ELRA Update 2011

Environmental Liabilities Risk Assessment 2011

Pfizer Ireland Pharmaceuticals, Askeaton

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1. INTRODUCTION

1.1. Background

Pfizer Ireland Pharmaceuticals (t/a Wyeth Nutritionals Ireland), hereafter referred to as Pfizer was granted an IPPC licence, Register No. P0395-02, by the Environmental Protection Agency on 24th January 2004. This licence was amended on the 26th June 2006 by the amendment document titled 678 S82 (11) and was amended again in July 2007 to account for fuel provisions in the CHP plant. The details of both amendments must be read in conjunction with the licence. The IPPC licence covers:

"*manufacture of Dairy products where the processing capacity exceeds 50 million gallons of milk equivalent per year"*

"the burning of any fuel in a boiler or furnace with a nominal heat output exceeding 50MW"

The IPPC licence was transferred from AHP manufacturing B.V. trading as Wyeth Nutrionals Ireland to Pfizer Ireland Pharmaceuticals in January 2011.

The Pfizer site is located in Askeaton, Co. Limerick. The Pfizer facility is an integrated manufacturing facility which produces a comprehensive range of Infant Nutritional products, in both canned powder form and Liquid Ready-to-Feed (RTF) form in glass bottles and Tetra-Paks. Can manufacture also takes place on the site.

Condition 15.2 of the operating IPPC licence requires the licensee to arrange for the preparation of an Environmental Liabilities Risk Assessment (ELRA) covering the Pfizer Askeaton site. The ELRA must address liabilities arising from past and present activities and must be completed by an independent and appropriately qualified consultant.

URS, as an independent and appropriately qualified consultant, was appointed to complete an ELRA. URS completed the original ELRA (date of report 19th August 2005). The second revision in 2007, in addition to updating the ELRA to account for any changes in risk, also accounted for the requirements of the most Recent EPA Guidance Document entitled "*Guidance on Environmental Liability Risk Assessment, Residuals Management Plans and Financial Provision 2006*" (hereafter referred to as the EPA ELRA Guidance Document). The ELRA was again updated in 2008, 2009 and 2010 to account for any changes in risk in the previous years.

This is the sixth revision of the ELRA and will account for any changes in risk since the 2010 ELRA update.

1.2. Environmental Liability Risk Assessments

Any industrial site has the potential to generate environmental liabilities, i.e. damage to the environment which must be remedied, such remediation associated with a quantifiable financial cost.

Environmental liabilities may arise from *anticipated* or *foreseeable* events, i.e. known and quantifiable releases to the environment which arise due to the day-to-day operation of the facility. Examples of such potential liabilities include the long-term management and aftercare of a tailings pond at a mining or minerals refining site or on-site land filling of waste materials. For a site subject to IPPC Licensing, regular emissions to air, water and land have been the subject of detailed quantification and consequence analysis, i.e. assessment of the impact of emissions, during the licence application process. The resulting IPPC licence either establishes emission limits and other conditions at a level which prevents the arising of new liabilities or may require bonding or other secure funding mechanism to cover the expected liability. The latter case applies usually to, for example, on-site land filling activities.

Environmental liabilities may also arise from unanticipated or unforeseen events. Such events may be loosely classified under the following headings:

- events which are *sudden* and which are identifiable as an incident or series of related incidents which give rise to an environmental liability concurrent with the incident or shortly thereafter;
- events which develop gradually or go unnoticed for a long period of time which *gradually* give rise to an environmental liability.

Examples of the former would include explosion/fire or accidental release of chemicals from a storage tank to a watercourse.

An example of the latter would be leaks in underground storage tanks or transfer lines, which would result in the gradual build-up of soil and/or groundwater contamination.

An Environmental Liability Risk Assessment (ELRA) considers the risk of unplanned events occurring during the operation of a facility that could result in unknown liabilities materialising. Based on an initial risk categorisation of the activity into Low, Medium or High risk (refer to Section 3), different approaches are recommended according to the risk category. Simple approaches are proposed for low risk facilities to more detailed site-specific approaches involving detailed environmental liability risk assessment for higher risk facilities.

1.3. Structure of the ELRA

The ELRA report is structured as follows:

Section 2 provides an overview of Pfizer including details of existing process carried out on-site and the buildings and structures present on the site at the time this report was prepared.

Section 3 describes the initial screening and operational risk assessment carried out for the Pfizer facility.

Section 4 provides an overview of the historical environmental liabilities associated with the facility.

Section 5 described the site specific risk assessment which was carried out for the facility. It includes section on Risk Identification, Occurrence Likelihood, Severity Assessment, Risk Evaluation and Prevention/Mitigation

Section 6 describes the financial provisions in place and recommended to deal with any unknown liabilities

Section 7 is the assessment conclusion.

1.4. Independent and Appropriately Qualified Consultants

Condition 15.2.1 requires that the ELRA be carried out by independent and appropriately qualified consultants.

URS is a world-wide environmental consultancy, offering a full range of environmental services. We have been operating in Ireland since 1995, employing a multi-disciplinary staff of highly qualified engineers and scientists. We have completed numerous environmental assessment projects, including environmental due diligence, soil and groundwater investigation and remediation, waste management, IPPC support, EMS support, legal support, and hazard ranking. URS has completed several projects for Pfizer (Formerly Wyeth Nutritionals Ireland) at their Askeaton site, including Phase I and Phase II assessments, IPPCL compliance audits, hydrogeological investigations, Air Dispersion Modelling and Closure Restoration and Aftercare Management Plans. We are currently monitoring groundwater at the site on a biannual basis to fulfil IPPC licence requirements.

2. OVERVIEW OF PFIZER

2.1. The Company

Wyeth Corporation was acquired by Pfizer Inc. in 2009. Pfizer and Wyeth began joint operations on October 16, 2009. The IPPC licence was transferred from AHP manufacturing B.V. trading as Wyeth Nutrionals Ireland to Pfizer Ireland Pharmaceuticals in January 2011. Pfizer operates under strict environmental policies and procedures.

The corporation's financial strength, coupled with their commitment to maintaining their environmental policy indicates that there is both the will and the financial depth to cope with any environmental liabilities that may arise through the operation of the Askeaton site in a responsible manner.

2.2. Site Description and History

Pfizer was established in Askeaton Co. Limerick in 1973 then operating as Wyeth Nutritionals Ireland (WNI) and developed from a green field site status. Over time, the site expanded to the North and now includes a portion of a farm originally adjacent to the north border of the site. The site is adjacent to the main Limerick-Foynes road near Askeaton town. The site is situated in farmland and is bordered on its eastern perimeter by the River Deel, a tributary of the river Shannon.

There are no other notable industrial activities in the immediate surrounds of the Pfizer plant.

The Pfizer facility is an integrated manufacturing facility which produces and distributes a range of infant nutritional products. The use of hazardous materials on site is limited. Products are manufactured by compounding, sterilisation and homogenisation of liquid and powder milked based raw materials. Products have dedicated process lines. The products are packaged on site and dispatched to customers from the site. Approximately 45% of product is exported to the U.K.

There are approximately 550 permanent personnel employed at the Askeaton site. The facility operates continuously, seven days a week/ twenty-four hours/day.

The production part of the site comprises of 11.5 acres of the total 36 acre site area. The main areas of the production operation are summarised as follows:

RTF-Wet Process	Materials Handling
RTF-Krones Filling Room	Can Manufacturing Plant
RTF-LAN/Barriquand Room	Powder Plant Wet
RTF-Tetra-Pak Filing Line	Canning Lines 2,3,4,5,6
RTF-Packing Line/Warehouse	Pouch Filling Line
Batch Make-up and Dispensing	Tote Bin Filling

Fat Blending	Stickpack Filling Line
Process 1,2,2 X , 3	Utilities Operations
Evaporation/Drying	Laboratory Operations
Dry Blending Plant	Air Abatement Systems
Tote Bin C.I.P Station	CHP Plant
Water Treatment Plant	

The manufacturing operation is supported by a range of Administration, Utilities and Laboratory services on site as well as a new product and process development department.

