policy will detail hazard evaluation, emergency response procedures and organizational control during normal business hours and outside of these hours.

J.7 Bunding and Containment

Any onsite bunds will be tested and certified and a programme put in place to retest the integrity and water tightness of all bunds on a regular cycle (at least every three years).

J.8 Site Drainage

All underground pipes and drains will be tested and certified and a programme put in place to retest the integrity and water tightness of underground pipes and drains on a regular cycle (at least every three years).

Section K Attachment

Attachment K: Environmental Liability Risk Assessment
(PM Document No. IE0311171-22-RP-0006)

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REGENERON

Environmental Liability Risk Assessment

Celebrating 40 Years in Business

Regeneron Ireland
Biopharmaceutical Manufacturing Facility
IE0311171-22-RP-0006, Issue: A

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Document Sign Off

Environmental Liability Risk Assessment

Regeneron Ireland
 Biopharmaceutical Manufacturing Facility
 IE0311171-22-RP-0006, Issue A

File No: IE0311171.22.040

| CURRENT ISSUE | | | | | |
|---------------|----------------------------------|---------------------------------------|--------------|--------------|---------------------------------|
| Issue No: A | Date: 10/04/2014 | Reason for issue: For IEL Application | | | |
| Sign Off | Originator | Checker | Reviewer | Approver | Customer Approval (if required) |
| Print Name | Brian Tiernan | Kayleen Curtin | Tony McGrath | Tony McGrath | |
| Signature | Authorised Electronically | | | | |
| Date | 10/04/2014 | 10/04/2014 | | 10/04/2014 | |

| PREVIOUS ISSUES | | | | | | | |
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| Issue No | Date | Originator | Checker | Reviewer | Approver | Customer | Reason for issue |
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1 Executive Summary

Activity Details

Name: Regeneron Ireland Ltd.
Address: Ballycummin,
Raheen Business Park,
Raheen,
Co. Limerick

Activities licensed:

The relevant activity in the First Schedule of the EPA Act 1992, as amended, to which the installation relates:

5.16 *The production of pharmaceutical products including intermediates*

The relevant category of industrial activity referred to in Annex I of the Industrial Emissions Directive (2010/75/EU) to be carried out at the installation is:

4.5 *Production of pharmaceutical products including intermediates*

Report Preparation:

The report was prepared on behalf of the operator by PM Group.

Address: PM Group
LoughMahon Technology Park
Blackrock
Cork
Ireland

Comparison with Previous ELRAs:

N/A

Overview of the Plan:

The operator has prepared an ELRA in accordance with Section K of the Industrial Emissions Licence (IEL) application form. The methodology for the development of the report follows the EPA Guidance on assessing and costing environmental liabilities, March 2014.

Financial Provision:

Taking the 'worst case scenario' financial model and probability for each risk, costs are ascribed for remediation. The total cost determined for unplanned environmental liabilities associated with the proposed facility is **€1,000,000**.

Once operational Regeneron Ireland will have a comprehensive insurance programme in place for all significant insurable risks and major catastrophes including potential environmental liabilities. The insurance policies for the operating facility will cover any single environmental incident or accident and will cover environmental incidents or accidents in the aggregate for the period of insurance.

The insurance cover will be sufficient to return the environment to its original condition and cover all associated costs of liabilities arising from incidents identified in the ELRA. A Financial Security Agreement will be put in place between Regeneron and the EPA following a grant of the IEL.

2 Introduction

2.1 Facility and Licence Details

Regeneron Ireland propose to convert the former Dell EMF3 computer assembly plant at Ballycummin, Raheen Business Park, for use as a state-of-the-art biopharmaceutical manufacturing facility suitable for medical products worldwide.

The relevant activity in the First Schedule of the EPA Act 1992, as amended, to which the installation relates:

5.16 *The production of pharmaceutical products including intermediates*

The relevant category of industrial activity referred to in Annex I of the Industrial Emissions Directive (2010/75/EU) to be carried out at the installation is:

4.5 *Production of pharmaceutical products including intermediates*

PM Group has prepared this Environmental Liabilities Risk Assessment (ELRA) in accordance with the EPA Document *Guidance on assessing and costing environmental liabilities, March 2014*.

2.2 Site Description

The proposed development is located on a site of approx. 18 hectares located in the Raheen Business Park, Limerick. Raheen Business Park is located within the town land of Ballycummin to the south west of Limerick City. The Business Park is bound to the north and west by the R526 and to the south and east by the M20 Limerick to Cork motorway. Figure 2.1 shows the location of the proposed Regeneron facility.

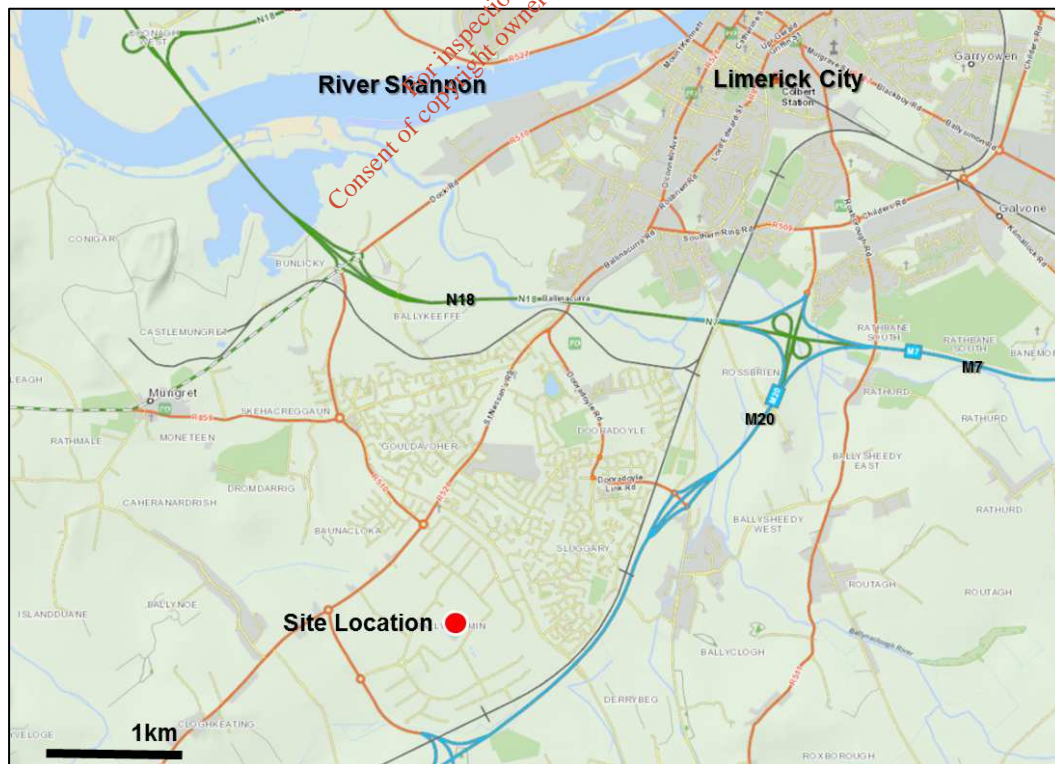


Figure 2.1 Site Location

The proposed development site is the former Dell EMF3 facility. It currently consists of a large assembly area, a warehouse and manufacturing support area, a utility building, a two storey office building, service yards, car parking spaces for c.1,100 vehicles and an access road linking the site to the R526. The area currently comprises hard standing underlain by predominantly made ground

material. The surrounding lands are flat and low lying with a gradual drop in ground level to the east and south and are currently used for agricultural purposes. A protected structure, Roche Castle, is located adjacent to the proposed development site on the North Western boundary. The existing Dell EMF1 facility and Adhesives Research Ltd. are located adjacent to the south and south eastern boundary of the proposed development.

