#### **Wyeth Nutritionals Ireland**

Askeaton, Co. Limerick Ireland 061 392168 tel 061 392155 fax



Ms. Liz Leacy
Office of Licensing, Climate & Resource Use,
Environmental Protection Agency,
PO Box 3000,
Johnstown Castle Estate,
Co. Wexford.

18<sup>th</sup> November 2010

Re: AHP Manufacturing B.V. trading as Wyeth Nutritionals Ireland, Askeaton, Co. Limerick - Licence Register Number P0395-02 – Transfer.

Dear Ms. Leacy:

We refer to the application made to the Agency by AHP on 11 December 2009 in relation to the transfer of the above licence to a new entity. At the time of the original application, which the identity of the proposed transferee nor the date from which the transfer would take effect were known. This is no longer the case, and the proposed transferee is a newly incorporated company Prizer (NEW PIP) Holdings while the transfer is to take effect from 27 January 2011.

Accordingly, enclosed please find by way of updating the application already submitted by AHP:

- an original and 1 hard copy and 2 electronic (PDF) copies of a completed Transfer of a Licence Application Form for the transfer of Licence Register Number P0395-02 from 'AHP Manufacturing B.V. trading as Wyeth Nutritionals Ireland' to 'Pfizer (New PIP) Holdings'.
- We declare by this letter that the information contained on the electronic copies of the Transfer is the same as that in the original.

As outlined in the application form the date that the transfer is to take effect from is 27 January 2011.

Wyeth Nutritionals Ireland is a business name of AHP Manufacturing bv., a company incorporated (Reg. No. 80067) with limited liability in The Netherlands Registered in Ireland – No. E3277 Managing Directors: J.H.G. Neels (Dutch)

J.H.G. Neels (Dutch)
E. Slijkoord (Dutch)
L. Blauwhoff (Dutch)
A. Petrunoff (US)
D. Reid (US)
A. Th. W. M. Van der Knaap (Dutch)
R. Van Aperen (Dutch)

Peter Duffy (Irish)
Paul Duffy (Irish)

## Wyeth

Trusting this is to the satisfaction of the Agency. Should you, however, have any queries please do not hesitate in contacting me.

Yours sincerely,

Brian Shiel

Environmental, Health & Safety Manager

Consent of copyright owner required for any other use.





# Licensing

Transfer of a Licence Application Form

This document does not purport to be and should not be considered a legal interpretation of the provisions and requirements of the Waste Management Acts, 1996 to 2008 / Environmental Protection Agency Acts 1992 to 2007.

#### **Environmental Protection Agency**

P.O. Box 3000, Johnstown Castle, County Wexford Telephone: 053-9160600 Fax: 053-9160699



Not withstanding the provisions of Section 47 of the Waste Management Acts 1996 to 2008 or Section 94 of Environmental Protection Agency Acts 1992 to 2007 the following should be completed when applying to the Agency for the transfer of a Waste or IPPC Licence.

Licence Register Number	P0395-02	
Contact details for a contact person or persons in relation to the application to transfer.	Brian Shiel EHS Manager AHP Manufacturing B.V. T/A Wyeth Nutritionals Ireland, Askeaton Co. Limerick. Telephone No.: 061 601307 Fax No.: 061 601157 E-mail:brian.shiel@pfizer.com	
Location of activity to which the licence relates	Askeaton, Co. Limerick.	
Name address and contact details of current licence holder	Askeaton, Co. Limerick.  Brian Shiel EHS Manager AHP Manufacturing B.V. T/A Wyeth Nutritionals Ireland, Askeaton Co. Limerick, 1977 Telephone No.: 061 601307 Fax No. 061 601157 E-mant:brian.shiel@pfizer.com	
Name address and contact details of proposed transferee	Brian Shiel EHS Manager Pfizer (New PIP) Holdings Pfizer Askeaton Askeaton Co. Limerick. Telephone No.: 061 601307 Fax No.: 061 601157 E-mail:brian.shiel@pfizer.com	
When do the applicants want the transfer to take effect?	27 January 2011	



### Transfer of Licence Application Form

Classes / Nature of Activity	Class: 7.2.2 The manufacture of dairy products where the processing capacity exceeds 50 million gallons of milk equivalent per year, not included in paragraph 7.2.1.  Class: 2.1 The operation of combustion installations with a rated thermal input equal to or greater than 50 MW.
Attachment A: Licence	Please find attached as <b>Attachment A</b> , a copy of IPPC Licence Register No. P0395-02.





#### <u>Transfer of Licence Application Form</u>

#### Attachment B:

Please find as **Attachment B** the following information:

Pfizer (New PIP) Holdings.

- Attachment B.(a) Certified Copy of Certificate of Incorporation of Pfizer (New PIP) Holdings
- Attachment B.(b): Company's Number in Company's Registration Office
- Attachment B(c): Particulars of Registered Office of Company –

Does the proposed transferee have a parent company? If so please provide details here.

The immediate corporate parent of Pfizer (New PIP) Holdings is Pfizer Ireland Ventures [Registered No. 331419]. The corporate parent and beneficial owner of Pfizer Ireland Ventures and the indirect parent of Pfizer (New PIP) Holdings in Europe is CP Pharmaceuticals International CV.\*

\* C.P. Pharmaceuticals International C.V. is a limited partnership (commanditaire vennoottschap) formed and established under the law of the Netherlands and for all purposes represented by and acting through its general partner, Pfizer manufacturing LLC, a company organized under the laws of the State of Delaware, United States of America, with an address at 235 East 42<sup>nd</sup> Street, New York, New York 10017, United States of America, and Pfizer Productions LLC, a company organized under the laws of the State of Delaware, United States of America, with an address at 235 East 42<sup>nd</sup> Street, New York, New York 10017, United States of America, in their capacity as general partners of such C.V.

Does the proposed transferee have any subsidiaries involved in the industrial installation or waste facility management? If so please give details here.

Not Applicable



## Transfer of Licence Application Form

Attachment C: Fit and Proper Person	Please find attached as Attachment C information to address the following:	
	1. A statement indicating whether the applicant or other relevant person has been convicted under the PoE Act, the Waste Management Act 1996 to 2008, the Local Government (Water pollution) Acts 1977 and 1990 or the Air Pollution Act 1987.	
	2. A statement detailing that there is no change in management of the facility.	
	3. A statement to show that the person is likely to be in a position to meet any financial commitments or liabilities that may have been or will be entered into or incurred in carrying on the activity to which the application relates or in consequence of ceasing to carry out that activity.	
Attachment D: Liabilities, requirements & obligations	Please find attached as <b>Attachment D</b> a signed statement that the applicant Pfizer (New PIP) Holdings has assumed and accepted all liabilities, requirements and obligations provided for in or arising under Dicence Register No. P0395-02, or revised licence, regardless of how and in respect of what period, including the period prior to the transfer of the licence or revised licence as they may arise.	
Attachment E: Transferee Licence details	Please find as <b>Attachment E</b> information relating to the proposed transferee, their parent company or any 'relevant person' having an application for a licence granted, or having an application for a licence rejected; having a licence revoked or being refused as a transferee for a licence	
Attachment F: Estimated Expenditure & Financial Provisions	Please provide, as <b>Attachment F</b> , a plan showing the estimated expenditure for each phase of the activity/activities. The plan should include the likely costs of:  (i) Abatement Installation, Control & Monitoring  (ii) Closure & Remediation of the site  (iii) Clean-up following a plausible accident/incident  (iv) Long-term aftercare for residual environmental liabilities.	
	The Plan should include a statement or details of provisions made for the underwriting of these costs/liabilities.	
	Please find information attached as <b>Attachment F.</b>	



### <u>Transfer of Licence Application Form</u>

Application Fee	IPPC Licence Transfer Application – A cheque for €2,000 has previously been submitted.

We, the undersigned, are applying to the Environmental Protection Agency, as per Section 94 of the Environmental Protection Agency Acts 1992 to 2007 (IPPC Transfer) for the transfer of licence no P0395-02 from AHP Manufacturing B.V. T/A Wyeth Nutritionals Ireland to Pfizer (New PIP) Holdings.

Signed:	Signed :
Licensee Mr. Jim Shorten Managing Director AHP Manufacturing B.V. T/A Wyeth Nutritionals I Askeaton, Co. Limerick.	Proposed Transferee  Mr. Peter Duffy  For and on behalf of Pfizer (New PIP) Holdings  ireland,
Date:	Date:
Ŷ	Company Seal
Company Seal	Company Seal

### Transfer of Licence Application Form

#### ATTACHMENT A Licence Number P0395-02

Consent of copyright owner required for any other use.

This licence was amended on 9<sup>th</sup> June 2006 under Section 82(11) of the Environmental Protection Acts, 1992 and 2003. The details of the amendment must be read in conjunction with this licence. The amendment document is entitled 678 S82(11)

Amendment A.

This licence was amended on 14<sup>th</sup> June 2007 under Section 96(1) (b) and (c) of the Environmental Protection Agency Acts, 1992 and 2003. The details of the amendment must be read in conjunction with this licence. The amendment document is entitled 395-2S96(1)Amendment B.