The CHP plant was commissioned in October 2004 with start up completed during the 1st quarter 2005.

Pfizer reported that the Askeaton operation is not a Seveso II (Major Accidents Directive) facility.

3. SCREENING AND OPERATIONAL RISK ASSESSMENT

3.1. General

As a starting point in the process, a straightforward risk assessment decision matrix can be used to classify sites according to Low, Medium and High risk and thereby select the specific ELRA and Financial Provision (FP) requirements that will be needed. The risk assessment decision matrix outlined in the EPA's ELRA Guidance Document 2006 was used.

The risk assigned to the facility depends on the complexity of operations at the site, the environmental sensitivity of the receiving environment and the pollution record (compliance history) of the facility.

- **Complexity** – the extent and magnitude of potential hazards present due to the operation of the facility (e.g. a function of the nature of the activity, the volumes of hazardous materials stored on site etc.). A Complexity Band (G1 least complex to G5 most complex) for each class of activity has been assigned and included in a Look-Up Table (Appendix A to the ELRA Guidance Document 2005).
- **Environmental Sensitivity** – the sensitivity of the receiving environment in the vicinity of the facility, with more sensitive locations given a higher score (e.g. the presence of aquifers below the site, groundwater vulnerability, the proximity to surface water bodies and their status, the proximity to sensitive human receptors, etc). The Environmental Sensitivity is calculated on a site-specific basis using a sub-matrix (Table 3.2).
- **Compliance Record** – the compliance history of the facility and whether soil and/or groundwater contamination is present below the site.

Each aspect is multiplied to give the **Total Score** for the facility, and this can be used to place the facility into an appropriate Risk Category as follows:

- Low Risk = Score < 5
- Medium Risk = Score 5 - 9
- High Risk = Score = > 9.

Once this has been completed, the licensee proceeds through the relevant steps of ELRA and Financial Provision (FP) that are considered appropriate for the Risk Category.

3.2. Complexity

The Complexity Band is used to determine the value used in the Operational Risk Assessments as follows:

G1 = 1, G2 = 2, G3 = 3, G4 = 4 and G5 = 5

The relevant complexity band for Pfizer according to the EPA's ELRA Guidance Document 2005 is G3 both relating to the combustion facilities on site >50 Megawatts (but less than 300 Megawatts) and due to the manufacture of dairy products where the processing capacity exceeds 50 million gallons of milk equivalent per year.

Thus, a complexity score of '3' is assigned to Pfizer.

3.3. Environmental Sensitivity

A sub-matrix for environmental sensitivity for the Pfizer site is presented in Table 3.2 and is based on an assessment of the site sensitivity presented in Appendix A. The sub-matrix considers 6 key potential environmental receptors and assigns individual scores that are added together to arrive at a total environmental attribute score. The total environmental attribute score is used to look up the environmental sensitivity classification in Table 3.1 below. The environmental sensitivity classification is used in the operational risk assessment to calculate the total score.

The key receptors include:

- Human Beings
- Groundwater
- Surface Water
- Air Quality
- Protected Ecological Sites
- Sensitive Agricultural Receptors

Table 3.1 Environmental Sensitivity Classification

Total Environmental Attribute Score	Environmental Sensitivity Classification
Low <7	1
Moderate 7-12	2
High >12	3

Table 3.2 - Environmental Sensitivity Sub-Matrix

Environmental Attribute	Environmental Attribute Score
Human Occupation	
<50m	**5**
50m-250m	3
250m–1,000m	1
>1km	0
Groundwater Protection	
Regionally Important Aquifer	**2**
Locally Important Aquifer	1
Poor Aquifer	0
Vulnerability Rating – Extreme	**3**
Vulnerability Rating – High	2
Vulnerability Rating - Moderate	1
Vulnerability Rating - Low	0
Sensitivity of Receiving Water	
Class A	3
Class B	2
Class C	**1**
Class D	0
Designated Coastal & Estuarine Waters	2
Potentially Eutrophic Coastal & Estuarine Waters	1
Air Quality & Topography	
Complex Terrain	2
Intermediate Terrain	1
Simple Terrain	**0**
Protected Ecological Sites	
Within or directly bordering protected site	2
<1km to protected site	**1**
>1km to protected site	0
Sensitive Agricultural Receptors	
<50m from site boundary	**2**
50m-150m from site boundary	1
>150m from site boundary	0

Note 1 – The environmental attribute, which is relevant to the Pfizer facility is underlined – the reasoning for the selections are explained in Appendix A Site Characterisation.

Scores in Table 3.2 appropriate for Pfizer is underlined in bold font typeface. Based on the above Environmental Sensitivity Sub-Matrix, the total environmental attribute score for Pfizer is 14 which indicates that that the Environmental sensitivity Classification (referring to Table 3.1) for the site and surrounds is 'High' with an assigned score of '3'.

3.4. Compliance Record

The Compliance record score is derived from the compliance record of the facility and whether significant ground contamination is present below the facility.

For newly licensed facilities and those operating without non-compliance of emission limits, then these are classified as **Compliant/New Facility** and have a score of 1.

Licensed facilities with administrative non-compliances only are classified as administrative non-compliant and have a score of 2.

Licensed facilities with minor emission non-compliances (< 5 non-compliances in 12 months) are classified as being **Minor Non-Compliant** and have a score of 3. Facilities with minor soil and groundwater contamination (i.e. those with concentrations above background but not posing risk to the environment) are also considered in the class.

Licensed facilities with major emission non-compliance history (≥ 5 non-compliances in 12 month period) and/or those with significant soil and groundwater contamination (i.e. requiring remediation and/or long-term monitoring requirements) are classified as **Major Non-Compliant/Significant Ground Contamination** and have a score of 4.

Those facilities with repeated non-compliances (≥ 10 Total) during a 12 month period are classified as Repeat Non-Compliance and have a score of 5.

As part of the preparation of the ELRA, documentation relating to IPPC licence compliance, in particular monitoring reports to the EPA were reviewed for 2008, 2009 and 2010. This documentation review demonstrated a high compliance level with IPPC licence specified emission limit values.

There was one non-compliance for emissions to water that occurred during the 24-hour period between January 23rd – 24th of 2008. This non-compliance was due to an exceedence of the ELV for total nitrogen (42 mg/l versus an ELV of 15 mg/l). The cause of the non-compliance was investigated and corrective actions have been put in place to prevent a re-occurrence. There was one non-compliance for emissions to atmosphere during 2008. The non-compliance was due to an exceedence of the ELV for particulates (60.86 mg/Nm3 versus an ELV of 50 mg/Nm3) and was detected during routine emission monitoring on one of the process exhaust outlets during November.

There were three non-compliances for emissions to water during 2009. The first occurred during the 24-hour period beginning at 8:00 am on June 17th and was due to an exceedence of the ELV for BOD (54.94 mg/l versus an ELV of 40 mg/l). The second non-compliance occurred during the 24-hour period beginning at 8:00 am on June 20th and was also due to an exceedence of the ELV for BOD (60.25 mg/l versus an ELV of 40 mg/l). The third non-compliance occurred during the 24-hour period beginning at 8:00 am on November 16th and was due to an exceedence of the ELV for Ammonia (as N) (16.0 mg/l versus an ELV of 10 mg/l). The causes of the non-compliances were investigated and corrective actions have been put in place to prevent re-occurrences. There was one non-compliance for emissions to atmosphere during the reporting period. The non-compliance was due to an exceedence of the ELV for particulates (52.3 mg/Nm3 versus

an ELV of 50 mg/Nm3) and was detected during routine emission monitoring on one of the process exhaust outlets during February.

In 2010, there were no non-compliances with regard to emission to air or water.