The proposed site layout is shown in Figure 2.2. It includes the installation of new biopharmaceutical manufacturing processes to the existing Production Area, development of a new Quality Control (QC) Laboratory Building and the installation of the following external utilities in existing yard areas:

- Emergency generators (5No.)
- Generator electrical room
- Bunded cooling towers (5No.)
- Water chillers (3No.)
- Process water storage tanks (2No.)
- Fire water storage tank (1No.)
- Pumphouse
- Bunded chemical and diesel storage tanks
- Gas storage area
- 38kV electrical substation with dedicated ESB access
- Bunded wastewater management facility
- Natural gas pressure reducing station



Figure 2.2 Proposed Site Layout

2.3 Environmental Liability Risk Assessment

The ELRA considers the risk of unplanned events occurring during the operation of a facility that could result in environmental liabilities materialising. The two key objectives of the ELRA process are:

- to identify and quantify environmental liabilities focusing on unplanned, but possible and plausible events occurring during the operational phase; and
- to provide a mechanism to encourage continuous environmental improvement through the management of potential environmental risks.

In accordance with the guidance document specified by the EPA, the procedures to achieve these objectives are as follows:

- scoping to determine the type of environmental liabilities to be covered;
- risk assessment including risk identification, risk analysis and risk evaluation.
- risk treatment – ensuring appropriate risk mitigation is incorporated into the facility design, construction and operation to manage potential environmental risks.
- identification, quantification and costing of the plausible worst case scenario for financial provision.

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3 Risk Identification

This section gives an overview of the proposed facility activities, performance and environmental sensitivity to provide more information for the risk assessment, which is included in Table 4.3.

The Environmental Impact Statement (EIS) and IEL documentation for the proposed facility were used as a starting point to identify potential environmental hazards/risks associated with the facility.

Each risk was considered for relevance, potential hazards, environmental effects, potential severity and probability of occurrence. A number of additional risks were identified and considered. For each potential hazard to be considered appropriate for inclusion in the risk assessment table, it must pose an environmental risk leading to a potential or anticipated liability including risks to:

- Surface water
- Groundwater
- Land / Ground
- Atmosphere
- Human health
- Ecology

3.1 Site Operation

3.1.1 Facility Activities & Materials

The manufacturing processes to be employed by Regeneron at the Raheen facility will follow what are now considered as industry standard techniques for the production of “medicines for patients” using biotechnology derived processes. Today, this approach is favoured over traditional organic chemistry routes used in the past because it is capable of yielding more complex molecules for medicinal applications, is more efficient in terms of productivity, poses lower safety risks to the surrounding community, and has less environmental impact in terms of hazardous chemicals used or waste generated for disposal.

This facility is intended to ultimately accommodate four production trains within the existing production building. The installation is being scheduled in two phases, each comprising two trains and associated support functions.

The primary process steps in the Regeneron manufacturing scheme are;

- Cell Culture
- Harvest
- Purification
- Product Formulation

3.1.2 Site Buildings and External Plant

The scope of the project can be broadly described under 4 headings, each of which is described as follows.

1. Installation of new biopharmaceutical manufacturing processes to the existing production area, involving;
 - Central production cleanrooms
 - Warehousing
 - Clean water and steam utilities, including boilers
 - Heating ventilation and air conditioning (HVAC) systems

- Electrical switch rooms

The project will require the following modifications to the existing production area to accommodate the above elements;

- Extension of the floor area by 3,909m² to accommodate required internal warehousing and electrical rooms
- Increase in height of the roof over part of the existing production area from 10.16m to 16.76m through the addition of 1st floor plant room for HVAC equipment
- Installation of 5No. new boiler flues (stacks)
- Modification to the elevations of the existing production area including removal and sealing of all redundant dock leveller doors along the northern and southern elevations and creation of new access points.

2. Development of a new Quality Control (QC) Laboratory Building;

- Development of a 4,440m² building over 3 floors
- 2-storey link corridor connecting to existing Administration Headblock
- Landscaped courtyard

3. Installation of new external utilities in existing yard areas, including;

- Emergency generators (5No.)
- Generator electrical room
- Bunded cooling towers (5No.)
- Water chillers (3No.)
- Process water storage tanks (2No.)
- Fire water storage tank (1No.)
- Pumphouse
- Bunded chemical and diesel storage tanks
- Gas storage area
- 38kV electrical substation with dedicated ESB access
- Bunded wastewater management facility
- Natural gas pressure reducing station

4. Miscellaneous site works, including;

- Modifications and additions to existing underground site services covering; sewers, water mains, fire mains, electrical ducting, communications ducting and natural gas
- New internal landscaping works and improvements to boundary landscaping and fencing
- New bicycle shelter
- New security hut at personnel entrance
- Upgrade of existing security hut at deliveries entrance
- Diversion and undergrounding of overhead 38kV crossing south west corner of the site

3.1.3 Overview of Wastes Generated

Waste will be generated in solid, liquid and gaseous forms from the facility; these will include, but are not limited to the following list;

Solid Wastes

- Packaging components used for the supply of raw materials and consumables (such as plastic bags and cartridge filters). Damaged or unused bottles, caps etc. will also be disposed of.
- Disposable waste materials such as production bags, tubings and spent filters that potentially have been in contact with the manufacturing process will be treated on-site in autoclaves to render them inactive and classified as non-hazardous waste.
- Some of the empty material drums and containers used to store process raw materials may be classified as hazardous waste. The majority of drums and containers of this nature will be returned to the original suppliers for cleaning, recovery and reuse.
- From the laboratory there will be consumables, such as disposable scoops, broken glass etc. Laboratory waste chemicals will be segregated where possible and stored in a designated chemical store in suitable labelled containers.

Liquid Wastes/Effluent

- Sources include CIP rinses between batches; flushes of purified water user points; purified water dumped prior to sanitisation; reject streams and backwashes from purified water generation.
- From the laboratories there will be general laboratory chemical waste for specialist disposal and general laboratory waste from sinks.

Gaseous Wastes/Emissions

- From boiler flues, process vents and other utility vents throughout the facility.

3.2 Operator Performance

Regeneron Ireland currently has no operator performance history record in Ireland however has an excellent environmental performance in the US and is committed to continuous environmental improvement and protection. An Environmental Management System (EMS) / Environmental Management Programme (EMP) will be developed and implemented as part of the IEL.