Headquarters, Johnstown Castle Estate, County Wexford, Ireland

INTEGRATED POLICENCE

**Licence Register Number:** 678

**Licensee:** AHP Manufacturing B.V.

t/a Wyeth Nutritionals Ireland

**Location of Activity:** Askeaton

**County Limerick** 

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## Glossary of Terms

The Agency Environmental Protection Agency.

The Licensee AHP Manufacturing B.V. t/a Wyeth Nutritionals Ireland, Askeaton,

County Limerick.

AER Annual Environmental Report.

Agreement Agreement in writing.

Annually All or part of a period of twelve consecutive months.

BATNEEC Best Available Technology Not Entailing Excessive Cost.

Biannually All or part of a period of six consecutive months.

Biennially Once every two years.

BOD 5 day Biochemical Oxygen Demand.

COD Chemical Oxygen Demand.

Daily During all days of plant operation, and in the case of emissions, when

emissions are taking place; with no more than 1 measurement on any

one day.

Day Any 24 hour period.

Daytime 0800 hrs to 2300 hrs.

dB(A) Decibels (A weighted).

DO Dissolved Oxygen.

EMP Environmental Management Programme.

EPA Environmental Protection Agency

EWC European Waste Catalogue (Commission Decision 2000/532/EC as

amended)

Fortnightly At least 20 measurements in a calendar year with no more than one

measurement in any one week.

IPC Integrated Pollution Control.

K Kelvin.

kPa kilo Pascals.

Leq Equivalent continuous sound level.

Lighting-up time 30 minutes after sun set.

List I As listed in the EC Directives 76/464/EEC and 80/68/EEC and

amendments.

List II As listed in the EC Directives 76/464/EEC and 80/68/EEC and

amendments.

Local Authority Limerick County Council.

Mass Flow Limit An Emission Limit Value which is expressed as the maximum mass of

a substance which can be emitted per unit time. The limit is usually

expressed in kilograms per hour (kg/h).

Mass Flow Threshold A mass flow rate, above which, a concentration limit applies. The rate

is usually expressed in kilograms per hour (e.g. at mass flow rates > 2

kg/h).

Monthly At least 12 times per year at approximately monthly intervals.

Night-time 2200 hrs to 0800 hrs.

Noise sensitive location Any dwelling house, hotel or hostel, health building, educational

establishment, place of worship or entertainment, or any other facility or area of high amenity which for its proper enjoyment requires the

absence of noise at nuisance levels.

PER Pollution Emission Register.

ppm Parts per million.

Quarterly All or part of a period of three consecutive months beginning on the

first day of January, April, July or October.

Regional Fisheries Board Shannon Regional Fisheries Board

Sanitary Authority Limerick County Council.

Standard Methods As detailed in "Standard Methods for the Examination of Water and

Wastewarer", (prepared and published jointly by A.P.H.A., A.W.W.A & W.E.F. 20th Ed. 1998, American Public Health Association, 1015 Fifteenth Street, N.W., Washington DC 20005, USA; or, an alternative

method as may be agreed in writing by the Agency.

Waste Management Acts 1996 to 2003.

Waste recovery operation Means any of the operations included in the Fourth Schedule to the

Waste Management Acts 1996 to 2003.

Weekly During all weeks of plant operation, and in the case of emissions,

when emissions are taking place; with no more than one measurement

in any one week.

WWTP Waste Water Treatment Plant.

## Reasons for the Decision

The Agency is satisfied, on the basis of the information available, that subject to compliance with the conditions of this licence, any emissions from the activity will comply with and not contravene any of the requirements of Section 83(3) of the Environmental Protection Agency Act, 1992.

In reaching this decision the Agency has considered the application and supporting documentation received from the Licensee, objection received and the report of its inspectors.

### Activities Licensed

In pursuance of the powers conferred on it by the Environmental Protection Agency Act, 1992, the Agency hereby grants a licence to:

AHP Manufacturing B.A. t/a Wyeth Nutritionals Ireland, Askeaton, County Limerick,

under Section 83(1) of the said Act to carry on the following activities

the manufacture of dairy products where the processing capacity exceeds 50 million gallons of milk equivalents per year,
and
the burning of any fuel in a boiler or furnace with a nominal heat output exceeding 50 MW, milk equivalents per year,

at Askeaton, County Limerick, subject to the following fifteen Conditions, with the reasons therefor and associated schedules attached thereto?

### **Conditions**

#### **Condition 1.** Scope

- 1.1 The activity shall be controlled, operated, and maintained and emissions shall take place as set out in this Integrated Pollution Control (IPC) licence. All programmes required to be carried out under the terms of this licence, become part of this licence.
- 1.2 No alteration to, or reconstruction in respect of, the activity or any part thereof which would, or is likely to, result in
  - (a) a material change or increase in:
    - 1.2.1 The nature or quantity of any emission,
    - 1.2.2 The abatement/treatment or recovery systems,
    - 1.2.3 The range of processes to be carried out,
    - 1.2.4 The fuels, raw materials, intermediates, products or wastes generated, or
  - (b) any changes in:
    - 1.2.5 The site management and control with adverse environmental significance,

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

- 1.3 This licence is for the purposes of IPC licensing under the EPA Act, 1992 only and nothing in this licence shall be construed as negating the licensee's statutory obligations or requirements under any other enactments or regulations.
- 1.4 Any reference in this licence to site shall mean the plan area edged in red and labelled "Site Plan (Drawing No. C002266 001RevA)" in the IPC licence application.
- 1.5 This licence has been granted in substitution for IPC licence granted to the licensee on 27<sup>th</sup> October, 2000 and bearing Register No.: 395. The previous IPC licence (Reg. No. 395) is replaced by this licence.

Reason: To clarify the scope of this licence.

### **Condition 2.** Management of the Activity

- 2.1 The licensee shall maintain an Environmental Management System (EMS) which shall fulfil the requirements of this licence. The EMS shall assess all operations and review all practicable options for the use of cleaner technology, cleaner production and the reduction and minimisation of waste, and shall include as a minimum those elements specified in the Conditions 2.2 to 2.9 below.
- 2.2 A schedule of Environmental Objectives and Targets
  - 2.2.1 The licensee shall prepare a schedule of Environmental Objectives and Targets. The schedule shall include time frames for the achievement of set targets. The schedule shall address a five year period as a minimum. The schedule shall be reviewed annually and amendments thereto notified to the Agency for agreement as part of the Annual Environmental Report (AER) (See also Condition 2.9).

- 2.3 Environmental Management Programme (EMP)
  - 2.3.1 The EMP shall be maintained by the licensee. It shall include:
    - designation of responsibility for targets; (i)
    - the means by which they may be achieved; (ii)
    - (iii) the time within which they may be achieved.

The EMP shall be reviewed annually and amendments thereto notified to the Agency for agreement as part of the Annual Environmental Report (AER) (Condition 2.9).

- 2.3.2 A report on the programme, including the success in meeting agreed targets, shall be prepared and submitted to the Agency as part of the AER. Such reports shall be retained on-site for a period of not less than seven years and shall be available for inspection by authorised persons of the Agency.
- 2.4 Pollution Emission Register (PER)
  - 2.4.1 The substances to be included in the PER shall be agreed by the Agency each year by reference to the list specified in the AER guidance note. The PER shall be prepared in accordance with any relevant guidelines issued by the Agency and shall be submitted as part of the AER.
  - The licensee shall, not later than six months from the date of grant of this licence 2.4.2 and thereafter as part of the AER agree with the Agency the list of substances to be included in the PER, and the methodology to be used in their determination.
- 2.5 Documentation
- OWNer 2.5.1 The licensee shall maintain an environmental management documentation system which shall be to the satisfaction of the Agency.
  - The licensee shall issue a copy of this licence to all relevant personnel whose 2.5.2 duties relate to any condition of this licence.
- 2.6 Corrective Action
  - 2.6.1 The licensee shall maintain procedures to ensure that corrective action is taken should the specified requirements of this licence not be fulfilled. responsibility and authority for initiating further investigation and corrective action in the event of a reported non-conformity with this licence shall be defined.
- 2.7 Awareness and Training
  - 2.7.1 The licensee shall maintain procedures for identifying training needs, and for providing appropriate training, for all personnel whose work can have a significant effect upon the environment. Appropriate records of training shall be maintained.
  - 2.7.2 Personnel performing specifically assigned tasks shall be qualified on the basis of appropriate education, training and/or experience, as required.
- 2.8 Responsibilities
  - 2.8.1 The licensee shall ensure that a person in charge, as defined under the terms of the Environmental Protection Agency Act, 1992 shall be available on-site at all

times when the activity is in operation. The person in charge shall also be available to meet with authorised persons of the Agency at all reasonable times.