In relation to soil contamination, a leak from an underground effluent pipeline in January 2006 resulted in minor contamination of the sub-surface soil and groundwater on the site. However, this impact was temporary and by April 2006 parameter concentrations had returned to normal, indicating the absence of sewage contamination. On the 20 September 2006, a leak from an overground effluent pipeline resulted in the release of process effluent. Some minor contamination was identified in the wells closest to the release. In February 2008, total and faecal coliforms results in groundwater from BH202 were at their highest concentrations since monitoring for bacteriological parameters began in July 2007. This borehole is close to the River Deel and continuous groundwater monitoring indicates that boreholes near the river are subject to mixing between the groundwater and surface water bodies. Further, monitoring results the river water show total and faecal coliforms counts to be consistently high.

The detection of major ion and microbial concentrations in groundwater from wells 101, 202 and 203 during recent years is thought to be a result of influent water flow from the river to the groundwater (See Section 4.3).

Considering all of the above the above, a compliance score of '3' is assigned to Pfizer.

3.5. Risk Category

The proceeding subsections of this section has determined the:

Complexity Score (G4) = 3

Environmental Sensitivity Score = 3

Compliance Record Score = 3

The product of these scores is used to calculate a total score, which is then used to assign the site specific risk category (Table 3.3). The product of the above scores is 27, which according to Table 3.3 below indicates that Risk Category 3 is applicable to the Pfizer Site.

Table 3.3 – Risk Category

Risk Category	Total Score
Category 1	<5
Category 2	5-23
Category 3	>23

The Pfizer site is classified in Risk Category 3 which infers the overall risk of the facility is high. The guidance provided in the EPA RMP Guidance Document 2006 for such facilities was used when carrying out the remainder of this assessment.

4. HISTORIC ENVIRONMENTAL LIABILITIES

4.1. Releases to Air

There is no evidence to suggest that any historical release to air, either sudden/accidental or gradual arising from the site has resulted in the development of any off-site environmental liability.

With regard to sudden and unexpected incidents, there is no history of:

- major fires or explosions;
- run-away reactions resulting in significant discharge to atmosphere;
- significant accidental releases of hazardous gases.

Regular emissions, via licensed sources, at the site have been subject of a comprehensive monitoring programme, the results of which are forwarded to the EPA on a regular basis.

Any off-site impact of emissions to air which have been noted have been transient in nature, i.e. occasional short-term noise episodes and a once-off dust complaint.

Vegetation on and near the site is in good condition with no evidence of blight or damage due to either atmospheric quality or deposition.

Any required changes or modifications to the understanding of emissions monitoring or interpretation of reporting requirements are agreed with the EPA. Additional reporting requirements, e.g., through regular EPA site inspections, are dealt with promptly by Pfizer.

4.2. Releases to Surface Water

The River Deel is the receptor for licensed treated wastewater emissions from the facility.

There is no evidence to suggest that releases from the site to the River Deel have had any significant impact or resulted in an environmental liability.

There have been some recorded accidental releases of untreated effluent to the River Deel. An incident occurred in April 2004, when discoloration was noted in the River Deel. An initial investigation by Pfizer revealed that there was a defect in part of the effluent drainage system and this had caused an overflow to ground near the oil and fat skimming pit, which contained effluent. In January 2006 a defective underground process effluent pipeline resulted in the release of process effluent and domestic sewage derived from the RTF process building, resulting in increased major ion concentrations and electrical conductivity in well 202. On the 20 September 2006, a leak from an over ground effluent pipeline resulted in the release of process effluent. The release effluent entered fissured rock beneath the gravel surface, with some of the effluent migrating directly to the bank of the River Deel and some of it entering the groundwater in the rock.

With regard to these incidents full survey's and remedial work was completed. There is currently no evidence to suggest that the release from the site to the River Deel has resulted in a medium to long-term environmental liability.

As the products handled at Pfizer are readily biodegradable, no significant, long term contamination or deterioration in water quality is predicted.

There is a comprehensive database of monitoring data on the quality of treated effluent. Difficulties had been encountered with regard to exceedance of certain licensed parameters, however none of these events may be considered to be significant in terms of the quality of the receiving waters. More importantly, Pfizer has spent considerable time and money in improving the operation of the wastewater treatment plant, especially in 2005. This includes the installation and operation of a pilot plant operated under a number of various operating parameters. This work was carried out on request of the Agency. This has resulted in a significant decrease in the number of exceedances of emission limit values relating to the emissions to the River Deel from the wastewater treatment plant.

New instrumentation for the on-line measurement of Ammonia, Turbidity and COD prior to discharge was installed in 2006. The ammonia and turbidity analysers became operational in 2007. The COD analyser is not currently being utilised owing to operational problems with it.

4.3. Releases to Ground/ Groundwater

There is no reported history of landfilling or burial of waste material on any part of the site.

Table 4.1 contains a summary of the historical aspects of releases to ground and groundwater on the site. The incidents summarised in Table 4.1 have been detailed in previous versions of the ELRA.

Table 4.1: Historical incidents leading to soil and groundwater pollution on the site

Date	Incident & Effects	Current Status
2001	Temporary storage of fructose resulting in elevated sugar sourced COD in certain groundwater wells.	Sugar contamination largely flushed from limestone aquifer and significantly reduced well COD concentrations
2001	Defective process drain resulting in slightly elevated pH and COD in groundwater well BH202.	Process drain repaired. Contamination levels reduced.
2004	Effluent overflow from the production areas. Groundwater in the area of well 202 was impacted, with an elevated COD.	COD had declined to below detection limits within several days.

Date	Incident & Effects	Current Status
2006	In January defective underground process effluent pipeline resulted in the release of process effluent and domestic sewage derived from the RTF process building, resulting in increased major ion concentrations and electrical conductivity in well 202. In September, a leak from an over-ground effluent pipeline resulted in the release of process effluent, resulting in the elevated major ion concentrations, COD and presence of coliforms in wells 101, 202 and 203.	Continuous groundwater monitoring confirmed that impact on groundwater quality was temporary.
2008	High total and faecal coliforms in groundwater from BH202 in February 2008.	It appears that this is as a result of mixing between groundwater and surface water bodies close to the river.

Site management confirmed that all wastes generated on-site since the commencement of site operations have been either recycled, disposed of to local authority landfill, by a licensed composting facility, or disposed via specialist hazardous waste management contractors (exported for recycling or incineration). There is no evidence to suggest that any waste generated at the site has resulted in any off-site liabilities.

In April 2007 major ion results were within their normal concentration ranges with the exception of chloride in well 202. BOD concentrations were also within their normal ranges when compared with previous monitoring rounds, however the sample for well 203 returned significantly elevated results for faecal and total coliforms. This high result suggests impact from sewer effluent in the vicinity of well 203, which may be related to the leak in September 2006. Pfizer have confirmed that there have been no leaks in the sewer system since that time.

Wells 202 and 203 were re-sampled in July 2007. Surface water from the River Deel was also sampled in July as a result of an EPA recommendation. The concentration of chloride in well 202 has declined compared to that recorded in April 2007. Concentrations of chloride in well 202 have fluctuated over time and may reflect differing brackish conditions in the adjacent River Deel during different stages of the tidal cycle. Similarly, the presence of coliforms in groundwater from wells adjacent to the River Deel may reflect influent water flow from the river into groundwater as coliform counts in the river are significantly higher than in the adjacent wells. Wells 202 and 203 are sampled bi-annually as part of the IPPC licence conditions for the site. Elevated chloride concentrations are typically recorded in groundwater from monitoring points BH202, BH203. This is consistent with their close proximity to the River Deel adjacent to the site, which is tidal and brackish.

Major ion and microbial concentrations in groundwater from wells 101 and 202 were again elevated in October 2007 and December 2007, which is likely to be a result of influent water flow from the river to the groundwater. In 2010, microbial concentration monitoring all of the major ion concentrations and microbial concentrations were within previously observed ranges for the site.

Following the detection of faecal and total coliforms in groundwater from well 203 in April and July 2007 the EPA requested that all groundwater monitoring wells on site be sampled for faecal and total coliforms on a quarterly basis. The EPA also requested that water from the River Deel (upstream and down stream off the site) and discharge effluent from Pfizer's wastewater treatment plant be sampled during bi-annual monitoring rounds.