3.3 Environmental Sensitivity

The site is located within the Shannon International River Basin District. The River Shannon is located approximately 3.5km northwest of the facility with the Lower River Shannon Tributary approximately 2.5 km to the northeast of the facility. The closest surface water feature to the facility is Barnakyle River, which skirts the southern end of Raheen Business Park. This river currently shows 'Poor' status, under the Water Framework Directive monitoring programme. The surface water discharge from the Raheen Business Park discharges to the Loughmore Common canal (NHA Site Code 000438), which enters the Barnakyle Stream, which in turn flows into the Maigue River and subsequently the River Shannon (both rivers being in the Lower River Shannon SAC (Site Code 002165) and River Shannon and River Fergus SPA (Site Code 004077)).

The closest nationally important site is Loughmore Common Turlough (Site Code 000438), which is located c.3km west of the facility. This turlough, also known as a seasonal lake consists of a shallow basin, elongated in an east-west direction. Shallow flooding patterns are a feature of this ecological site which attracts plant and bird species which depend on this pattern.

Due to the current design of the surface water drainage system within Raheen Business Park and the accident and emergency response procedures that will be put in place on site when the site is operational, it is highly unlikely that any significant emissions could discharge to the surface water drainage system and therefore, no significant potential impacts are anticipated in relation to the Lower River Shannon SAC and the River Shannon and River Fergus SPA. In addition, the SACs

are considered to be at a sufficient distance from the proposed development with no connecting pathways (e.g., rivers or streams) for indirect effects to occur. It is therefore not anticipated that there will be any likely significant impacts on these sites.

There is no record of flooding within the facility or within the Raheen Business Park according to Office of Public Works flood mapping database.

Wastewater from the proposed development will discharge to the Shannon Development/Irish Water sewer. The sewer is part of the Limerick City and Environs agglomeration and has a waste water treatment plant at Bunlicky with a design capacity of 130,000 population equivalent.

The Geological Survey of Ireland (GSI) provides information on its public online mapping service at www.gsi.ie on bedrock aquifers and vulnerability. The underlying subsoil is glacial till derived chiefly of limestone of moderate permeability overlain by poorly drained gley soil. The bedrock geology underlying the site is Visean Limestones. Volcaniclastic rocks and basalt are also located in the immediate vicinity of the site. The underlying aquifer is classified as a Locally Important Aquifer - Bedrock which is Moderately Productive only in Local Zones. The GSI vulnerability classification for the site is 'High'. The aquifer vulnerability determines the limitations of the drainage, i.e. whether infiltration drainage methods will be appropriate.

According to the EPA the current air quality in Limerick City is considered 'Good'. At present there are a number of EPA licenced facilities within Raheen Business Park that are sources of air emissions e.g. Adhesives Research, Analog Devices and Stryker Howmedica. Each facility has the necessary abatement systems in place in accordance with licence requirements. Air emissions from the proposed development will be in accordance with EPA licence requirements.

Noise will arise from two sources – traffic and plant related services (fans, heating, cooling and ventilation). The proposed development site is located in an industrial development site, which already experiences a degree of industrial and traffic noise. Two noise sensitive locations were identified; NSL1 - individual residential dwelling on the northern side of the R526 road to the north-west of the site, located 610 metres from the site and NSL2 - residential area on the Ballycummin Road, located ca. 400 metres to the north/north-east of the site.

3.4 Plausible Risks

Based on a review of the site activities, proposed site buildings and plant and the environmental sensitivity of the site the plausible risks for the activity have been identified in Table 3.1.

Table 3.1 Plausible Risks identified for the Activity

| Risk ID | Process | Potential Risk |
|---------|--|---|
| 1 | Loading and unloading of materials on site | Leak or spill during loading/unloading of drums, IBCs or other containers containing hazardous and/or polluting materials. Potential to discharge to surface water and/or ground. |
| 2 | Storage and handling of hazardous and/potentially polluting materials on site (e.g. raw materials, diesel, engineering materials - hydraulic oil, lubricants etc.) | Leak or spill to surface water, ground or groundwater from storage and handling of hazardous and polluting materials on site |
| 3 | Bulk liquid storage tanks | Failure of tank resulting in spill of contents to surface water, ground water and/or ground. |
| 4 | Bunded areas | Loss of bund integrity. Direct discharge of contents to ground//surface water |
| 5 | Use of vehicles onsite | Leaks of fuel, oil etc. from vehicles to surface water, ground or groundwater |
| 6 | Production Process | Spillages during the production process. Contained within production area. |

| Risk ID | Process | Potential Risk |
|---------|--|---|
| 7 | Movement of process (trade) effluent onsite to wastewater treatment area | Loss of pipeline integrity. Leaks from drains and discharges/spills of process effluent to surface water, ground or groundwater |
| 8 | Movement of foul and sanitary effluent on-site to waste water treatment area | Loss of integrity. Leaks from drains and discharges/spills of foul and sanitary effluent to surface water, ground or groundwater |
| 9 | Discharge of rainfall/storm water runoff from roofs and paved-areas on site | Discharge of excessive volumes of storm water containing excessive suspended solids and/or hazardous materials |
| 10 | Operation of Boilers and associated air abatement systems | Failure of abatement, release of unabated emissions to atmosphere in excess of Emission Limit Values (ELVs). |
| 11 | General operational activities including plant operation, use of process and mechanical equipment and traffic movement on site | Excessive noise generated on site and at noise sensitive locations off site |
| 12 | Gas Tank Yard | Leak or pipe rupture leading to fire or explosion |
| 13 | Fire at the facility | Emissions to air, firewater discharge to ground, surface water and/or groundwater |
| 14 | Unauthorised disposal of hazardous/non-hazardous waste | Improper classification of waste for purpose of disposal/recovery. Discharges/spills of waste materials to surface water, ground or groundwater. Incorrect handling procedures by contractor. |
| 15 | Failure of wastewater treatment area | Failure of treatment resulting in untreated effluent discharge to sewer in excess of Emission Limit Values (ELVs). Impact on Bunlicky WWTP. |
| 16 | Monitoring and control systems | Failure of on-site monitoring control systems. Release of hazardous emissions to air, surface water and/or wastewater. |
| 17 | Site Closure | Existing environmental liabilities remaining on site. |

4 Risk Analysis

A risk assessment was carried out to identify potential environmental hazards and quantify the associated risks inherent in the construction and operation of the facility. The risk classification Tables 4.1 and 4.2 were used to evaluate and rank risks by assigning a likelihood and occurrence to each potential hazard identified. The results are presented in Table 4.3.