#### 2.9 Communications

- 2.9.1 The licensee shall maintain a programme to ensure that members of the public can obtain information concerning the environmental performance of the licensee at all reasonable times.
- 2.9.2 For each full calendar year from the date of grant of this licence, the licensee shall submit to the Agency, by the 31<sup>st</sup> March of the following year, an AER which shall be to the satisfaction of the Agency. This report shall include as a minimum the information specified in *Schedule 5(i) Recording and Reporting to the Agency* and shall be prepared in accordance with any relevant guidelines issued by the Agency.

Reason:

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

### **Condition 3.** Interpretation

- 3.1 Emission limit values for emissions to atmosphere in this licence shall be interpreted in the following way:-
  - 3.1.1 For Non-Continuous Monitoring.
    - (i) For any parameter where, due to sampling/analytical limitations, a 30 minute sample is inappropriate, a suitable sampling period should be employed and the value obtained therein shall not exceed the emission limit value.
    - (ii) For flow, no hourly or daily mean value, calculated on the basis of appropriate spot readings, shall exceed the relevant limit value.
    - (iii) For all other parameters, no 30 minute mean value shall exceed the emission limit value.
- 3.2 The concentration and volume flow limits for emissions to atmosphere specified in this licence shall be achieved without the introduction of dilution air and shall be based on gas volumes under standard conditions of:-
  - 3.2.1 In the case of non-combustion gases:
    - Temperature 273K, Pressure 101.3 kPa (no correction for oxygen or water content).
  - 3.2.2 In the case of combustion gases:
    - (i) Temperature 273K, Pressure 101.3 kPa, dry gas; 3% oxygen for liquid and gas fuels.
  - 3.2.3 In the case of CHP and Bypass gases (Gas Turbine):
    - (i) Temperature 273K, Pressure 101.3kPa, dry gas; 15% oxygen for liquid and gas fuels.
- 3.3 Emission limit values for emissions to waters in this licence shall be interpreted in the following way:-

- 3.3.1 Continuous monitoring:
  - (i) No flow value shall exceed the specified limit.
  - (ii) No pH value shall deviate from the specified range.
  - (iii) No temperature value shall exceed the limit value.
- 3.3.2 Non-Continuous Monitoring:
  - (i) No pH value shall deviate from the specified range.
  - (ii) No temperature value shall exceed the limit value.
  - (iii) For parameters other than pH, temperature and flow, eight out of ten consecutive results, calculated as daily mean concentration or mass emission values on the basis of flow proportional composite sampling, shall not exceed the emission limit value. No individual result similarly calculated shall exceed 1.2 times the emission limit value.
  - (iv) For parameters other than pH, temperature, and flow, no grab sample value shall exceed 1.2 times the emission limit value.
- 3.4 Noise
  - 3.4.1 Noise from the activity shall not give rise to sound pressure levels (Leq,T) measured at the specified noise sensitive locations which exceed the limit value(s) by more than 2 dB(A).

Reason: To clarify the interpretation of enission limit values fixed under the licence.

### **Condition 4.** Notification

- 4.1 The licensee shall notify the Agency by both telephone and facsimile, if available, to the Agency's Headquarters in Wexford, or to such other Agency office as may be specified by the Agency, as soon as practicable after the occurrence of any of the following:
  - 4.1.1 Any release of environmental significance to atmosphere from any potential emission point.
  - 4.1.2 Any emission which does not comply with the requirements of this licence.
  - 4.1.3 Any malfunction or breakdown of control equipment or monitoring equipment set out in;

Schedule 1(ii) Emissions to Atmosphere: Abatement/Treatment Control, and Schedule 2(ii) Effluent Treatment Control,

- which is likely to lead to loss of control of the abatement system.
- 4.1.4 Any incident with the potential for environmental contamination of surface water or groundwater, or posing an environmental threat to air or land, or requiring an emergency response by the Local Authority.

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

- 4.2 The licensee shall make a record of any incident as set out in Condition 4.1 above. This record shall include details of the nature, extent, and impact of, and circumstances giving rise to, the incident. The record shall include all corrective actions taken to; manage the incident, minimise wastes generated and the effect on the environment, and avoid recurrence. The licensee shall as soon as practicable following incident notification, submit to the Agency the incident record.
- 4.3 A summary report of reported incidents shall be submitted to the Agency as part of the AER. The information contained in this report shall be prepared in accordance with any relevant guidelines issued by the Agency.
- 4.4 In the case of any incident as set out in Condition 4.1.2 above which relates to discharges to water, the licensee shall notify the Shannon Regional Fisheries Board as soon as practicable after such an incident.
- 4.5 In the event of any incident, as set out in Condition 4.1.4 having taken place, the licensee shall notify the Local Authority as soon as practicable, after such an incident.

Reason:

To provide for the notification of incidents and update information on the activity.

### **Condition 5.** Emissions to Atmosphere

- No specified emission to the atmosphere shall exceed the emission limit value set out in *Schedule 1(i) Emissions to Atmosphere*, subject Condition 3 of this licence. There shall be no other emission to the atmosphere of convironmental significance.
- All equipment, including backup equipment, specified in *Schedule 1(ii) Emissions to Atmosphere: Abatement/Treatment Control* of this licence shall be provided on-site. All treatment/abatement, control and monitoring equipment shall be calibrated and maintained when in use, in accordance with the information submitted in Table 12A(iv) of the IPC licence application or as otherwise approved by the Agency under the Environmental Management Programme.
- 5.3 Monitoring and analyses of each emission shall be carried out as specified in *Schedule 1(iii)*Monitoring of Emissions to Atmosphere of this licence. A report on the results of this monitoring shall be submitted to the Agency on an annual basis.
- A summary report of emissions to atmosphere shall be submitted to the Agency as part of the AER. The information contained in this report shall be prepared in accordance with any relevant guidelines issued by the Agency.
- 5.5 The licensee shall ensure that all operations on-site shall be carried out in a manner such that air emissions and/or odours do not result in significant impairment of, or significant interference with amenities or the environment beyond the site boundary.
- 5.6 Boilers shall normally be fired on natural gas unless otherwise agreed by the Agency.

Reason: To provide for the protection of the environment by way of control, limitation, treatment and monitoring of emissions.

#### **Condition 6.** Emissions to Water

- No specified emission to water shall exceed the emission limit values set out in *Schedule* 2(i) *Emissions to Water* subject to Condition 3 of this licence. There shall be no other emissions to water of environmental significance.
- The equipment, including backup equipment, specified in *Schedule 2(ii) Effluent Treatment Control* of this licence, shall be provided on-site. All treatment/abatement, control and monitoring equipment shall be calibrated and maintained at all times when in use, in accordance with the information submitted in Table 13A(iii) of the IPC licence application or as otherwise approved by the Agency under the EMP. All treatment/abatement and control equipment shall be functioning at all times when the activity is being carried on unless alternatives have been agreed in writing by the Agency.
- 6.3 Monitoring and analyses of each emission shall be carried out as specified in *Schedule 2(iii)*Monitoring of Emissions to Water of this licence. A report on the results of this monitoring shall be submitted to the Agency biannually.
- A summary report of emissions to water shall be submitted to the Agency as part of the AER. The information contained in this report shall be prepared in accordance with any relevant guidelines issued by the Agency.
- 6.5 The acute toxicity of the undiluted final effluent to at least four aquatic species from different trophic levels shall be determined by standardised and internationally accepted procedures and carried out by a competent laboratory. The name of the laboratory and the scope of testing to be undertaken shall be submitted, in writing, to the Agency, within three months of the date of grant of this licence. Once the testing laboratory and the scope of testing have been agreed by the Agency withe Agency shall decide when this testing is to be carried out and copies of the complete reports shall be submitted by the licensee to the Agency within six weeks of completion of the testing.
- 6.6 Having identified the most sensitive species outlined in Condition 6.5, subsequent compliance toxicity monitoring on the two most sensitive species shall be carried out by the laboratory identified in Condition 6.5 as per *Schedule 2(iii) Monitoring of Emissions to Water*. The Agency shall decide when this testing is to be carried out and copies of the complete reports shall be submitted by the licensee to the Agency within six weeks of completion of the testing.
- No substance shall be discharged in a manner, or at a concentration which, following initial dilution, causes tainting of fish or shellfish.

Reason: To provide for the protection of the environment by way of control, limitation, treatment and monitoring of emissions.