A decrease in major ion concentrations and microbial concentrations was recorded in continuously throughout 2008, with exception of total and faecal coliforms results in groundwater from BH202 being recorded at their highest concentrations in February 2008 since monitoring for bacteriological parameters began in July 2007. A decrease in major ion concentrations and microbial concentrations was recorded in March 2009, relative to November 2008. In general, there was an increase in major ion concentrations across the site in September 2009 compared to the previous round of monitoring in March 2009. In September 2009 and 2010 monitoring all of the major ion concentrations were within previously observed ranges for the site.

There appears to be negative impact on the groundwater quality adjacent to the River Deel in terms of COD and bacteriological quality, thought to be due to the Limerick County Council sewage discharge to the River Deel from their sewage treatment facility within the Pfizer site. This influence on groundwater quality is illustrated by the elevated faecal coliform result for groundwater from well BH202, adjacent to the outfall from the Limerick County Council sewage facility.

The combined sampling and analysis of groundwater and surface water samples collected on 25 August 2010 demonstrates the interaction between groundwater and surface water (River Deel) along the site's eastern boundary.

There is considered to be a degree of mixing between groundwater and surface water bodies close to the tidal River Deel estuary. During high tide in the river, the gradient of water flow is expected to be from the river outwards into the surrounding limestone aquifer, reversing under low tide conditions.

Specifically, historical data indicates a negative impact on the groundwater quality at well BH202 adjacent to the River Deel in terms of bacteriological quality (elevated total and faecal coliform results), due to the Limerick County Council sewage discharge to the River Deel from their sewage treatment facility located within the Pfizer site.

The incidents in 2006 resulted in a detailed test programme and risk assessment of underground pipelines where there is a pumped flow involved. Remedial works are well underway, with remaining works due to be completed during August 2011. Also there are new secondary bunds around four groups of mixed process tanks. There is now a bund solely designated to the storage of waste solvent drums.

All incidents reported above have involved one-off incidents with short-lived impacts on groundwater. As most of the products handled at Pfizer are highly biodegradable (milk powder and sugars) no significant, long-term contamination of the soil or underlying bedrock aquifer are predicted.

Localised hydrocarbon contamination around fuel storage facilities is possible but has not been evident in groundwater sampling to date.

The current management strategy for groundwater is based on bi-annual monitoring to confirm the absence of contaminants in groundwater concentrations.

5. HIGH RISK FACILITY – SITE SPECIFIC ELRA

5.1. General

For High Risk facilities such as Pfizer, a detailed site specific ELRA should be conducted. The objectives of the proposed ELRA are:

- To identify and quantify environmental liabilities at the facility focusing on: unplanned, but possible and plausible events occurring during the operational phase.
- To calculate the value of financial provisions required to cover unknown liabilities.
- To identify suitable financial instruments to cover each of the financial provisions; and
- To provide a mechanism to encourage continuous environmental improvement through the management of potential environmental risks.

The proposed methodology is based on that provided in the EPA ELRA Guidance Document 2006. This detailed assessment includes a Risk Management Programme for the mitigation and management of any environmental liabilities identified at Pfizer. This programme is not required for the calculation or implementation of a financial provision at a facility. However, such a programme would encourage continuous environmental improvement and the reduction of environmental liabilities.

The ELRA covers environmental risks leading to a potential or anticipated liability. Environmental risks will be deemed to cover all risks to: surface water, groundwater, atmosphere, land and human health.

5.2. Methodology - Risk Identification, Likelihood and Consequence

The following steps were undertaken as part of the site specific ELRA;

- Risk Identification
- Risk Classification (includes an Occurrence Assessment and a Severity Assessment)
- Risk Evaluation
- Risk Prevention/Mitigation

5.2.1. Risk Identification

Risks were identified on the site through a combination of:

1. What-if analysis - A suggested method of carrying out this process is to initially identify all the 'processes' on site, list the hazards associated with each process, identify potential causes of failure of the processes and analyse the effect impacts on the environment.

2. Site Visit – A one day site visit of the facility was carried out to examine all process areas, storage areas and associated utilities present at the Pfizer Site.

Table 5.1: Example Hazard Identification Table

Risk ID	Potential Hazard	Environmental Effect
1	Describe scenario for occurrence of potential liability e.g. spill of acid from acid storage tank.	Describe consequence of proposed scenario e.g. spill of acids goes to the River Deel.

5.2.2. Risk Classification - Occurrence Analysis

Having identified the potential risk, the likelihood of its occurrence needs to be assessed. An analysis of historical data and existing environmental controls was the method used for estimating likelihood of identified potential risks occurring at Pfizer.

Table 5.2 provides the means to quantify the likelihood of occurrence.

Table 5.2: Risk Classification Table - Occurrence

Rating/ Score	*Category*	*Description*	*Likelihood of Occurrence (%)*
1	Very Low	Very low chance of hazard occurring in 30 yr period	0-5
2	Low	Low chance of hazard occurring in 30 yr period	5-10
3	Medium	Medium chance of hazard occurring in 30 yr period	10-20
4	High	High chance of hazard occurring in 30 yr period	20-50
5	Very High	Very high chance of hazard occurring in 30 yr period	>50

Important: When categorising the Occurrence Rating relating to a specific risk, the occurrence rating assigned must be based on the likelihood of the **event occurring and resulting in an environmental incident**. e.g. if assigning an occurrence rating to "*failure of a storage tank resulting in contamination of surface water*", the occurrence rating is not assigned to just the tank failing. It is based on the risk of that failure resulting in contamination of surface water. In doing so, account must be taken of all mitigation measures employed to prevent that failure or release resulting in contamination of surface water, i.e. presence of a bund, presence of a surface water diversion system, etc.

5.2.3. Risk Classification - Severity Assessment

Once the environmental impact had been identified one of the following consequences is assigned.

Table 5.3: Risk Classification Table - Severity Criteria

Rating/ Score	*Category*	*Description*	*Cost of Remediation (€)*
1	Trivial	No damage or negligible change to the environment	<10,000
2	Minor	Minor impact/localised or nuisance	10,000-100,000
3	Moderate	Moderate damage to the environment	100,000-500,000
4	Major	Severe damage to the environment	500,000-1,000,000
5	Massive	Massive damage to a large area, irreversible in medium term	>1,000,000

In order to determine an appropriate cost range for each of the Severity scores above, the following aspects were considered:

- The sensitivity of the receiving environment;
- The anticipated damage that would realistically be expected to occur as a result of an incident occurring at the site; and
- Current anticipated costs associated with remediation and clean up of environmental liabilities.

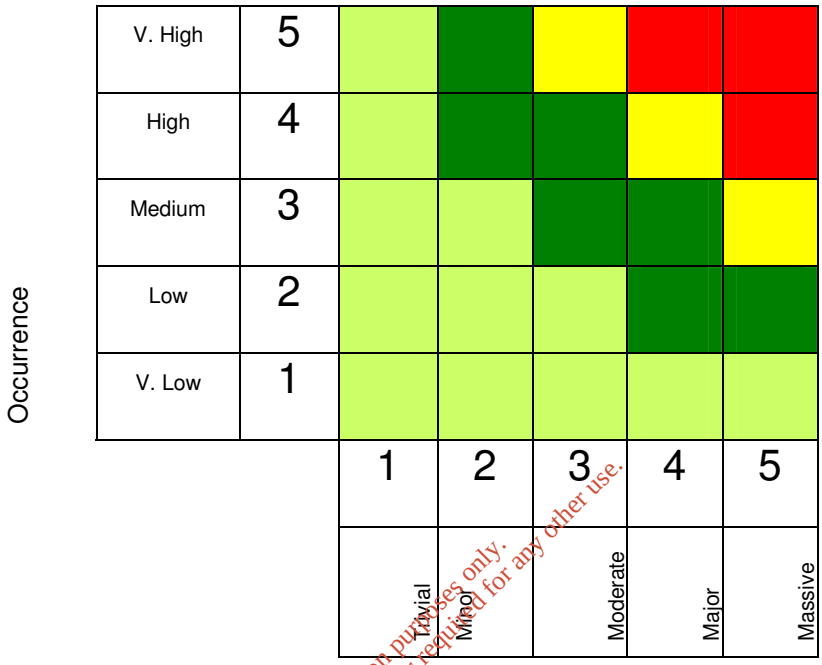
As per the EPA Guidance document, environmental risks will be deemed to cover all risks to: surface water, groundwater, atmosphere, land and human health. In categorising the severity of an event and therefore the cost of its remediation, one of the most significant costs (i.e. the one which can prove most difficult to fix a maximum anticipated financial provision) are costs associated with the remediation of effects on Human Health.