Table 4.1 Risk Classification Table – Likelihood

| Rating | Likelihood | |
|--------|------------|--------------------------------------|
| | Category | Description |
| 1 | Very Low | Very low chance of hazard occurring |
| 2 | Low | Low chance of hazard occurring |
| 3 | Medium | Medium chance of hazard occurring |
| 4 | High | High chance of hazard occurring |
| 5 | Very High | Very High chance of hazard occurring |

Table 4.2 Risk Classification Table – Consequence

| Rating | Consequence | |
|--------|-------------|---|
| | Category | Description |
| 1 | Trivial | No damage or negligible change to the environment |
| 2 | Minor | Minor impact/localised or nuisance |
| 3 | Moderate | Moderate impact to environment |
| 4 | Major | Severe impact to environment |
| 5 | Massive | Massive damage to a large area, irreversible in medium term |

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Table 4.3 Risk Analysis

| Risk ID | Process | Potential Risks | Environmental Effects | Consequence Rating | Basis of Consequence | Likelihood Rating | Basis of Likelihood | Risk Score (Consequence X Likelihood) |
|---------|--|---|--|--------------------|--|-------------------|--|---------------------------------------|
| 1 | Loading and unloading of materials on site | Leak or spill during loading/unloading of drums, IBCs or other containers containing hazardous and/or polluting materials. Potential to discharge to surface water and/or ground. | Contamination/pollution of surface water, ground and or groundwater. | 2 | Losses would be of minor volume due to the size of material containers, mainly 200 litre drums and similar volume IBCs. No direct pathway to the soil or groundwater. The loading/unloading area will be concrete with properly sealed joints and within a remote bunded area. Area has spill containment drains to prevent spills going into storm water. The transfer pumps associated with loading/unloading of tankers will not operate unless spill containment system is operational. An oil interceptor will be put in place to prevent oil/petrol entering the surface water sewer. If compromised, the subsoil would slightly impede the migration of contaminants. | 3 | Unlikely more than one container would leak or spill at any one time. Small chemical inventory on site. Employees will be trained to deal with spills. | 6 |

| Risk ID | Process | Potential Risks | Environmental Effects | Consequence Rating | Basis of Consequence | Likelihood Rating | Basis of Likelihood | Risk Score (Consequence X Likelihood) |
|---------|--|--|--|--------------------|--|-------------------|--|---------------------------------------|
| 2 | Storage and handling of hazardous and/potentially polluting materials on site (e.g. raw materials, diesel, engineering materials - hydraulic oil, lubricants etc.) | Leak or spill to surface water, ground or groundwater from storage and handling of hazardous and polluting materials on site | Contamination / pollution of surface water, ground or groundwater. | 3 | Some cleaning agents on site but in little quantities. Containers/drums/IBCs are located within bunds or remote bunds on hard standing areas. Underground drains contain secondary containment. Bund integrity inspections will be carried out as part of IEL requirements | 2 | Unlikely more than one container would leak or spill at any one time. Small chemical inventory on site. Employees will be trained to deal with spills. | 6 |
| 3 | Bulk liquid storage tanks | Failure of tank resulting in spill of contents to surface water, ground water and/or ground. | Contamination / pollution of surface water, ground or groundwater. | 3 | Large volume bulk storage tanks on site – ethanol, sodium hydroxide, phosphoric acid. Certain material has the capacity to cause environmental damage if failure was to occur. This would result in surface water, ground and/or groundwater contamination. Any impact will be localised to the area surrounding the tank. | 1 | Tanks are compatible with the material they store. All bulk storage tanks are contained within bunded areas to 110% of their capacity. The bulk storage tanks will be sealed to prevent ingress of rainwater. Remote bunding will be provided by a containment system. A bund inspection programme will be detailed as | 3 |

| Risk ID | Process | Potential Risks | Environmental Effects | Consequence Rating | Basis of Consequence | Likelihood Rating | Basis of Likelihood | Risk Score (Consequence X Likelihood) |
|---------|------------------------|---|--|--------------------|---|-------------------|---|---------------------------------------|
| | | | | | | | part of the IEL. A procedure will be put in place to check the capacity in the tanks before filling. | |
| 4 | Bunded areas | Loss of bund integrity. Direct discharge of contents to ground//surface water | Contamination / pollution of surface water, ground or groundwater. | 3 | Any spills are likely to be localised and less than the contents of the largest tank on site. | 1 | Spill response and emergency response procedure will be in place. Bunds will be inspected regularly as part of commissioning and operational. All bunds will be located on paved areas. A 3 year bund inspection programme will be detailed as part of the IEL. | 3 |
| 5 | Use of vehicles onsite | Leaks of fuel, oil etc. from vehicles to surface water, ground or groundwater | Contamination / pollution of surface water, ground or groundwater. | 2 | Minor quantity leak from a single vehicle - delivery vehicles (HGVs) and employee/visitors cars in the car parking areas. | 2 | Vehicle speed restrictions in place. Employees will be trained to deal with spills. | 4 |
| 6 | Production Process | Spillages during the production process. | Contamination / pollution of surface water, | 2 | Any spills are likely to be localised, within the production | 2 | Emergency response team will be available | 4 |

| Risk ID | Process | Potential Risks | Environmental Effects | Consequence Rating | Basis of Consequence | Likelihood Rating | Basis of Likelihood | Risk Score (Consequence X Likelihood) |
|---------|--|--|--|--------------------|---|-------------------|--|---------------------------------------|
| | | Contained within production area. | ground or groundwater. | | area and less than the contents of the largest container. | | on site with the capability to control and contain spillages of hazardous materials. | |
| 7 | Movement of process (trade) effluent onsite to wastewater treatment area | Loss of pipeline integrity. Leaks from drains and discharges/spills of process effluent to surface water, ground or groundwater | Contamination / pollution of surface water, ground or groundwater. | 2 | Pipes are double walled with leak detection. If a leak occurs in the pipes they will be contained via the double skin and drain into one of the sumps present on the system. A leak detection alarm will also activate if liquid is detected in any of these sumps. | 2 | Process effluent would drain to process drainage system and onto Bunlicky WWTP after pre-treatment. A CCTV survey will be completed every 3 years as part of the IEL. Groundwater monitoring will be completed on the boreholes on site. | 4 |
| 8 | Movement of foul and sanitary effluent on-site to waste water treatment area | Loss of integrity. Leaks from drains and discharges/spills of foul and sanitary effluent to surface water, ground or groundwater | Contamination / pollution of surface water, ground or groundwater. | 2 | Pipes are existing and operational since 1999. Single lined. CCTV survey carried out to identify potential weaknesses. | 3 | Sanitary wastewater collected and pumped directly off-site to Bunlicky WWTP. Foul drainage system will be inspected regularly. A CCTV survey will be completed every | 6 |