### **Condition 7.** Waste Management

- 7.1 Disposal or recovery of waste shall take place only as specified in *Schedule 3(i) Hazardous Wastes for Disposal/Recovery* and *Schedule 3(ii) Other Wastes for Disposal/Recovery* of this licence and in accordance with the appropriate National and European legislation and protocols. No other waste shall be disposed of/recovered either on-site or off-site without prior notice to, and prior written agreement of, the Agency.
- 7.2 Waste sent off-site for recovery or disposal shall be conveyed only by an authorised waste contractor. The waste shall be transported only from the site of the activity to the site of

- recovery/disposal in a manner which will not adversely affect the environment and in accordance with the appropriate National and European legislation and protocols.
- 7.3 No amendment or variation in any agreed waste classification or consignment or haulage or disposal or recovery arrangements shall be made without the prior written agreement of the Agency.
- 7.4 The licensee shall ensure that waste transferred to another person is packaged and labelled in accordance with National, European and any other standards which are in force in relation to such labelling. While awaiting collection, recovery or disposal all waste shall be stored in designated areas protected, as may be appropriate, against spillage and leachate run-off. The waste is to be clearly labelled and appropriately segregated.
- 7.5 No waste classified as green list waste in accordance with the EU Transfrontier Shipment of Waste Regulations (Council Regulation EEC No.259/1993, as amended) shall be consigned for recovery without the prior agreement of the Agency.
- 7.6 Unless approved in writing by the Agency the licensee is prohibited from mixing a hazardous waste of one category with a hazardous waste of another category or with any other non-hazardous waste.
- 7.7 A full record, which shall be open to inspection by authorised persons of the Agency at all times, shall be kept by the licensee on matters relating to the waste management operations and practices at this site. This record shall as a minimum contain details of the following:
  - 7.7.1 The tonnages and EWC Code for the waste materials listed in *Schedule 3(i)*Hazardous Wastes for Disposal/Recovery and Schedule 3(ii) Other Wastes for Disposal/Recovery, sent off-site for disposal/recovery.
  - 7.7.2 The names of the agent and carrier of the waste, and their permit details (to include issuing authority).
  - 7.7.3 Details of the ultimate disposal/recovery destination facility for the waste and its appropriateness to accept the consigned waste stream, to include its permit details and issuing authority.
  - 7.7.4 Written confirmation of the acceptance and disposal/recovery of any hazardous waste consignments sent off-site.
  - 7.7.5 Details of all wastes consigned abroad for Recovery and classified as 'Green' in accordance with the EU Transfrontier Shipment of Waste Regulations (Council Regulation EEC No. 259/1993, as amended). The rationale for the classification must form part of the record.
  - 7.7.6 Details of any rejected consignments.
  - 7.7.7 Details of any approved waste mixing as per Condition 7.6.

A copy of this Waste Management record shall be submitted to the Agency as part of the AER for the site.

Reason: To provide for the disposal/recovery of waste and the protection of the environment.

#### **Condition 8.** Noise

8.1 The licensee shall carry out a noise survey of the site operations annually. The survey programme shall be undertaken in accordance with the methodology specified in the

'Environmental Noise Survey Guidance Document' as published by the Agency. The licensee shall consult with the Agency on the timing of the survey. A record of the survey results shall be available for inspection by any authorised persons of the Agency, at all reasonable times and a summary report of this record shall be included as part of the AER.

8.2 Activities on-site shall not give rise to noise levels off-site, at noise sensitive locations, which exceed the following sound pressure limits (Leq, 15 mins) subject to Condition 3 of this licence:

8.2.1 Daytime: 55 dB(A), 8.2.2 Night-time: 45 dB(A).

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

Reason: To provide for the protection of the environment by control of noise.

#### **Condition 9.** Non-Process Water

- 9.1 Surface water
  - 9.1.1 A visual examination of the surface water discharge shall be carried out daily. A log of such inspections shall be maintained.
  - 9.1.2 The licensee shall monitor surface water discharges in accordance with *Schedule*4(i) Surface Water Discharge Monitoring of this licence. A report on the results of this monitoring shall be submitted to the Agency biannually and a summary report shall be submitted as part of the AER.
  - 9.1.3 In the event that any analyses or observations made on the quality or appearance of surface water runoff should indicate that contamination has taken place, the licensee shall
    - (i) Carry out an immediate investigation to identify and isolate the source of the contamination,
    - (ii) put in place measures to prevent further contamination and to minimise the effects of any contamination on the environment,
    - (iii) and notify the Agency as soon as is practicable.
- 9.2 Groundwater
  - 9.2.1 Groundwater monitoring points BH101, BH201, BH202, BH203, BH204 shall be sampled and analysed in accordance with *Schedule 4(ii) Groundwater Monitoring* of this licence. A report of such results shall be submitted annually as part of the AER.
- 9.3 Facilities for the Protection of Groundwater and Surface Water
  - 9.3.1 All tank and drum storage areas shall be rendered impervious to the materials stored therein. In addition, tank and drum storage areas shall, from the date of grant of licence, as a minimum be bunded, either locally or remotely, to a volume not less than the greater of the following;
    - (i) 110% of the capacity of the largest tank or drum within the bunded area,

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

Drainage from bunded areas shall be diverted for collection and safe disposal. All bunds shall be tested at least once every three years. A report on such tests shall be included in the AER.

- 9.3.2 The integrity and water tightness of all the bunding structures and their resistance to penetration by water or other materials stored therein shall be tested and demonstrated by the licensee to the satisfaction of the Agency and shall be reported to the Agency within three months from the date of grant of this licence.
- 9.3.3 The loading and unloading of materials shall be carried out in designated areas protected against spillage and leachate run off.
- 9.3.4 All pump sumps or other treatment plant chambers from which spillage of environmentally significant materials might occur in such quantities as are likely to breach local or remote containment or interceptors, shall be fitted with high liquid level alarms (or oil detectors as appropriate) from the date of grant of this licence.
- 9.3.5 The licensee shall undertake a programme of testing and inspection of active underground tanks and pipelines to ensure that all such structures are tested at least once every three years. A report on such tests shall be included in the AER.
- 9.3.6 All flanges and valves on over-ground pipes used to transport materials other than uncontaminated water, where no permanent provision for containment of leaks is provided, shall be subject to weekly visual inspection or otherwise monitored for leaks to the satisfaction of the Agency. All such inspections shall be recorded in a log which shall be available for inspection by Agency.
- 9.3.7 The licensee shall wave in storage an adequate supply of containment booms and suitable absorbent material to contain and absorb any spillage.

Reason: To provide for the projection of surface waters and groundwater.

### Condition 10. Energy Use

- The licensee shall carry out an audit of the energy efficiency of the site within one year of the date of grant of this licence. The licensee shall consult with the Agency on the nature and extent of the audit and shall develop an audit programme to the satisfaction of the Agency. The audit programme shall be submitted to the Agency in writing at least one month before the audit is to be carried out. A copy of the audit report shall be available on-site for inspection by authorised persons of the Agency and a summary of the audit findings shall be submitted as part of the Annual Environmental Report. The energy efficiency audit shall be repeated at intervals as required by the Agency.
- The audit shall identify all opportunities for energy use reduction and efficiency and the recommendations of the audit will be incorporated into the Schedule of Environmental Objectives and Targets under Condition 2.2 above.

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

#### **Condition 11.** Monitoring

11.1 The licensee shall carry out such sampling, analyses, measurements, examinations, maintenance and calibrations as set out in Schedules:-

Schedule 1(ii) Emissions to Atmosphere: Abatement/Treatment Control,

Schedule 1(iii) Monitoring of Emissions to Atmosphere,

Schedule 2(ii) Effluent Treatment Control,

Schedule 2(iii) Monitoring of Emissions to Water,

Schedule 4(i) Surface Water Discharge Monitoring,

Schedule 4(ii) Groundwater Monitoring,

of this licence.

- Where the ability to measure a parameter is affected by mixing before emission, then, with prior written agreement from the Agency, the parameter may be assessed before mixing takes place.
- All automatic monitors and samplers shall be functioning at all times (except during maintenance and calibration) when the activity is being carried on unless alternative sampling or monitoring has been agreed in writing by the Agency for a limited period. In the event of the malfunction of any continuous monitor, the licensee shall contact the Agency as soon as practicable, and alternative sampling and monitoring facilities shall be put in place. Prior written agreement for the use of alternative equipment, other than in emergency situations, shall be obtained from the Agency.
- Monitoring and analysis equipment shall be operated and maintained as necessary so that monitoring accurately reflects the emission or discharge. The licensee shall submit to the Agency within three months of date of grant of licence an updated drawing showing the location and reference minuter of all monitoring and emission points specified in the licence. The licensee shall maintain a copy of this drawing on-site at all times.
- The frequency, methods and scope of monitoring, sampling and analyses, as set out in this licence, may be amended with the written agreement of the Agency following evaluation of test results.
- 11.6 The licensee shall install on all emission points such sampling points or equipment, including any data-logging or other electronic communication equipment, as may be required by the Agency. All such equipment shall be consistent with the safe operation of all sampling and monitoring systems.
- 11.7 The licensee shall provide safe and permanent access to the following sampling and monitoring points:
  - 11.7.1 Final effluent as discharged from the site.
  - 11.7.2 Emission to atmosphere sampling points.
  - 11.7.3 Noise sources on-site.
  - 11.7.4 Waste storage areas on-site.
  - 11.7.5 Surface waters discharge.
  - 11.7.6 On-site ground-water monitoring wells.

and safe access to any other sampling and monitoring points required by the Agency.

11.8 The licensee shall operate a weather monitoring station on the site at a location agreed by the Agency, which records conditions of wind speed and wind direction.

The licensee shall maintain in a prominent location on the site a wind sock, or other wind direction indicator, which shall be visible from the public roadway outside the site.