Based on the above considerations it is felt that the cost of remediation for the various severity categories outlined in Table 5.3 are appropriate and specific to the Pfizer site.

Important: When categorising the Severity Rating relating to a risk, the severity rating assigned must assume that all current mitigation measures in place have failed to prevent the environmental discharge to the environment, e.g. if assigning a severity rating to a failure in a storage tank resulting in contamination of surface water, the severity rating is based on the assumption that the material contained in the storage tank has discharged to surface waters, i.e. all mitigation measures employed to prevent that failure resulting in contamination of surface water have failed, i.e. bund failure has occurred, surface water diversion system has failed, etc.

5.2.4. Risk Evaluation

Having identified the hazard and decided on its likelihood and severity the significance of the risk is assigned. A risk score is determined by multiplying the occurrence score by the severity score. The risk scores can be tabulated in a risk matrix.



Where:

- **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.
- **Amber** / **Yellow** – These are medium-level risks requiring action, but are not as critical as a red coded risk.
- **Green (light and dark green**) – These are lowest-level risks and indicate a need for continuing awareness and monitoring on a regular basis. Whilst they are currently low or minor risks, some have the potential to increase to medium or even high-level risks and must therefore be regularly monitored and if cost effective mitigation can be carried out to reduce the risk even further this should be pursued.

For all risks ('high', 'medium' or 'low') an insurance policy or other financial instrument must be put in place to cover any liabilities.

With regard to 'medium' and 'high' risks the licensee must detail in the ELRA how these risks will be made 'acceptable'.

With regard to liabilities that are not covered by insurance, or other financial instrument, the licensee must indicate how these liabilities will be underwritten in the future.

5.2.5. Risk Prevention/Mitigation

Mitigation measures are assigned to each risk and each Risk Score is revised using post-mitigation severity and occurrence rankings. The risks are then re-ranked and tabulated in the risk matrix to illustrate the overall degree of risk reduction resulting from the risk mitigation measures. Where appropriate, the mitigation measures are accepted for implementation. A Risk Management Programme is then prepared which allocates a Risk owner for the ongoing management of risks and the implementation of risk mitigation measures. Timeframes are also allocated for the implementation of each risk mitigation measure.

5.3. Identification of Risks at Pfizer

Through a combination of site visits and utilising information supplied by Pfizer URS identified all of the key 'processes' (key relating to environmental risk) on site, listed the hazards associated with each process and identified any potential causes of failure of the processes. If any effect to the environment could be perceived from the failure the effect was analysed and so the potential failure became a Risk. A Risk Register was developed which contained all the Risks identified on site. Table 5.4 illustrates the Risk Register.

Table 5.4: Pfizer Risk Register

Risk ID	Potential Failure Mode
1	Wastewater treatment plant overflow
2	Wastewater treatment plant overloading and so failure of biological treatment
3	Release of petroleum oil product to ground or surface water
4	Accidental spillage of hazardous chemicals in yard areas during transport to and from local storage (e.g., chlorine based disinfectants, detergents, thinners, coating laquor)
5	Accidental spillage of drummed solvents and laquor in the waste storage compound
6	Accidental release of food oils from ISO tanker parking areas
7	Failure of underground pipelines or sumps
8	Failure of over ground secondary containment
9	Overfilling of process storage tanks
10	Loss of containment of contaminated firewater
11	Contamination of by-product sold as animal feed
12	Blocking of dryer cyclone
13	Generation of odours

These risks were assessed against the risk classification tables (RCTs) as provided in Table 5.2 and 5.3. The risk classification table was designed to reflect the critical levels of risk appropriate to the Pfizer site. Ratings, taken from a risk classification table, were applied to the severity and chance of occurrence of each risk. Table 5.5 below illustrates the assessment carried out for each risk in terms of its severity and likelihood of occurrence.

Table 5.5 – Risk Assessment

Risk ID	Process	Potential Hazard	Environmental Effect	Occurrence Rating	Basis of Occurrence	Severity Rating	Basis of Severity
1	Operation of Wastewater Treatment Plant	Wastewater treatment plant overflow	Pollution of River Deel and potential impact on groundwater.	1	No previous incidents in 33 years of Pfizer operation. Adequate space volumetric capacity is maintained in the Balance Tank and the SBR's.	3	Due to proximity to tidal zone and non-hazardous nature of effluent, effect of release would be short to medium term, however large quantity of wastewater would be released.
2	Operation of Wastewater Treatment Plant	Wastewater treatment plant overloading and so failure of biological treatment	Release of partially treated wastewater to the River Deel and threat of pollution.	2	No IPPCL ELV breaches in 2010. New better management of process tanks. Procedures and training implemented.	2	Although partially treated effluent would be non-hazardous in nature, some adverse effects to River Deel water quality could be expected.
3	Storage of gas oil	Release of gas oil to ground or surface water	Pollution of soil and groundwater	1	No history of oil pollution of soil or groundwater on the site. Gas oil tanks are bunded, and bunds are regularly integrity tested. Also, there is an oil interceptor on site.	3	Vulnerable aquifer but oil products are not very mobile and contamination would probably be localised.

Table 5.5 – Risk Assessment

Risk ID	Process	Potential Hazard	Environmental Effect	Occurrence Rating	Basis of Occurrence	Severity Rating	Basis of Severity
4	Transport of chemicals to and from local storage	Accidental spillage of hazardous chemicals in yard areas during transport (e.g., chlorine based disinfectants, detergents, thinners, coating laquor)	Pollution of River Deel through migration of pollutants through the surface water drainage system.	1	No previous incidents in 33 years of WNI operation. Sodium hypochlorite is now delivered in a 1000 litre IBC, and transfer is supervised into a bunded tank. Also, there is a new oxonia automated bunded delivery system which is contained. In 2010 a new storage area was constructed for the storage of aluminium sulphate and a salt saturator. A risk assessment was carried out by URS in December 2009 for the area.	3	Amounts released probably small due to storage in small drums. However, chlorine product largest risk with large adverse impact on salmonid population in the river possible, even in small quantities.
5	Current storage arrangements	Accidental spillage of drummed solvents and laquor in the waste storage compound.	Potential pollution of soil and groundwater immediate to storage areas.	1	No previous incidents in 33 years of WNI operation. Detailed risk assessment completed in 2007. Waste storage compound upgrade	3	Solvent containing materials, including toluene, with vulnerable and regionally important aquifer beneath the site. Maximum possible amount of spillage is

Table 5.5 – Risk Assessment

Risk ID	Process	Potential Hazard	Environmental Effect	Occurrence Rating	Basis of Occurrence	Severity Rating	Basis of Severity
					complete. All solvent transfers handled on a concrete surface.		1000 litres.
6	Parking of ISO tankers	Accidental release of food oils from ISO tanker parking areas.	Potential pollution of soil and groundwater immediate to storage areas.	1	No previous incidents in 33 years of WNI operation. The tanks are built to withstand a drop and rough handling during the transport.	2	Large quantity of product loss possible. However, non-hazardous material.
7	Process effluent and domestic effluent drainage	Failure of underground and overground pipelines or sumps.	Potential pollution of soil and groundwater and possibly River Deel (depending on nature of failure).	3	Four recorded incidents between 2004 and 2008. However, on-going testing and repair programme implemented. Underground pipe testing involving hydrostatic inspections and CCTV is conducted in different area of the site each year. The entire site will be	3	Costs to date relating to remediation of environment from known spills.