| Risk ID | Process | Potential Risks | Environmental Effects | Consequence Rating | Basis of Consequence | Likelihood Rating | Basis of Likelihood | Risk Score (Consequence X Likelihood) |
|---------|---|--|--|--------------------|---|-------------------|--|---------------------------------------|
| | | | | | | | 3 years as part of the IEL. Groundwater monitoring will be completed on the boreholes on site. | |
| 9 | Discharge of rainfall/storm water runoff from roofs and paved-areas on site | Discharge of excessive volumes of storm water containing excessive suspended solids and/or hazardous materials | Contamination / pollution of surface water, ground or groundwater. | 2 | Could result in moderate damage to local watercourses area. Low volume. | 2 | Large dilution washed down drain from rainwater and dilution of any spills. Severity of contamination low due to interceptors and silt traps on emission points, which are cleaned regularly by suppliers/manufacturers. | 4 |
| 10 | Operation of Boilers and associated air abatement systems | Failure of abatement, release of unabated emissions to atmosphere in excess of Emission Limit Values (ELVs). | Air pollution causing adverse impacts on human health and the environment. | 3 | Negligible impact as combustion by-products from modern efficient plant running on relatively clean fuel (natural gas) during normal operation. Boilers fitted with BAT low NOx burners. All bioreactors fitted with filters for removal of particles | 1 | It is unlikely that a large quantity of emissions would be emitted due to the proposed monitoring and control techniques e.g. HEPA filters and low NOx boilers. | 3 |

| Risk ID | Process | Potential Risks | Environmental Effects | Consequence Rating | Basis of Consequence | Likelihood Rating | Basis of Likelihood | Risk Score (Consequence X Likelihood) |
|---------|--|---|--|--------------------|---|-------------------|--|---------------------------------------|
| | | | | | and micro-organisms as appropriate. Fugitive emissions from the emergency generators, lab building and wastewater treatment area are considered negligible for the purpose of this risk assessment. | | | |
| 11 | General operational activities including plant operation, use of process and mechanical equipment and traffic movement on site | Excessive noise generated on site and at noise sensitive locations off site | Noise nuisance to local residents / fauna in vicinity. | 2 | Localised short term noise impact. | 2 | Noise modelling results show that the operation of the plant will not significantly impact the existing noise levels at the noise sensitive locations. | 4 |
| 12 | Gas Tank Yard | Leak or pipe rupture leading to fire or explosion | Leak of flammable gas to environment / combustion by-products released to environment as a result of fire. | 4 | Gas explosion and associated fire/effects could cause significant damage to local environment. | 1 | Gas supply installed using BAT by Bord Gais. Equipment will be regularly inspected. | 4 |

| Risk ID | Process | Potential Risks | Environmental Effects | Consequence Rating | Basis of Consequence | Likelihood Rating | Basis of Likelihood | Risk Score (Consequence X Likelihood) |
|---------|---|---|--|--------------------|---|-------------------|--|---------------------------------------|
| 13 | Fire at the facility | Emissions to air, firewater discharge to ground, surface water and/or groundwater | Firewater discharge to sewer, surface water or groundwater, emissions to air. | 4 | In the event of a fire on site, the main products of combustion will be as for any typical light industry fire. The risk of environmental impacts arising from firewater is low in all areas due to the small chemical inventory on site. All processes, equipment and techniques used on site are in line with industry standard manufacturing techniques. | 1 | Extensive fire protection measures will be present within the facility including high level of detection and sprinkler system. Emergency Response Team proposed. In the event of failure of abatement systems, contaminated firewater will enter surface water, ground and/or groundwater. | 4 |
| 14 | Unauthorised disposal of hazardous/n on-hazardous waste | Improper classification of waste for purpose of disposal/recovery. Discharges/spills of waste materials to surface water, ground or groundwater. Incorrect handling procedures by | Human Beings. Contamination / pollution of surface water, ground or groundwater. | 3 | Litter nuisance, odour, dust, contamination / pollution of surface water, ground and groundwater; off-site contamination by incorrect disposal of hazardous waste. SOPs prepared and used on-site to ensure correct waste classification, hazardous waste load preparation and | 2 | Waste Management recording procedures will be in place to ensure correct disposal of all wastes off site. A total waste management solutions contract to be put in place and contractor to liaise with other | 6 |

| Risk ID | Process | Potential Risks | Environmental Effects | Consequence Rating | Basis of Consequence | Likelihood Rating | Basis of Likelihood | Risk Score (Consequence X Likelihood) |
|---------|--------------------------------------|--|---|--------------------|--|-------------------|---|---------------------------------------|
| | | contractor. | | | maintenance of waste records. Only licenced waste contractors are used on site. All solid waste from bio-containment areas go through a decontamination autoclave prior to disposal. Due to the procedures that will be used on site it is very unlikely that a large quantity of waste will be incorrectly classified/disposed. | | waste sub-contractors. If a large quantity of waste was incorrectly categorised it would lead to financial costs and non-compliances with licence. | |
| 15 | Failure of wastewater treatment area | Failure of treatment resulting in untreated effluent discharge to sewer in excess of ELVs. | Contamination / pollution of surface water, ground or groundwater; Impact on Bunlicky WWTP. | 1 | Costs associated with remediation if control systems failed and major discharge occurs. | 3 | The tanks within the wastewater treatment area are compatible with the contents they store and have sufficient buffering capacity to deal with significant fluctuations in influent feed. The system will be alarmed and will have a standby tank available. Inspection and | 3 |

| Risk ID | Process | Potential Risks | Environmental Effects | Consequence Rating | Basis of Consequence | Likelihood Rating | Basis of Likelihood | Risk Score (Consequence X Likelihood) |
|---------|--------------------------------|--|---|--------------------|---|-------------------|--|---------------------------------------|
| | | | | | | | maintenance will be carried out as part of the bund inspection programme. pH and other parameters will be monitored before discharge to sewer. | |
| 16 | Monitoring and control systems | Failure of on-site monitoring control systems. Release of hazardous emissions to air, surface water and/or wastewater. | Release of toxic and/or hazardous material to atmosphere, surface water, ground and/or groundwater. | 2 | Minor impact/localised and nuisance. | 2 | Proposed plant control systems will be in place in accordance with IEL. The site will operate an ongoing preventative maintenance programme. | 4 |
| 17 | Site Closure | Existing environmental liabilities remaining on site. | Legacy risks to air, surface water, ground and groundwater. | 2 | Site can accommodate changes to process manufacturing techniques. | 1 | Costs associated with site closure. A detailed Closure Plan will be developed to manage the closure and any potential remediation. | 2 |

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5 Risk Evaluation

The risks presented in the risk analysis are ranked in Table 5.1 to assist in identifying the risks for prioritisation in the risk treatment process.