Reason:

To ensure compliance with the requirements of other conditions of this licence by provision of a satisfactory system of measurement and monitoring of emissions.

#### **Condition 12.** Recording and Reporting to Agency

- 12.1 The licensee shall record all sampling, analyses, measurements, examinations, calibrations and maintenance carried out in accordance with the requirements of this licence.
- 12.2 The licensee shall record all incidents which affect the normal operation of the activity and which may create an environmental risk.
- The licensee shall record all complaints of an environmental nature related to the operation of the activity. Each such record shall give details of the date and time of the complaint, the name of the complainant and give details of the nature of the complaint. A record shall also be kept of the response made in the case of each complaint. The licensee shall submit a report to the Agency, during the month following such complaints, giving details of any complaints which arise. A summary of the number and nature of complaints received shall be included in the AER.
- The format of all records required by this licence shall be to the satisfaction of the Agency. Records shall be retained on-site for a period of not less than seven years and shall be available for inspection by the Agency at all reasonable times.
- Reports of all recording, sampling analyses, measurements, examinations, calibrations and maintenance as set out in *School of the Agency of this licence*, shall be submitted to the Agency Headquarters as specified in this licence. The format of these reports shall be to the satisfaction of the Agency. One original and three copies shall be submitted as and when specified.
- Provision shall also be made for the transfer of environmental information, in relation to this licence, to the Agency's computer system, as may be requested by the Agency.
- 12.7 All reports shall be certified accurate and representative by the licensee's Plant Manager or other senior officer designated by the Plant Manager.
- 12.8 All written procedures controlling operations affecting this licence shall be available on-site for inspection by the Agency at all reasonable times.
- 12.9 The frequency and scope of reporting, as set out in this licence, may be amended by the Agency following evaluation of test results.

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

### Condition 13. Accidents and Emergency Response

- 13.1 The licensee shall, within six months of date of grant of this licence, ensure that a documented Accident Prevention Policy is in place which will address the hazards on-site, particularly in relation to the prevention of accidents with a possible impact on the environment.
- The licensee shall, within six months of date of grant of this licence, ensure that a documented Emergency Response Procedure is in place, which shall address any emergency situation which may originate on-site. This Procedure shall include provision for minimising the effects of any emergency on the environment.
- 13.3 The policy and procedure referred to in Conditions 13.1 and 13.2 shall be reviewed annually and up-dated as necessary. They shall be made available on-site for inspection by the Agency at all reasonable times.

Reason: To provide for the protection of the environment.

### Condition 14. Residuals Management

- 14.1 Following termination, or planned cessation for a period greater than six months, of use or involvement of all or part of the site in the licensed activity, the licensee shall, to the satisfaction of the Agency, decommission, render safe or remove for disposal/recovery, any soil, subsoils, buildings, plant or equipment, or any waste, materials or substances or other matter contained therein or thereon, that may result in environmental pollution.
- 14.2 Residuals Management Plan:
  - 14.2.1 The licensee shall prepare, to the satisfaction of the Agency, a fully detailed and costed plan for the decommissioning or closure of the site or part thereof. This plan shall be submitted to the Agency for agreement within six months of the date of grant of this licence.
  - 14.2.2 The plan shall be reviewed annually and proposed amendments thereto notified to the Agency for agreement as part of the AER. No amendments may be implemented without the written agreement of the Agency.
- 14.3 The Residuals Management Plan shall include as a minimum, the following:
  - 14.3.1 A scope statement for the plan.
  - 14.3.2 The criteria which define the successful decommissioning of the activity or part thereof, which ensures minimum impact to the environment.
  - 14.3.3 A programme to achieve the stated criteria.
  - 14.3.4 Where relevant, a test programme to demonstrate the successful implementation of the decommissioning plan.
  - 14.3.5 Details of costings for the plan and a statement as to how these costs will be underwritten.
- 14.4 A final validation report to include a certificate of completion for the residuals management plan, for all or part of the site as necessary, shall be submitted to the Agency within three months of execution of the plan. The licensee shall carry out such tests, investigations or

submit certification, as requested by the Agency, to confirm that there is no continuing risk to the environment.

Reason:

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

#### **Condition 15. Financial Provisions**

#### 15.1 Agency Charges

- 15.1.1 The licensee shall pay to the Agency an annual contribution of €12,916, or such sum as the Agency from time to time determines, having regard to variations in the extent of reporting, auditing, inspection, sampling and analysis or other functions carried out by the Agency, towards the cost of monitoring the activity as the Agency considers necessary for the performance of its functions under the Environmental Protection Agency Act, 1992. The first payment shall be a pro-rata amount for the period from the date of this licence to the 31st day of December 2004, and shall be paid to the Agency within one month from the date of the licence. In subsequent years the licensee shall pay to the Agency such revised annual contribution as the Agency shall from time to time consider necessary to enable performance by the Agency of sits relevant functions under the Environmental Protection Agency Act 1992, and all such payments shall be made within one month of the date upon which demanded by the Agency.
- 15.1.2 In the event that the frequency of extent of monitoring or other functions carried out by the Agency needs to be increased the licensee shall contribute such sums as determined by the Agency to defraying its costs in regard to items not covered by the said annual contribution.

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#### 15.2 Environmental Liabilities

- 15.2.1 The licensee shall arrange for the completion, by an independent and appropriately qualified consultant, of a comprehensive and fully costed Environmental Liabilities Risk Assessment for the operation, which will address liabilities from past and present activities. A report on this assessment to be submitted to the Agency for agreement within twelve months of date of grant of this licence.
- 15.2.2 Within six months of agreement by the Agency under Condition 15.2.1, the licensee shall make financial provision in a form acceptable to the Agency to cover any liabilities incurred by the licensee. The amount of indemnity must always be capable of covering the liabilities identified in Condition 15.2.1.
- 15.2.3 The amount of indemnity, held under Condition 15.2.2 shall be reviewed and revised as necessary, but at least annually.
- 15.2.4 The licensee shall within two weeks of purchase, renewal or revision of the financial indemnity required under Condition 15.2.2, forward to the Agency written proof of such indemnity.

Reason:

To provide for adequate financing for monitoring and financial provisions for measures to protect the environment.

#### Schedule 1(i) Emissions to Atmosphere

**Emission Point Reference No.:** A1-1 and A2-7

Location: CHP Boiler Stack and By-Pass Stack

Volume to be emitted: Maximum in any one day: 1,474,080 m<sup>3</sup>

> $61,420 \text{ m}^3$ Maximum rate per hour:

Minimum discharge height: 40 m above ground

Parameter	Emission Limit Value
Nitrogen oxides (as NO <sub>2</sub> )	$300 \text{ mg/m}^3$
Nitrogen oxides (as NO <sub>2</sub> ) Note I	450mg/m <sup>3</sup>

Note 1: This emission limit value applies only when using Gas oil during system test or emergency supply and not exceeding 20 hours per annum in total.

Emission Point Reference No.:  A1-2, A1-4  Boilers 1, 3  Minimum discharge height:  40 manage ground			
Parameter			
COR	Until 31/12/2004	From 1/1/2005	
Oxides of sulphur (as SO <sub>2</sub> )  Nitrogen oxides as (NO <sub>2</sub> )	1700	340 Note 1	
Nitrogen oxides as (NO <sub>2</sub> )	750	115 <sup>Note 2</sup>	
СО	150	115 Note 1	
Smoke	<1(Ringelmann Shade)	-	

Note 1: These emission limit values shall only apply when Gas Oil is in use as backup fuel.

Note 2: An emission limit value off 220 mg/m<sup>3</sup> shall apply when Gas Oil is in use as backup fuel.

**Emission Point Reference No.:** A1-3 **Location:** Boiler 2

Minimum discharge height: 40 m above ground

Parameter	Emission Limit Value (mg/m³)	
	Until 31/12/2004	From 1/1/2005
Oxides of sulphur (as SO <sub>2</sub> )	1700	340
Nitrogen oxides as (NO <sub>2</sub> )	750	220
со	150	115
Smoke	<1(Ringelmann Shade)	-

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Emission Point Reference No's.: Dryers A2-1, A2-2, A2-3, A2-4 and A2-6 and

Agglomerator A2-5 Production area

Minimum discharge height: 23 m above ground

Parameter	only and Emission Limit Value	
Total Particulates	50 mg/m <sup>3</sup>	
	n puttedit	

Schedule 1(ii) Emissions to Atmosphere: Abatement/Treatment Control

Emission Point Reference No.:

Dryer A2-2

Description of Treatment:

Bag filtration

**Monitoring:** 

Location:

Control Parameter	Monitoring to be Carried Out	Monitoring Equipment
Filter pressure drop	Monthly emission concentration	Manometer

#### **Equipment:**

Control Parameter	Equipment	Backup equipment
Filter pressure drop	Bag filter	Spare bags



### Schedule 1(iii) Monitoring of Emissions to Atmosphere

**Emission Point Reference No.:** A1-1 (and A1-2, A1-4 from 1/1/2005)

Parameter	<b>Monitoring Frequency</b>	Analysis Method/Technique
NOx	Biannually	Flue gas analyser