Table 5.5 – Risk Assessment

Risk ID	Process	Potential Hazard	Environmental Effect	Occurrence Rating	Basis of Occurrence	Severity Rating	Basis of Severity
					covered by the end of August 2011. Improvements included replacement of some pipes and manholes bringing pipes above ground and inserting liners within the piping.		
8	Storage of potentially polluting materials	Failure of over ground secondary containment.	Potential pollution of soil and groundwater and possibly River Deel (depending on nature of failure).	1	No previous incidents in 34 years of the sites operation. There are new secondary bunds around all four mixed process tanks. A new bund was constructed in 2010 due to the installation of two new tanks for storage of aluminium sulphate and a salt saturator.	3	Releases likely to be observed early. However, with high BOD dairy based material storage, sudden and large releases of such material could have a high impact.
9	Bulk storage of liquid raw materials	Overfilling of process storage tanks	Release of potentially polluting substances to River Deel and/or soil.	1	The only overfilling incident occurred on site in 2008. Consequently, process storage tanks	3	Large release directly to ground & groundwater or surface water possible however, good

Table 5.5 – Risk Assessment

Risk ID	Process	Potential Hazard	Environmental Effect	Occurrence Rating	Basis of Occurrence	Severity Rating	Basis of Severity
					were fitted with high level alarms and automatic fill shut off. All process storage tanks are bunded since 2008.		management of the process tanks and secondary containment and improved instrumentation.
10	All processes	Loss of containment of contaminated firewater	Potential pollution of River Deel and/or groundwater.	1	No previous incidents in 33 years of WNI operation.	4	Assumes large fire and so generation of large volumes of firewater.
11	All processes	Contamination of by-product sold as animal feed	Health effects on animals or humans.	1	No recorded incidents.	4	By-products in question not contaminated with substances that can significantly adversely effect animal or human health. However, given recent lawsuits with another Pfizer facility , the financial exposure from any contamination event, regardless of risk, could be significant.
12	Air emissions	Blocking of cyclones resulting	Nuisance	2	Only one dust complaint	1	Localised impact

Table 5.5 – Risk Assessment

Risk ID	Process	Potential Hazard	Environmental Effect	Occurrence Rating	Basis of Occurrence	Severity Rating	Basis of Severity
	from dryers	in dust deposition			received in recent years.		
13	Various	Odorous Fugitive Emissions	Odour Nuisance	2	Only one odour complaint received in recent years.	1	Localised impact

5.4. Assessment of Risks at Pfizer

5.4.1. Risk Register

The risk register below ranks the risks in order to prioritise mitigation and management measures.

Table 5.6 Risk Register ranked by Risk Score

Risk ID	Description	Occurrence	Severity	Overall
7	Failure of underground and overground pipelines or sumps.	3	3	9
2	Wastewater treatment plant overloading and so failure of biological treatment	2	2	4
11	Contamination of by-product sold as animal feed	1	4	4
10	Loss of containment of contaminated firewater	1	4	4
9	Overfilling of process storage tanks	1	3	3
8	Failure of over ground secondary containment.	1	3	3
5	Accidental spillage of drummed solvents and laquor in the waste storage compound. Protective drain blocked with silt.	1	3	3
4	Accidental spillage of hazardous chemicals in yard areas during transport (e.g., chlorine based disinfectants, detergents, thinners, coating laquor)	1	3	3

Table 5.6 Risk Register ranked by Risk Score

Risk ID	Description	Occurrence	Severity	Overall
3	Release of gas oil to ground or surface water	1	3	3
1	Wastewater treatment plant overflow	1	3	3
13	Odorous Fugitive Emissions	2	1	2
12	Blocking of cyclones resulting in dust deposition	2	1	2
6	Accidental release of food oils from ISO tanker parking areas.	1	2	2

5.4.2. Risk Matrix

The risk matrix below, specific to Pfizer, pictorially indicates the critical nature of each risk. (Risk ID's from the Risk Register have been used to complete this matrix.)

Table 5.7 – Risk Matrix (specific to Pfizer)

Occurrence		Severity					
		1	2	3	4	5
		Trivial	Minor	Moderate	Major	Massive
V. High	5					
High	4					
Medium	3			7		
Low	2	12, 13	2			
V. Low	1		6	1, 3, 4, 5, 8, 9	10, 11	

Where:
Red is a high level risk.
Yellow is a medium level risk.
Green (light and dark) is a low level risk.

Table 5.7 above indicates that there are currently no risks identified in the red zone or yellow zones requiring priority attention. This is a result of existing environmental controls in place at the site. All risks identified are located in the green zone (light and dark) indicating that these are currently low risk. However, it is important to note that these risks are considered low risk as a result of existing controls measures employed at the site aimed at reducing/eliminating both the occurrence and where this is not possible the severity of these risks. There is a need for continuing awareness and monitoring of these risks on a regular basis.

5.5. Risk Prevention, Mitigation and Management

The risk assessment and categorisation phase identified no red or yellow zone risk, which requires immediate action as outlined above. All risks were classified as green zone risks. Current measures to control these risks are considered adequate with no further control measures considered necessary. However, the green zone risks may have the potential to increase to yellow or red zone risks, and where additional risk management measures are available to manage them at their current levels or reduce them further, these may be implemented if considered cost-effective

5.5.1. Quantification of Unknown Environmental Liabilities

The costs associated with the known environmental liabilities (e.g. closure and aftercare costs and on-site contamination) for the Pfizer facility were calculated through the preparation and costing of the RMP (refer to Site Specific RMP prepared for Pfizer).

For the unknown liabilities identified in this report a financial model is necessary to estimate the environmental liability associated with these risks.

Each Risk has two characteristics that are derived from the Risk Classification Tables (See tables 5.2, 5.3 and as applied in Table 5.5) that are used in the financial models:

• The range in probability (X-Y%) of the risk occurring

• The range in cost implications (€A-B) if the risk occurs

The requirements of the financial model must first be defined in terms of worst, most likely or best case scenarios. If the model is for the worst case scenario, then the higher end of each range is used in the calculations, if the model is for the most likely case then the median of each range is used and similarly if the best case scenario is required then the lower end of each range is used resulting in the lowest cost.

The simplest form of financial model can be based on simply multiplying the minimum, median or maximum value of each range for each Risk (depending on the scenario considered) and totalling the values for each Risk in the Register.

For the Pfizer facility the worst case scenario was calculated. Table 5.8 illustrates how the financial output for the worst case scenario is calculated.

From this, financial instruments for unknown liabilities can be selected as outlined in Section 6 of this report.

Table 5.8– Worst Case Scenario Financial Model

Risk ID	Potential Hazard	Occurrence Rating	Likelihood of Occurrence Range (%)	Severity Rating	Cost Range (€)	Worst Case Probability (%)	Worst Case Severity (€)	Most Likely Cost (€)
7	Failure of underground and overground pipelines or sumps.	3	50 to 100	3	100,000-500,000	20	500,000	100,000
11	Contamination of by-product sold as animal feed	1	0 to 5	4	500,000-1,000,000	5	1,000,000	50,000
10	Loss of containment of contaminated firewater	1	0 to 5	4	500,000-1,000,000	5	1,000,000	50,000
1	Wastewater treatment plant overflow	1	0 to 5	3	100,000-500,000	5	500,000	25,000
3	Release of gas oil to ground or surface water	1	0 to 5	3	100,000-500,000	5	500,000	25,000
4	Accidental spillage of hazardous chemicals in yard areas during transport (e.g., chlorine based disinfectants, detergents, thinners, coating laquor)	1	0 to 5	3	100,000-500,000	5	500,000	25,000
5	Accidental spillage of drummed solvents and laquor in the waste storage compound. Protective drain blocked with silt.	1	0 to 5	3	100,000-500,000	5	500,000	25,000