Table 5.1 Risk Evaluation Table

| Risk ID | Process | Potential Risks | Consequence Rating | Likelihood Rating | Risk Score |
|---------|--|---|--------------------|-------------------|------------|
| 1 | Loading and unloading of materials on site | Leak or spill during loading/unloading of drums, IBCs or other containers containing hazardous and/or polluting materials. Potential to discharge to surface water and/or ground. | 2 | 3 | 6 |
| 2 | Storage and handling of hazardous and/potentially polluting materials on site (e.g. raw materials, diesel, engineering materials - hydraulic oil, lubricants etc.) | Leak or spill to surface water, ground or groundwater from storage and handling of hazardous and polluting materials on site | 3 | 2 | 6 |
| 3 | Bulk liquid storage tanks | Failure of tank resulting in spill of contents to surface water, ground water and/or ground. | 3 | 1 | 3 |
| 4 | Bunded areas | Loss of bund integrity. Direct discharge of contents to ground/surface water | 3 | 1 | 3 |
| 5 | Use of vehicles onsite | Leaks of fuel, oil etc. from vehicles to surface water, ground or groundwater | 2 | 2 | 4 |
| 6 | Production Process | Spillages during the production process. Contained within production area. | 2 | 2 | 4 |
| 7 | Movement of process (trade) effluent onsite to wastewater treatment area | Loss of pipeline integrity. Leaks from drains and discharges/spills of process effluent to surface water, ground or groundwater | 2 | 2 | 4 |
| 8 | Movement of foul and sanitary effluent on-site to waste water treatment area | Loss of integrity. Leaks from drains and discharges/spills of foul and sanitary effluent to surface water, ground or groundwater | 2 | 3 | 6 |
| 9 | Discharge of rainfall/storm water runoff from roofs and paved-areas on site | Discharge of excessive volumes of storm water containing excessive suspended solids and/or hazardous materials | 2 | 2 | 4 |
| 10 | Operation of Boilers and associated air abatement systems | Failure of abatement, release of unabated emissions to atmosphere in excess of Emission Limit Values (ELVs). | 3 | 1 | 3 |
| 11 | General operational activities including plant operation, use of process and mechanical equipment and traffic movement on site | Excessive noise generated on site and at noise sensitive locations off site | 2 | 2 | 4 |
| 12 | Gas Tank Yard | Leak or pipe rupture leading to fire or explosion | 4 | 1 | 4 |
| 13 | Fire at the facility | Emissions to air, firewater discharge to ground, surface water and/or groundwater | 4 | 1 | 4 |
| 14 | Unauthorised disposal of | Improper classification of waste | 3 | 2 | 6 |

| Risk ID | Process | Potential Risks | Consequence Rating | Likelihood Rating | Risk Score |
|---------|--------------------------------------|--|--------------------|-------------------|------------|
| | hazardous/non-hazardous waste | for purpose of disposal/recovery. Discharges/spills of waste materials to surface water, ground or groundwater. Incorrect handling procedures by contractor. | | | |
| 15 | Failure of wastewater treatment area | Failure of treatment resulting in untreated effluent discharge to sewer in excess of Emission Limit Values (ELVs). Impact on Bunlicky WWTP. | 1 | 3 | 3 |
| 16 | Monitoring and control systems | Failure of on-site monitoring control systems. Release of hazardous emissions to air, surface water and/or wastewater. | 2 | 2 | 4 |
| 17 | Site Closure | Existing environmental liabilities remaining on site. | 2 | 1 | 2 |

Each risk has been given an ID number which is displayed on the Risk Matrix (Table 5.2). The matrix shows the ranking/rating for each hazard/risk. A colour coding system is used to give an indication of the risk level for each identified hazard/risk as follows:

Red: These are considered to be high-level risks requiring priority attention. These risks have the potential to be catastrophic and as such should be addressed quickly.

Yellow: These are medium-level risks require action, but are not as critical as a red-coded risk.

Green (light and dark): 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 and if cost-effective practicable mitigation can be carried out to reduce the risk even further, this should be considered.

Table 5.2 Risk ID Matrix

| | | | | | | | |
|--------------------|-----------------|----------|-------------------|----------------------|---------------|--------------|----------------|
| CONSEQUENCE | Massive | 5 | | | | | |
| | Major | 4 | | | | | |
| | Moderate | 3 | 3,4,15 | 2 | | | |
| | Minor | 2 | 17 | 5,6,7,9,11,16 | 1,8,14 | | |
| | Trivial | 1 | | | 10 | 12,13 | |
| | | | V. Low | Low | Medium | High | V. High |
| | | | 1 | 2 | 3 | 4 | 5 |
| | | | LIKELIHOOD | | | | |

It can be seen from the matrix above that there are no risks in the red area, requiring priority attention. All risks are located in the light green zone, indicating 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 and if cost-effective practicable mitigation can be carried out to reduce the risk even further.

6 Risk Treatment

The output of the risk treatment process is the development of a statement of measures to be taken to minimise the environmental risk of the activity. The statement of measures is presented in Table 6.1 where a set of appropriate and achievable mitigation measures are assigned to each risk, with a risk owner responsibility for the on-going management of the risk and a timeframe for implementation of the risk mitigation measure. It should be noted that as the facility is not yet constructed or operational, the risk mitigation measures identified and associated timeframes are subject to change.

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Table 6.1 Statement of Measures

| Risk ID | Potential Risks | Risk Score | Mitigation Measures to be Taken | Outcome | Action | Date for Completion | Owner/Contact Person |
|---------|--|------------|---|---------|--------|---|--|
| 1 | Loading and unloading of materials on site | 6 | 1. Loading/unloading areas bunded and/or designed to contain accidental releases 2. Routine inspection of all drums and containers delivered to site 3. Best practice operational procedures for loading/unloading of materials. 4. Site spill response procedure | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |
| 2 | Storage and handling of hazardous and/potentially polluting materials on site (e.g. raw materials, diesel, engineering materials - hydraulic oil, lubricants etc.) | 6 | 1. Any hazardous materials stored in appropriately designed sealed containers. 2. Emergency generator will be bunded. 3. Routine inspection/maintenance of bunded areas, tanks, containers, equipment & pipework 4. Best practice operational procedures for handling of materials 5. Site spill response procedure | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |
| 3 | Bulk liquid storage tanks | 3 | Adherence to the conditions assigned in the IEL. Regular inspection and monitoring undertaken in accordance with IEL | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |
| 4 | Bunded areas | 3 | Adherence to the conditions assigned in the IEL. Regular inspection and monitoring undertaken in accordance with IEL | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |
| 5 | Use of vehicles onsite | 4 | 1. Paved roads and car parks on site which drain to site surface water runoff drainage system 2. Oil/petrol interceptor on surface water drainage system 3. Periodic inspection/cleaning of | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |

| Risk ID | Potential Risks | Risk Score | Mitigation Measures to be Taken | Outcome | Action | Date for Completion | Owner/Contact Person |
|---------|--|------------|---|---------|--------|---|--|
| | | | interceptor 4. Routine inspection/maintenance of operational vehicles e.g. forklifts | | | | |
| 6 | Production Process | 4 | Adherence to the conditions assigned in the IEL. Regular inspection and monitoring undertaken in accordance with IEL | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |
| 7 | Movement of process (trade) effluent onsite to wastewater treatment area | 4 | 1. Process effluent collected in process drainage system and sent to on-site balancing tank for pre-treatment prior to discharge to local authority sewer and then Bunlicky waste water treatment plant 2. Continuous monitoring of process effluent prior to discharge to local authority sewer 3. Periodic inspection/maintenance | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |
| 8 | Movement of foul and sanitary effluent on-site to waste water treatment area | 6 | 1. Foul and sanitary effluent discharged to local authority foul sewer which drains to bunlicky waste water treatment plant 2. Periodic inspection/maintenance of pipework and on site pumping station | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |
| 9 | Discharge of rainfall/storm water runoff from roofs and paved-areas on site | 4 | 1. Trigger levels to be established and monitored as part of IEL. | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |
| 10 | Operation of Boilers and associated air abatement systems | 3 | 1. Modern efficient plant and equipment designed in accordance with BAT and air dispersion modelling has shown no significant adverse impact on air quality 2. Annual monitoring at emission point 3. Routine inspection/maintenance of equipment as part of site maintenance management system | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |

| Risk ID | Potential Risks | Risk Score | Mitigation Measures to be Taken | Outcome | Action | Date for Completion | Owner/Contact Person |
|---------|--|------------|--|---------|--------|---|--|
| 11 | General operational activities including plant operation, use of process and mechanical equipment and traffic movement on site | 4 | <ol style="list-style-type: none"> 1. Noise criteria specified for all plant and equipment as part of design and procurement process 2. Plant will be designed not to exceed limits at noise sensitive locations specified in IEL. 3. Noise modelling has indicated facility will not have any significant adverse impact at noise sensitive locations 4. Plant and equipment will be suitably serviced and maintained 5. Periodic ambient noise monitoring will be carried out | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |
| 12 | Gas Tank Yard | 4 | <ol style="list-style-type: none"> 1. Above ground installation designed, installed and maintained by utilities company / Bord Gais 2. Gas pipework is designed, installed and inspected to appropriate standard | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |
| 13 | Fire at the facility | 4 | <ol style="list-style-type: none"> 1. Fire detection throughout building. 2. Sprinkler system 3. Building designed into separate fire compartments. 4. Site emergency response procedure | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |
| 14 | Unauthorised disposal of hazardous/non-hazardous waste | 6 | <p>Adherence to the conditions assigned in the IEL.</p> <p>Regular inspection and monitoring undertaken in accordance with IEL and site Environmental Management System</p> | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |
| 15 | Failure of wastewater treatment area | 3 | <p>Adherence to the conditions assigned in the IEL.</p> <p>Regular inspection and monitoring undertaken in accordance with IEL and site Environmental Management System</p> | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |

| Risk ID | Potential Risks | Risk Score | Mitigation Measures to be Taken | Outcome | Action | Date for Completion | Owner/Contact Person |
|---------|--------------------------------|------------|--|---------|--------|---|--|
| 16 | Monitoring and control systems | 4 | Adherence to the conditions assigned in the IEL. Regular inspection and monitoring undertaken in accordance with IEL and site Environmental Management System | N/A | N/A | Incorporated into design/ to be implemented as part of site Environmental Management System | Design Team / Operations Management Team / EHS Manager |
| 17 | Site Closure | 2 | N/A | N/A | N/A | Closure Plan to be prepared as part of the IEL. | Design Team / Operations Management Team / EHS Manager |

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7 Identification of Plausible Worst Case Scenario

The ELRA for this activity identified a number of risks with a major consequence; therefore, further analysis was conducted to determine the worst case scenario. It was determined that fire at the facility (Risk ID 13) could trigger Risk ID 2 (loss from above ground fuel tanks/pipelines, groundwater and/or soil contamination), Risk ID 9 increased discharge of rainfall/storm water runoff from roofs and paved-areas on site and Risk ID 14 (Unauthorised disposal of hazardous/non-hazardous waste following the event).

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8 Quantification & Costing

Based on the plausible worst case scenario identified in Section 7 the required items have been quantified and costed for the purposes of financial provision. See Table 8.1.

Table 8.1 Quantification and Costing of Worst Case Scenario

| Task | Description | Quantity (No.) | Measurement Unit | Unit Rate (€) | Cost (€) | Source of Unit Rates |
|---|---|----------------|------------------|----------------|------------------------------|------------------------------|
| In Response to: Risk ID 13 (Fire at the Facility) Resulting in Risk ID 2 Storage and handling of hazardous and/potentially polluting materials on site (e.g. raw materials, diesel, engineering materials - hydraulic oil, lubricants etc.) Risk ID 9 Discharge of rainfall/storm water runoff from roofs and paved-areas on site Risk ID 14 Unauthorised disposal of hazardous/non-hazardous waste | Fire Brigade | 4 x 24 hours | Call out | 1,100 per hour | 105,600 | Limerick County Council |
| | Site Supervisor | 20 | Days | 600 | 12,000 | PM Group Recent Tender Rates |
| | General Operatives x 4 | 80 | Days | 350 | 28,000 | PM Group Recent Tender Rates |
| | Warning Signage, Bollards, Beacons etc. | 1 | Item | 2,000 | 2,000 | PM Group Recent Tender Rates |
| | Plant & Machinery | 1 | Item | 5,000 | 5,000 | PM Group Recent Tender Rates |
| | Crane Hire | 1 | Item | 1,500 | 1,500 | PM Group Recent Tender Rates |
| | Water Pumps | 1 | Item | 3,000 | 3,000 | PM Group Recent Tender Rates |
| | Disposal of Firewater | 830 | m ³ | 85 | 70,550 | PM Group Recent Tender Rates |
| | Disposal of Raw Material | 80 | tonne | 450 | 36,000 | PM Group Recent Tender Rates |
| | Miscellaneous Waste Disposal | 1 | Item | 10,000 | 10,000 | PM Group Recent Tender Rates |
| | Excavation of Contaminated Soil | 800 | m ³ | 10 | 8,000 | PM Group Recent Tender Rates |
| | Removal of Contaminated Soils off Site | 1600 | tonne | 50 | 80,000 | PM Group Recent Tender Rates |
| | Disposal of Contaminated Soil at Gate | 1600 | tonne | 20 | 32,000 | PM Group Recent Tender Rates |
| | Imported Soils | 1600 | tonne | 40 | 64,000 | PM Group Recent Tender Rates |
| | Landscaping of Area effected | 1000 | m ² | 15 | 15,000 | PM Group Recent Tender Rates |
| | Environmental Monitoring – Various Samples throughout year. | 200 | Test | 150 | 30,000 | PM Group Recent Tender Rates |
| | Environmental Consultancy | 40 | Days | 1000 | 40,000 | PM Group Recent Tender Rates |
| | Security | 20 | Days | 600 | 12,000 | PM Group Recent Tender Rates |
| | Fuel | 1 | Item | 2,500 | 2,500 | PM Group Recent Tender Rates |
| | Power Supply | 1 | Item | 3,000 | 3,000 | PM Group Recent Tender Rates |
| Sub Total | | | | 560,150 | PM Group Recent Tender Rates | |
| Insurance @ 5% | | | | 28,008 | | |
| Sub –Total | | | | 588,158 | | |
| Contingency at 30% | | | | 176447.25 | | |
| TOTAL | | | | 764,605 | | |

9 Conclusion

The Financial Provision has been based on the combined risks that pose the plausible worst case scenario (Table 8.1). This is the maximum liability that may be incurred and as such, financial provision is calculated as **€764,605** based on this event. In accordance with Section 3.5.2 of the EPA Guidance the financial provision is rounded up to **€1,000,000**.