A1-3 (and A1-2, A1-4 until 1/1/2005) **Emission Point Reference No.:** 

Parameter	<b>Monitoring Frequency</b>	Analysis Method/Technique
SOx	Biannually	Flue gas analyser
NOx	Biannually	Flue gas analyser
со	Biannually	Flue gas analyser



### Schedule 2(i) Emissions to Water

**Emission Point Reference No.:** 

Name of Receiving Waters:

Location:

Volume to be emitted:

For the House

Maximum in any one day:

 $126 \, \text{m}^3$ Maximum rate per hour:

 $2,800 \, \mathrm{m}^3$ 

Parameter	Emission Limit Value	
рН	6-9	
Toxicity	5 TU	
	Mg/l Kg/day	
BOD	40	100
Suspended Solids	50	140
Total Nitrogen	15	42
Total Phosphorus (as P)	2	5.6
Oils, Fats and Greases	15	42
Ammonia (as N)	10	28



### Schedule 2(ii) Effluent Treatment Control

Emission Point Reference No.: SW

**Description of Treatment:** Biological sequencing batch reactor waste water treatment

#### Monitoring:

Monitoring to be Carried Out	Monitoring Frequency	Monitoring Equipment/Method
COD (Raw effluent)	Daily	Standard Methods
Phosphorus (Raw effluent)	Daily	Standard Methods
pH (ex Balance Tank)	Continuous	pH Meter/Recorder
SBR inflow	Continuous	Flow Meter/Recorder
Dissolved Oxygen (SBR)	Continuous	DO Meter/Recorder
Mixed Liquor Suspended Solids (SBR)	Continuous during react	MLSS Meter
ETP outflow	Continuous	Flow Meter/Recorder
Sludge Floc microscopy	Daily	Standard Methods

#### **Equipment:**

Equipment.	Nge.	
Control Parameter	Equipment officer	Backup Equipment
Fat and grease removal	Motor/belt Solved	Spares held on site
Effluent (pH) Neutralisation	Acid/Caustic Dosing Pump	Spares held on site
Effluent Transfer	Pumps Thill redit	Standby pumps and spares held on site
SBR Dissolved Oxygen	Air blowersit Anter	Spares held on site
	Fixed DO Meter	Portable DO Meter
MLSS	Studge transfer pumps	Spares held on site
Sludge Dewatering	Filtration/dryer	Spares held on site

### Schedule 2(iii) Monitoring of Emissions to Water

Emission Point Reference No.: SW1

Parameter	Monitoring Frequency	Analysis Method/Technique
Flow	Continuous	On-line flow meter with recorder
рН	Continuous	pH electrode/meter and recorder
Chemical Oxygen Demand	Daily	Standard Method
Biochemical Oxygen Demand	Daily	Standard Method
Suspended Solids	Daily	Gravimetric
Nitrates (as N)	Daily	Standard Method
Ammonia (as N)	Daily	Standard Method
Total Phosphorus (as P)	Daily	Standard Method
Total Nitrogen (as N)	Weekly	Standard Method
Oils, fats & greases	Weekly	Standard Method
Toxicity Note 1	Annually Note 1	To be agreed by the Agency

Note 1: The number of toxic units (Tu) = 100/x hour EC/LC<sub>50</sub> in percentage vol/vol so that higher Tu values reflect greater levels of toxicity. For test regimes where species death is not easily detected, immobilisation is considered equivalent to death.



#### Schedule 3(i) Hazardous Wastes for Disposal/Recovery

Waste Materials  Note 1	Further Treatment, Recovery/Recycling On-Site Note 2	On-Site Reuse Note 2	Method of Disposal/Recovery Note 3
Waste Solvents	None	None	Agreed hazardous waste disposal contractor
Light tubes – crushed glass and Aluminium ends	None	None	Agreed hazardous waste recovery contractor
Light tubes – Mercury filers	None	None	Agreed hazardous waste disposal contractor
Waste Oils	None	None	Agreed hazardous waste recovery contractor
Batteries	None	None	Agreed hazardous waste recovery contractor
Electronic equipment	None	None	Agreed hazardous waste recovery contractor
Empty Lacquer drums	None	None None	Agreed hazardous waste disposal contractor
Lab smalls	None	None other	Agreed hazardous waste recovery contractor
COD vials	None	None	Agreed hazardous waste recovery contractor
Aerosols	None citot put requir	None	Agreed hazardous waste disposal contractor
Miscellaneous once off hazardous material	None None None None None None None None	None	Agreed hazardous waste disposal contractor
Medical waste - sharps	None None	None	Agreed hazardous waste disposal contractor
Oily rags	Noneent	None	Agreed hazardous waste recovery contractor
Oil interceptor waste	None	None	Agreed hazardous waste recovery contractor
Oil filters	None	None	Agreed hazardous waste recovery contractor
Degreaser filters	None	None	Agreed hazardous waste recovery contractor
Waste turbine oils	None	None	Agreed hazardous waste recovery contractor
Other Note 4			

Note 1: Refer also to waste classification, labelling and management obligations specified in Condition 7.

Note 2: The licensee may treat, reuse, recycle or recover waste subject to the prior written agreement of the Agency.

Note 3: The agreed Method and any amendment thereto, shall include details of anticipated waste volumes, classification, transport arrangements, as well as identification (including authorisations and appropriateness) of facility of final destination of disposal/recovery.

Note 4: No other hazardous waste shall be disposed of/recovered off-site or on site without prior notice to, and prior written agreement of the Agency.



### Schedule 3(ii) Other Wastes for Disposal/Recovery

Waste Materials  Note 1	Further Treatment, Recovery/Recycling On-Site Note 2	On-Site Reuse Note 2	Method of Disposal/Recovery Note 3
Organic sludge	None	None	Agreed recovery contractor
General waste	None	None	Agreed disposal contractor.
Organic oils	None	None	Agreed recovery contractor
Powder sweepings	None	None	Agreed disposal contractor.
R & D samples	None	None	Agreed disposal contractor.
Out of spec raw material and product sweepings	None	None	Agreed disposal contractor.
Cardboard	None	None	Agreed recovery contractor
Metallic packaging	None	None	Agreed recovery contractor
Empty oil drums	None	None	Agreed recovery contractor
Timber Pallets	None	None	Returned to supplier
Composite packaging – laminated foil	None	None	Agreed disposal contractor.
Plastic packaging	None	None	Agreed recovery contractor
Paper and cardboard packaging – white paper	None	None None None	Agreed recovery contractor
Printer cartridges and mobile phones	None	on None	Agreed recovery contractor
Reject metal – raw material	None nitro	None	Agreed recovery contractor
Product tailings	None ston Price,	None	Reuse as animal feed
Construction waste material	None inspectional	None	Agreed disposal contractor.
Construction material containing asbestos	None colytist	None	Agreed disposal contractor.
Glass bottles Other Note 4	None None None None None None None None	None	Agreed recovery contractor

- Note 1: Refer also to waste classification, labelling and management obligations specified in Condition 7.
- Note 2: The licensee may treat, reuse, recycle or recover waste subject to the prior written agreement of the Agency.
- Note 3: The agreed Method and any amendment thereto, shall include details of anticipated waste volumes, classification, transport arrangements, as well as identification (including authorisations and appropriateness) of facility of final destination of disposal/recovery.
- Note 4: No other waste shall be disposed of/recovered off-site or on site without prior notice to, and prior written agreement of the Agency.

### Schedule 4(i) Surface Water Discharge Monitoring

Parameter	Monitoring Frequency	Analysis Method/Technique
Visual Inspection	Daily	Sample and examine for colouration and odour
рН	Weekly	pH electrode/meter
BOD	Weekly	Standard Method
Total Ammonia	Weekly	Standard Method
Total Nitrogen	Weekly	Standard Method



### Schedule 4(ii) Groundwater Monitoring

Emission Point Reference No's.: Bore-Holes BH101, BH201-204

Parameter	Monitoring Frequency	Analysis Method/Technique	
рН	Biannually .	pH electrode/meter	
COD	Biannually	Standard Method	
Major Anions	Biannually	Standard Method	
Major Cations	Biannually	Standard Method	
The fact of the control of the contr			

#### Schedule 5(i) Recording and Reporting to the Agency

Completed reports shall be submitted to:

The Environmental Protection Agency P.O. Box 3000 Johnstown Castle Estate County Wexford

Any other address as may be specified by the Agency <u>or</u>

Reports are required to be forwarded as set out below:

#### **Recurring Reports:**

Report	Reporting Frequency	Report Submission Date		
Monitoring of emissions to atmosphere	Annually	Ten days after end of the period being reported on.		
Monitoring of emissions to water	Biannually	Ten days after end of the period being reported on.		
Surface Water	Biannually	Ten days after end of the period being reported on.		
Noise monitoring programme	Annually	One month prior to survey		
Complaints (where these arise)	Monthly &	Ten days after end of the month being reported on.		
Annual Environmental Report(AER)	Annually See Annua	Eighteen months from the date of grant of licence and each calendar year thereafter.		
oction treet				
Emissions to atmosphere summary. Emissions to water summary. Waste management report.				
Emissions to atmosphere summary.	63,			
Emissions to water summary.				
Waste management report.				
Resource consumption summary.				
Complaints summary.				