Risk ID	Potential Hazard	Occurrence Rating	Likelihood of Occurrence Range (%)	Severity Rating	Cost Range (€)	Worst Case Probability (%)	Worst Case Severity (€)	Most Likely Cost (€)
9	Overfilling of process storage tanks	1	0 to 5	3	100,000-500,000	5	500,000	25,000
8	Failure of over ground secondary containment.	1	0 to 5	3	100,000-500,000	5	500,000	25,000
2	Wastewater treatment plant overloading and so failure of biological treatment	2	5 to 10	2	10,000-100,000	10	100,000	10,000
6	Accidental release of food oils from ISO tanker parking areas.	1	0 to 5	2	10,000-100,000	5	100,000	5,000
12	Blocking of cyclones resulting in dust deposition	2	5 to 10	1	<10,000	10	<10,000	1,000
13	Odorous Fugitive Emissions	2	5 to 10	1	<10,000	10	<10,000	1,000
Total worst-case cost of unknown liabilities (excluding CRAMP)								**367,000**
Site Closure note 2								**2,099,738**
Total worst-case cost of unknown liabilities (including site closure)								**2,466,738**

Note 1: The costs associated with a closure of the facility or with remediation of contaminated soils and groundwater are dealt with in the Residual management Plan along with details of the financial provisions in place to deal with this. (*) This figure is used instead of the calculation procedure described in Section 5.5.1 since the revised Residuals Management Plan, dealing with site closure, has separately provided a cost estimate (shown in this table).
Note 2: The amount included for site closure was taken from the CRAMP prepared for the site in March 2011.

6. FINANCIAL PROVISION

6.1. Current Financial Provisions

In the preceding sections we have summarised the site sensitivity, known historic environmental liabilities and the measures, both technical and managerial, currently in place to eliminate/reduce the risk of new environmental liabilities arising.

It has been concluded that the sites environmental and safety management system is robust in terms of preventing the development of any new significant off-site environmental liability.

In the following sections, we discuss the financial provisions at the site and whether these provisions are adequate to satisfactorily address the liabilities identified in section 5.

6.2. Current Financial Provisions

Pfizer Ireland Pharmaceuticals, Askeaton, is a component site of Pfizer Ireland Pharmaceuticals. Pfizer Inc. is the ultimate parent company of Pfizer Ireland Pharmaceuticals. Pfizer Inc., which is headquartered in New York, discovers, develops, manufactures and markets leading prescription medicines and healthcare solutions, for humans and animals. Pfizer Inc. has total consolidated assets of $212 billion (USD) as at 31 December 2009 and consolidated net income in excess of $8.6 billion (USD) for the financial year ended 31 December 2009.

In common with many multinational companies, Pfizer maintains a global public liability insurance providing indemnity in respect of legal liabilities arising from, for example, immediate, sudden and unforeseen discharge consequent upon an accident or due to defective drains, sewers or sanitary arrangements. The aggregate limit set for environmental liabilities in this respect is US$10,000,000 with no sub-limits for any particular type of claim and no requirement for Pfizer to assume any proportion of the costs before the indemnity applies.

The risks identified in the site-specific ELRA are most likely to arise from particular discrete and essentially sudden incidents such as fire, explosion, spillage, equipment failures, and process malfunctions. Such incidents would be detected by plant systems and would therefore be known events. Any potential environmental damage or contamination arising from such incidents would therefore be covered by the existing insurance arrangements. The current level of indemnity is more than adequate to cover the worst-case scenario financial model in the ELRA.

A discovery and confirmation of previously unknown environmental liabilities arising from gradually operating causes would be characterised and the costs of remediation would be estimated. Any required remediation would be funded centrally by Pfizer in a similar manner to that for RMP-associated costs. A scope of remediation work would be defined and developed, and a dossier then prepared for Pfizer central management. If approved, central funding would be released to cover the defined work. The release of funds may be structured as required to cover immediate and short-term activities, and if necessary,

funds may be released over more extended time periods to cover longer-term requirements, for example over several years or as required.

On the assumption that the risks in the worst-case scenario financial model defined in the site-specific ELRA, were to give rise exclusively to previously unknown environmental liabilities to be discovered at a future time (which is highly unlikely), then it is considered that the worst-case costs of these unknown liabilities would be adequately covered by Pfizer central funding as described.

Pfizer reviews its insurance and financial arrangements on a regular basis for its ongoing and continued adequacy. Any changes or updates to such arrangements shall be described in ELRA reviews to be submitted to the Agency.

6.3. Assessment of Pfizer Financial Provisions

The environmental liabilities identified and assessed in this report (refer to Section 5) are in the main unforeseen or unanticipated events that could occur suddenly as a result of an accident or failure of control systems. Other liabilities identified are the result of gradual and unforeseen discharge consequent upon failure of control systems which may result in a discharge to the environment such as leaking drains or undetected leaks in piperack systems.

Having consideration for the worst-case costs calculated in Table 5.10, a comparison of existing financial provisions presented in Section 5.1 above may be made with the type of unknown liabilities identified at the site.

Table 6.1 – Assessment of Pfizer Financial Provision

Risk Type	Existing Pfizer Financial Provision	Comment
Immediate, sudden and unforeseen discharge consequent upon an accident.	Pfizer Global Insurance	Pfizer Insurance coverage financially adequate to cover any liabilities identified.
Gradual unforeseen discharge consequent upon failure of control systems.	Pfizer Central Funds	This type of Financial Provision is adequate to cover any unknown liabilities which may arise but which may not be covered under the existing Pfizer Global insurance.
Closure Restoration and Aftercare Liabilities	Pfizer Central Funds	Pfizer have already used this to decommission and remediate other sites and facilities and it is deemed an adequate financial provision

Risk Type	Existing Pfizer Financial Provision	Comment
		instrument to cover the associated costs.

Based on the assessment of the current financial provisions in place, it is considered unlikely that Pfizer requires any additional financial provisions beyond those currently employed by the site as detailed in Section 6.1.

A statement of Parent Company Financial Guarantee by Pfizer Inc., approved by the EPA in February 2011, is presented in Appendix B.

Appendix A - Site Sensitivity Assessment

SITE CHARACTERISATION

Site Sensitivity

The site is adjacent to the main Limerick-Foynes road near Askeaton town. The surrounding land use is predominantly agricultural, consisting mainly of pasture land. The site is bordered on its eastern perimeter by the River Deel, a tributary of the river Shannon.

Site Geology

Soil and groundwater investigation work has been completed on behalf of Wyeth by URS Dames & Moore in January 2001 (Report 15282-143 dated 19 April 2001) The drilling investigation indicated that subsoils on site comprise of glacial till deposits with an increasing sand content moving west to east towards the Deel estuary. The depth to bedrock is approximately 3m.

Bedrock beneath the site has been mapped as Waulsortian limestone by the Geological Survey of Ireland (GSI). This limestone comprises fresh, massive, blue grey, fine to coarsely crystalline, occasionally cherty, unaltered, fossiliferous limestone. According to the Geological Survey of Ireland Online Maps, the bedrock aquifer in this region is classified as a Regionally important aquifer – Karsified, conduit (Rkc). This suggests the limestone is highly fractured and highly permeability. Local knowledge of the groundwater by site personnel supports this data.

Site Hydrogeology

The main mass of bedrock is largely impermeable, with groundwater movement only occurring within fractures in the bedrock. There is evidence for the karstification of this limestone in the Askeaton area, and local wells are subject to large variation in yields. This indicates that groundwater flow in karstified fracture zones will depend on whether or not wells intersect the fractures. The GSI (Geological Survey of Ireland) have classified the aquifer beneath the site as a regionally important karst aquifer, but with the development potential limited by concentrations of flow.

There are 4 wells reported on the GSI database within an approximate 2km radius of the site; 3 of the wells are recorded as having unknown yields and the fourth has a poor yield (<44m^3 / day). It should be noted that the well records in Ireland are not complete –wells used for domestic purposes are often not declared by the owners. Therefore there may be additional wells located within a 2km radius of the site.