The most costly risks identified in the ELRA relate to a one-off accident/incident where an unexpected incident has caused pollution or contamination. This type of incident is more than adequately covered by Regeneron's current insurance policy and is considered a suitable financial instrument. Regeneron has a comprehensive insurance programme in place for all significant insurable risks and major catastrophes including potential environmental liabilities to a value above the calculated environmental liability. Regeneron propose to enter into a Financial Security Agreement with the EPA following grant of the IEL.

Risk management at the facility will be a dynamic process and will be updated through the addition of new risks or the omission of redundant risks, where applicable. The Financial Provision will be reviewed in accordance with the requirements of the IEL to ensure that it continues to cover the environmental liabilities.

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Section L Attachment

Attachment L: Statutory Requirements

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Attachment L: Statutory Requirements

L.1 EPA Acts, 1992 to 2011

83(5)(a)(i) any emissions from the activity will not result in the contravention of any relevant air quality standard specified under section 50 of the Air Pollution Act 1987, and will comply with any relevant emission limit value specified under section 51 of the Air Pollution Act 1987.

The proposed facility will not lead to a contravention of the above. Atmospheric emissions from the proposed facility are minor and will not result in air pollution. A full air quality assessment is contained in the EIS included in this application and also in Attachment E.1 of this application.

83(5)(a)(ii) any emissions from the activity will comply with, or will not result in the contravention of, any relevant quality standard for waters, trade effluents and sewage effluents and standards in relation to treatment of such effluents prescribed under section 26 of the Local Government (Water Pollution) Act 1977.

The proposed facility will comply with the above legislation. Please consult the EIS included in this application and Attachment I.2 and I.3 of this application. Process and sanitary effluent will be sent to Bunlicky WWTP. Clean, uncontaminated storm water will be discharged, via a Class 1 bypass petrol interceptor to the Shannon Development sewer.

83(5)(a)(iii) any emissions from the activity or any premises, plant, methods, processes, operating procedures or other factors which affect such emissions will comply with, or will not result in the contravention of, any relevant standard including any standard for an environmental medium prescribed under regulations made under the European Communities Act 1972, or under any other enactment,

The proposed facility will not lead to a contravention of any relevant standard prescribed under the European Communities Act 1972 or under any other enactment. There are no predicted significant impacts associated with the proposed facility. This has been determined through the EIA process for the proposed development.

83(5)(a)(iv) any noise from the activity will comply with, or will not result in the contravention of, any regulations under section 106,

As detailed in Section I.7 of this application and the EIS for the proposed development, noise from the activity will comply with, or will not result in the contravention of, any regulations under section 106.

83(5)(a)(v) any emissions from the activity will not cause significant environmental pollution,

Emission from the activity will not cause significant environmental pollution. A full assessment of environmental impacts has been detailed in the EIS for the proposed development.

83(5)(a)(vii) having regard to Part III of the Act of 1996, production of waste in the carrying on of the activity will be prevented or minimised or, where waste is produced, it will be recovered or, where that is not technically or economically possible, disposed of in a manner which will prevent or minimise any impact on the environment,

The proposed facility will comply with the provisions of the Act of 1996. This will be achieved through the implementation of BAT, waste management best practice and through the implementation of an Environmental Management System during the operational phase. Refer to Attachment H of this application and the Chapter 14 of the EIS.

83(5)(a)(viii) energy will be used efficiently in the carrying on of the activity

Refer to Attachment G.2 of this application.

83(5)(a)(ix) necessary measures will be taken to prevent accidents in the carrying on of the activity and, where an accident occurs, to limit its consequences for the environment and, in so far as it does have such consequences, to remedy those consequences

Refer to Attachment J of this application.

83(5)(a)(x) necessary measures will be taken upon the permanent cessation of the activity (including such a cessation resulting from the abandonment of the activity) to avoid any risk of environmental pollution and return the site of the activity to a satisfactory state

Refer to Attachment K of this application.

L.2 Natura 2000 (Designated) Sites

An Appropriate Assessment screening was carried out on the proposed development which is included in Attachment B.6.

The proposed facility site is not protected under cSAC, SPA, NHA or pNHA designation. The closest protected site is the Loughmore Common Turlough pNHA, located approximately 650m to the west of the proposed development site. Other protected sites in the general area include the overlapping designations of the Lower River Shannon cSAC 2165 and the River Shannon and River Fergus Estuaries SPA 4077.

The Appropriate Assessment Screening assessed Qualifying Interests, their threats, and their underpinning conditions for all European sites potentially affected by the development, and concluded there would be no adverse impacts to site integrity of any European Sites as a result of the development, either alone or in combination with other plans or projects.

L.3 Environmental Objectives Regulations

The proposed facility is not liable to have an adverse impact on water quality in relation to the European Communities Environmental Objectives (Surface Water) Regulations 2009 (S.I. No. 272 of 2009) and the European Communities Environmental Objectives (Ground Water) Regulations 2010 (S.I. No. 9 of 2010).

L.4 Schedule of the EPA (Industrial Emissions) (Licensing) Regulations 2013, S.I. No. 137 of 2013

Air Pollutants Discharged by the Activity: Oxides of nitrogen and other nitrogen compounds, Carbon monoxide, Particulate Matter.

Water Pollutants Discharged by the Activity: Not applicable – trade effluent emissions from the site will go to the onsite waste balancing tanks for pre-treatment before being sent to the Bunlicky WWTP for treatment.

L.5 Best Environmental Practices

Indicate if the best environmental practices are in place for control of diffuse emissions from the installation as set out in the following legislation:

(a) a BAT Conclusions Implementing Decision published by the EC

Please refer to Section I.8 of Attachment I

(b) a specification prepared by the Agency in accordance with Section 5 of the Environmental Protection Agency Act 1992 as amended

Please refer to Section I.8 of Attachment I

(c) the Urban Waste Water Treatment Regulations 2001 (S.I. No. 254 of 2001) as amended by the Urban Waste Water Treatment (Amendment) Regulations 2004 (S.I. No. 440 of 2004) or any future amendment thereof

Not applicable

(d) the European Communities (Good Agricultural Practice for Protection of Waters) Regulations 20 (S.I. No. 610 of 2010) or any future amendment thereof

Not applicable

(e) the Local Government (Water Pollution) Act, 1977 (Control of Cadmium Discharges) Regulations 1985 (S.I. No. 294 of 1985)

Not applicable

(f) the Local Government (Water Pollution) Act, 1977 (Control of Hexachlorocyclohexane and Mercury Discharges) Regulations 1986 (S.I. No. 55 of 1986)

Not applicable

(g) the Local Government (Water Pollution) Acts, 1977 and 1990 (Control of Carbon Tetrachloride, DDT and Pentachlorophenol Discharges) Regulations 1994 (S.I. No. 43 of 1994)

Not applicable

(h) measures or controls identified in a pollution reduction plan for the river basin district prepared in accordance with Part V of the EC Environmental Objectives (Surface Waters) Regulations 2009 S.I. No. 272 of 2009 for the reduction of pollution by priority substances or the ceasing or phasing out of emissions, discharges and losses of priority hazardous substances

The proposed facility will not discharge priority substances as outlined in the EC Environmental Objectives (Surface Waters) Regulations 2009, S.I. 272 of 2009.

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