Complaints summary.

Environmental management programme - proposal

Environmental management programme - report

 $Pollution\ emission\ register-proposal$ 

Pollution emission register - report

Noise monitoring report

Schedule of Environmental Objectives and Targets

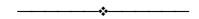
Energy efficiency audit report summary

Groundwater monitoring summary

Review of residuals management plan

Tank and pipeline testing and inspection report

Reported incidents summary



# **Once-off Reports:**

Report	Report Submission Date	
Toxicity monitoring programme as per condition 6.5	Within three months of the date of grant of licence.	
Energy Audit Programme Within eleven months of the date of grant of licence.		
Environmental Liabilities Assessment Report Within twelve months of the date of grant of licence.		
Residuals Management Plan	Within six months of the date of grant of licence.	
Bund integrity assessment.	Within three months from the date of grant of licence.	
Monitoring and Emissions Drawing	Within three months of date of grant of licence	

Signed on behalf of the Agency

Padraic Larkin

Director/Authorised Person

Consent of copyright owner required for any other use. Dated this 23<sup>rd</sup> day of January 2004.



Headquarters
P.O. Box 3000
Johnstown Castle Estate
County Wexford
Ireland

# AMENDMENT A TO TO THE TOTAL TO THE TOTAL TO THE TOTAL TOTAL THE TO

Licence Register Number:	678	
Licensee:	AHP Manufacturing B.V.	
	t/a Wyeth Nutritionals Ireland	
Location of Installation:	Askeaton	
	County Limerick	

# Reason for the Amendment of Condition(s)

The Environmental Protection Agency has examined the terms of licence Reg. No. 678 as required by the provisions of Section 82 (10) (a) of the Environmental Protection Agency Acts 1992 and 2003, and determined that the licence can be brought into conformity with the provisions and requirements of Council Directive 96/61/EC by the exercise of the powers conferred by Section 82 (11) of the Environmental Protection Agency Acts 1992 and 2003.

The Environmental Protection Agency is satisfied, on the basis of the information available, that subject to compliance with the conditions of licence Reg. No. 678 granted on the 23<sup>rd</sup> January 2004, as well as any amendments noted herein, any emissions from the activity will comply with and not contravene any of the requirements of Section 83(5) of the Environmental Protection Agency Acts, 1992 and 2003.

# Amendment of Condition(s)

In pursuance of the powers conferred on it by Section 82(11) of the Environmental Protection Agency Acts, 1992 and 2003, the Agency amends Licence Reg. No.678, granted to AHP Manufacturing B.V. t/a Wyeth Nutritionals Ireland for an installation located at Askeaton, Co. Limerick.

This amendment is limited to the following:

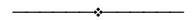
# **Amendments**

# Glossary of Terms

**BAT** 

Best Available Techniques.

To be inserted into the Glossary of the existing licence.



**Incident** 

The following shall constitute an incident for the purposes of this licence:

- (i) an emergency;
- (ii) any emission which does not comply with the requirements of this licence;
- (iii) any trigger level specified in this licence which is attained or exceeded; and,
- (iv) any indication that environmental pollution has, or may have, taken place.

To be inserted into the Glossary of the existing licence.

Resource Use and Energy Efficiency

Resource Use

- 10.3 The licensee shall identify opportunities for reduction in the quantity of water used on site including recycling and reuse initiatives, wherever possible. Reductions in water usage shall be incorporated into the Schedule of Environmental Objectives and Targets.
- 10.4 The licensee shall undertake an assessment of the efficiency of use of raw materials in all processes, having particular regard to the reduction in waste generated. The assessment should take account of best international practice for this type of activity. Where improvements are identified, these shall be incorporated into the Schedule of Environmental Objectives and Targets.

To be inserted after Condition 10.2 of the existing licence.

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

To replace the original reason in the existing licence

# **Accidents and Emergency Response**

- 13.4 In the event of an incident he licensee shall immediately:-
  - (i) isolate the source of any such emission;
  - (ii) carry out an immediate investigation to identify the nature, source and cause of the incident and any emission arising therefrom;
  - (iii) evaluate the environmental pollution, if any, caused by the incident;
  - (iv) identify and execute measures to minimise the emissions/malfunction and the effects thereof;
  - (v) identify the date, time and place of the incident.

Provide a proposal to the Agency for its agreement within one month of the incident occurring or as otherwise agreed with the Agency to:-

- identify and put in place measures to avoid reoccurrence of the incident;
   and
- identify and put in place any other appropriate remedial action.

These amendments should be read in conjunction with licence Reg. No. 678, granted on 23<sup>rd</sup> January 2004.

Sealed by the seal of the Agency on this the 9<sup>th</sup> day of June 2006.

PRESENT when the seal of the Agency was affixed hereto:

One of the Agency was affixed hereto:



Headquarters
P.O. Box 3000

Johnstown Castle Estate

County Wexford

Ireland

# County Wexford Ireland Ireland TECHNICAL AMENDMENT B LOCAL TO TO THE TO THE PROPERTY OF THE P

# INTEGRATED POLLUTION PREVENTION & CONTROL LICENCE

Licence Register Number:	P0395-02	
Licensee:	AHP Manufacturing B.V.	
	t/a Wyeth Nutritionals Ireland	
Location of Installation:	Askeaton	
	County Limerick	

# Reasons for the Decision

The Environmental Protection Agency is satisfied, on the basis of the information available, that subject to compliance with the conditions of licence Reg. No. P0395-02 granted on the 23/01/2004, (and amended on 09/06/2006) as well as any amendments noted herein, any emissions from the activity will comply with and not contravene any of the requirements of Section 83(5) of the Environmental Protection Agency Acts, 1992 and 2003.

# Technical Amendment

In pursuance of the powers conferred on it by Section 96(1)(b) and (c) of the Environmental Protection Agency Acts, 1992 and 2003, the Agency amends Licence Reg. No. P0395-02, granted to AHP Manufacturing B.V. t/a Wyeth Nutritionals Ireland, Askeaton, County Limerick.

Henceforth, IPPC Licence Register No. P0395-02 shall be read in conjunction with Amendment A issued on 09/06/2006, and the amendments set out below.

This technical amendment is limited to the following:-

# **Amendments**

# **Amend Condition 5**

**5.6** 

Natural gas, biodiesel meeting CEN standard EN14214 or gas oil (sulphur content not exceeding 0.2% by mass until December 31st 2007 and not exceeding 0.1% by mass thereafter) shall be used in the boilers or Combined Heat & Power plant on site. Boiler No. 2 shall only be operated with the prior written agreement of the Agency.

Amend Condition 5.6 of the existing licence as set out above.

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## Amend Schedule 1

# Schedule 1(i) Emissions to Atmosphere

**Emission Point Reference No.:** A1-1 and A2-7

Location: CHP Boiler Stack and By-Pass Stack

Volume to be emitted: Maximum in any one day: 1,474,080 m<sup>3</sup>

> $61,420 \text{ m}^3$ Maximum rate per hour:

Minimum discharge height: 40 m above ground

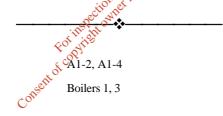
On natural gas

Parameter	Emission Limit Value
Nitrogen oxides (as NO <sub>2</sub> )	300 mg/m <sup>3</sup>

On gas oil or biodiesel

On gus on or bloureser				
Parameter	Emission Limit Value			
Sulphur oxides (as SO <sub>2</sub> ) Note 1	58 mg/m <sup>3</sup>			
Nitrogen oxides (as NO <sub>2</sub> )	450 mg/m <sup>3</sup>			
Carbon monoxide (as CO)	200 mg/m <sup>3</sup>			

Until December 31st 2007 the emission limit value shall be 195 bg/m³. Thereafter the boiler shall be fired on natural gas, biodiesel (meeting CEN standard EN14214) or gas oil (supphir content not exceeding 0.1% by mass). Note 1:



**Emission Point Reference No.:** 

Minimum discharge height:

**Location:** 

40 m above ground

On natural gas

Parameter Emission Limit Value (mg/m³)	
Nitrogen oxides (as NO <sub>2</sub> )	200
Carbon monoxide (as CO)	100

On gas oil or biodiesel

Parameter	Emission Limit Value (mg/m³)
Oxides of sulphur (as SO <sub>2</sub> ) Note 1	170 Note1
Nitrogen oxides (as NO <sub>2</sub> )	300
Carbon monoxide (as CO)	200

Until December 31st 2007 the emission limit value shall be 340mg/m<sup>3</sup>. Thereafter the boiler shall be fired on natural gas, Note 1: biodiesel (meeting CEN standard EN14214) or gas oil (sulphur content not exceeding 0.1% by mass).