The GSI have classified the aquifer beneath the site as being extremely vulnerable to contamination. The classification is based on the low soil thickness in the area as well as the karstified nature of the aquifer.

Groundwater flows from west to east across the site toward the Deel estuary, following the local topography.

Surface Water

The Pfizer site is located on a gently sloping estuarine site, which slopes down to the east to the estuary of the River Deel. There is a sharp drop on the eastern side of the site to the Deel estuary, which is bordered by steep slopes and rock outcrops on both sides, just to the east of the site. The land also slopes down gently from the site to the north towards the Shannon estuary and to the south towards the town of Askeaton. The River Deel is classified by the EPA River Quality Report 2005 (http://www.epa.ie/rivermap) as moderately polluted (Q3/Class C) at the nearest measurement point, Kilcool Bridge, approx 7.0km South and upstream of the site.

Limerick County Council indicate that the public water supply in the Askeaton area is abstracted from the River Deel close to the bridge in Askeaton village and upstream of the site.

The River Deel is fished although not on any large scale. However the inner Shannon South shore is a designated proposed Natural Heritage Area and a local boat repair facility is situated approximately 150m down river from the site. As these sensitive areas are near the site and hydraulically down gradient, it is a potential vulnerable receptor for any potential contamination from the site.

The River Deel is assumed to be the discharge point for site groundwater (see above) and is the discharge point for site surface water and effluent outfall

Treated Effluent from the site is discharged to a sewer owned and operated by Wyeth Nutritionals Ireland. The effluent comprises trade effluent, sewage effluent and contaminated waste water domestic and trade effluent. The effluent is treated in the onsite waste water treatment plant prior to discharge to the River Deel. Stormwater is discharged from the site in a separate stormwater pipeline system. There are also 8 separate surface water discharges from the site.

In 2001 Wyeth Nutritionals Ireland commissioned a Dye study at the effluent outfall to determine the adequacy of the outfall to ensure that the location and the mixing zone is compatible with protection of the receiving water. The study concluded that under 2001 emission rates the receiving waters are capable of diffusing the effluent with no significant impact to the surrounding environment.

Sensitive Receptors

The overall site sensitivity with regard to the development of significant environmental liabilities is considered to be moderate to high for the following reasons:

The surrounding land use is predominantly agricultural, consisting mainly of pasture land.

The site is situated approximately 1 km from Askeaton town and a number of residential dwellings are also located in the immediate vicinity of the site and are considered potentially sensitive receptors.

The nearest surface water bodies and hence potential receptors for accidental releases from the site include the River Deel and Shannon Estuary. Neither body of water is particularly sensitive given their tidal/saline nature and the very large dilution volumes available. Neither supports large-scale fisheries. However the inner Shannon South shore is a candidate Special Area of Conservation and the River Deel is utilised by the local boat repair facility. As this sensitive area is near the site and hydraulically down gradient, it is a potential vulnerable receptor for any potential contamination from the site.

The public water supply in the Askeaton area is abstracted from the River Deel close to the bridge in Askeaton village and upstream of the site.

The aquifer beneath the site has been classed by the GSI as being extremely vulnerable to contamination.

Animal Health Issues

The Askeaton area was subject to a number of animal health issues during the early 1990s. It is noted that Wyeth Nutritionals Ireland was never implicated or involved at any stage.

During subsequent investigations (1995-1998) managed by the Irish Environmental Protection Agency (published 2001) the Askeaton area, including lands close to the Wyeth Nutritionals Ireland were the subject of an extensive program, which included the assessment of a number of environmental factors such as air, soil and ground and surface water quality. Soils within 1 km (to the east and west) of the site were tested for a range of nutrients, heavy metals, pesticides, hydrocarbons, dioxins and PAHS. All analytes tested were below the respective guidelines values (mostly Dutch C Limits) and were within the typical background ranges for Irish agricultural soils.

Appendix B - Parent Company Guarantee

Pfizer Inc
235 East 42nd Street
New York, NY 10017-5755

Financial Provision
Licence Register No. P0395-02

The Wyeth facility located at Askeaton, Limerick, County Limerick (the **"Facility"**) is owned by Pfizer Ireland Pharmaceuticals [formerly called Pfizer (NEW PIP) Holdings] (the **"Licensee"**), an unlimited liability company incorporated under the laws of Ireland and registered in the Companies Registration Office [Registered Number 490938]. Pfizer Inc., a Delaware corporation, (**"Pfizer Inc."**) is the ultimate parent company of Pfizer Ireland Pharmaceuticals.

The Facility is a dairy products production facility and is licensed by the Environmental Protection Agency (**"EPA"**) under Integrated Pollution Prevention and Control Licence, reference number P0395-02 (the **"Licence"**).

Pfizer Inc. carries on business as a research-based global biopharmaceutical company and owns a large number of affiliates and subsidiaries in a number of different countries, the number of which may change from year to year. Certain affiliates of Pfizer Inc. also carry on the business of manufacturing pharmaceutical, animal health, consumer health and nutritional products. Pfizer Inc. has total consolidated assets of $212 billion (USD) as at 31 December, 2009 and consolidated net income in excess of $8.6 billion (USD) for the financial year ended 31 December 2009.

Pfizer Inc. undertakes that it will arrange and pay for the completion to the satisfaction of the EPA of all works required to ensure that the conditions of the Licence are complied with in the event that the Licensee does not carry out or procure the carrying out of such works for whatever reason.

Pfizer Inc. further undertakes to meet any financial commitments or liabilities to the EPA or to any relevant Local Authority relating to environmental pollution as provided for in the ELRA, RMP or CRAMP as the case may be for the Facility, that have been, or will be, entered into or incurred by the Licensee in carrying on the licensed activity in accordance with the terms thereof or in consequence of ceasing to carry on that activity and in the event that the Licensee fails to meet those commitments or liabilities.

Where the Licensee fails to meet any financial commitments or liabilities, and where Pfizer Inc. has not had the works referred to above carried out within a reasonable time of being called upon to do so by the EPA, Pfizer Inc. undertakes to pay to the EPA the cost of so doing. The EPA may use any such payment to carry out or arrange for the carrying out of such works, either by itself or by a third party, and / or to reimburse any person who has carried out those works to its satisfaction. Where the liability of the Licensee has not been quantified, Pfizer Inc. undertakes to pay the amount of liability reasonably estimated by the Agency subject to a reimbursement or additional payment when the final liability is determined.

The Facility is committed to ensuring protection of the environment in its operations and regards this as an integral part of its normal business practice. This includes a commitment to safe and responsible residuals management where required, including the provision of funding to implement and progress any required residuals management.

This Financial Provision shall enter into force on 27 January 2011 and shall not be unilaterally terminated. In the event of sale of the Facility or Pfizer Ireland Pharmaceuticals, Pfizer Inc. undertakes to continue this Financial Provision until such time as the EPA shall have approved the transfer of the Licence, as applicable, or until the new owner of the Facility or Pfizer Ireland Pharmaceuticals respectively shall have entered into a financial security agreement to the satisfaction of the EPA.

Pfizer Inc. confirms that this letter is intended to constitute a legally binding obligation on it, and shall be subject to the exclusive jurisdiction of the Courts of Ireland and subject to the laws of Ireland.

Pfizer Inc acknowledges that the purpose of the licence is to prevent environmental pollution as defined in the Environmental Protection Agency Act 1992 as amended, and to remediate such pollution where it has occurred; and that accordingly this undertaking should be interpreted in order to ensure that that purpose is achieved.

Pfizer Inc. warrants that it is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware, that it has all requisite corporate power to enter into this undertaking and that this undertaking has been duly executed by it in accordance with the laws of the State of Delaware and that the same is a valid and enforceable obligation under the laws of the State of Delaware.

For and behalf of:

PFIZER INC.

By: _____

Name: Camilla Uden
Title: Vice President & Assistant Treasurer
Date: 26-01-2011