**Emission Point Reference No.:** A1-3 **Location:** Boiler 2

Minimum discharge height: 40 m above ground

Parameter	Emission Limit Value (mg/m³)	
Oxides of sulphur (as SO <sub>2</sub> )	170 Note1	
Nitrogen oxides as (NO <sub>2</sub> )	220	
Carbon monoxide (as CO)	115	

Note 1: Until December 31st 2007 the emission limit value shall be 340mg/m³. Thereafter the boiler shall be fired on natural gas, biodiesel (meeting CEN standard EN14214) or gas oil (sulphur content not exceeding 0.1% by mass).

**----**

Emission Point Reference No's.: Dryers A2-1, A2-2, A2-3, A2-4 and A2-6 and

Agglomerator A2-5 Production area

Minimum discharge height: 23 m above ground

Parameter	Emission Limit Value
Total Particulates	50 mg/m <sup>3</sup>

Og it ight on the control of the con

# Schedule 1(iii) Monitoring of Emissions to Atmosphere

**Emission Point Reference No.:** A1-3, A2-7 A1-2, A1-4, A1-3

Parameter	Monitoring Frequency Analysis Method/Technique	
SO <sub>x</sub> (as SO <sub>2</sub> ) Note 1	Biannually	Flue gas analyser
NOx (as NO <sub>2</sub> )	Biannually	Flue gas analyser
со	Biannually	Flue gas analyser

Note 1: When fired on gas oil.

**Location:** 

Parameter	<b>Monitoring Frequency</b>	Analysis Method/Technique	
Particulates	Quarterly	Isokinetic/Gravimetric	



Amend Schedule 1(i) Emissions to Atmosphere and Schedule 1(iii) Monitoring of Emissions to Atmosphere of the existing licence as set out above.

This technical amendment shall be cited as Amendment By IPPC licence Reg. No. P0395-02.

Sealed by the Seal of the Agency on this the 14<sup>th</sup> day of June, 2007

PRESENT when the seal of the Agency was affixed hereto

Dr Padraic Larkin, Director



# Transfer of Licence Application Form

# ATTACHMENT B(a) Certified copy Certificate of Incorporation





# I hereby certify,

that company number

490938,

PFIZER (NEW PIP) HOLDINGS

Wednesday, the 3rd day of November, 2010. In Particular that the first the first that the first

for Registrar of Companies

Companies Act, 1963, sec. 370(1)



# Transfer of Licence Application Form

# ATTACHMENT B(b) Partnership's Number in Companies Registration Office

The Company's Number in the Companies Registration Office is: 490938





# <u>Transfer of Licence Application Form</u>

# ATTACHMENT B(c) Particulars of the Principal Place of Business of Company -

Pfizer (New PIP) Holdings Operations Support Group, Ringaskiddy, Cork.

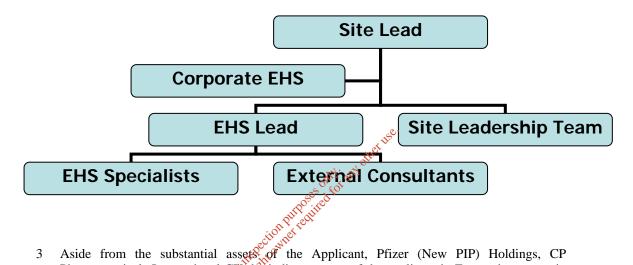


### <u>Transfer of Licence Application Form</u>

#### ATTACHMENT C Fit and proper Person

- Neither the Applicant nor any other relevant person have been convicted of any offence under the PoE Act, the Waste Management Act 1996 to 2008, the Local Government 9Water Pollution) Acts 1997 and 1990 or the Air Pollution Act 1987.
- 2 For the newly owned facility there is no change proposed to the current facility management.

For the newly owned facility there is no change proposed to the current facility management structure. The management structure associated with the implementation of Licence Register No. P0395-02 is summarised as follows:



Aside from the substantial assets of the Applicant, Pfizer (New PIP) Holdings, CP Pharmaceuticals International CV the indirect parent of the applicant in Europe has assets in excess of \$104 billion. Certified accounts for CP Pharmaceuticals International CV are presented in Attachment C(a). CP Pharmaceuticals International CV is fully prepared to provide appropriate funding in respect of liabilities that have been or will be entered into or incurred in carrying on the activity to which the transfer relates. The ability of the applicant to satisfy all financial commitments is demonstrated in Attachment F(c).



# Transfer of Licence Application Form

# ATTACHMENT D Liabilities, Requirements and Obligations

Pfizer (New PIP) Holdings has assumed and accepted all liabilities, requirements and obligations provided for in or arising under Licence register No. P0395-02, or revised licence, regardless of how and in respect of what period, including the period prior to the transfer of the licence or revised licence as they may arise.

\_\_\_\_\_

Mr. Peter Duffy
For and on behalf of Pfizer (New PIP) Holdings
Authorised Signatory

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# Transfer of Licence Application Form

#### ATTACHMENT E Licence Transferee Details

The proposed transferee has not had an application for a licence granted.

CP Pharmaceuticals International CV the proposed ultimate corporate parent of the transferee in Europe as part of a limited partnership with Pfizer Overseas Pharmaceuticals (having changed its name to Pfizer Ireland Pharmaceuticals) has had applications for a licence granted as follows:

Reg No.

P0013-04 Pfizer Overseas Pharmaceuticals (having changed its name to Pfizer Ireland Pharmaceuticals) and CP Pharmaceuticals International CV.

P0136-03 Pfizer Overseas Pharmaceuticals (having changed its name to Pfizer Ireland Pharmaceuticals) and CP Pharmaceuticals International CV.

P0019-02 Pfizer Overseas Pharmaceuticals (having changed its name to Pfizer Ireland Pharmaceuticals) and CP Pharmaceuticals International CV trading as Pfizer Ireland Pharmaceuticals.

Neither Pfizer (New PIP) Holdings (proposed transferee), nor Pfizer Ireland Ventures its parent company nor any 'relevant person' has had an application for a licence rejected; had a licence revoked; or been refused as a transferee for a licence.

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# <u>Transfer of Licence Application Form</u>

# ATTACHMENT F Estimated Expenditure and Financial Provisions

The requested documents are attached as follows:

- Attachment F(a): Residuals Management Plan (First revision sent to the Agency on August 19<sup>th</sup> 2005)
- Attachment F(b): Environmental Liability Risk Assessment (First revision sent to the Agency on August 19<sup>th</sup> 2005)

CP Pharmaceuticals International CV. Is prepared to provide funding in respect of liabilities that have been or will be entered into or incurred in carrying on the activity to which the transfer relates. This commitment in respect of providing for expenditure for associated costs/liabilities is presented in ATTACHMENT F(c).





# Transfer of Licence Application Form

# ATTACHMENT F(a) Residuals Management Plan



CRAMP Update 2010
Closure, Restoration and Aftercare Mariagement Plan

04 May 2010 Final

Issue No 2 49340715 /



**Project Title:** CRAMP Update 2010

Report Title: Closure, Restoration and Aftercare Management Plan

**Project No:** 49340715

Report Ref:

Status: Final

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# **Document Production / Approval Record**

ther use.

Issue No:	Name	Signature on Signature	Date	Position
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Checked and approved by	Peter Hassett		04.05.2010.	Transactions& Compliance, URS Ireland, Department Head

#### **Document Revision Record**

Issue No	Date	Details of Revisions
1	26.02.2010.	Original issue
2	04.05.2010.	Final issue



#### LIMITATION

URS has prepared this Report for the sole use of Wyeth Nutritionals Ireland in accordance with the Agreement under which our services were performed. No other warranty, expressed or implied, is made as to the professional advice included in this Report or any other services provided by us. This Report may not be relied upon by any other party without the prior and express written agreement of URS. Unless otherwise stated in this Report, the assessments made assume that the sites and facilities will continue to be used for their current purpose without significant change. The conclusions and recommendations contained in this Report are based upon information provided by others and upon the assumption that all relevant information has been provided by those parties from whom it has been requested. Information obtained from third parties has not been independently verified by URS, unless otherwise stated in the Report.

Where assessments of works or costs required to reduce or mitigate any environmental liability identified in this Report are made, such assessments are based upon the information available at the time and are subject to further investigations or information which may become available. Costs may therefore vary outside the ranges quoted. No allowance has been made for changes in prices or exchange rates or changes in any other conditions which may result in price fluctuations in the future. Where assessments of works or costs necessary to achieve compliance have been made these are based upon measures which, in URS's experience, could normally be negotiated with the relevant Peritum thinking teditied for an authorities under present legislation and enforcement practice, assuming a pro-active and reasonable approach by site management.

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#### **EXECUTIVE SUMMARY**

Wyeth Nutritionals Ireland is an integrated manufacturing facility which produces a comprehensive range of infant nutritional product located in Askeaton, Co. Limerick. The site is licensed by the Environmental Protection Agency (EPA), under IPPC licence Register No. P0395-02 (and associated Technical Amendments A & B, June 2006 and April 2008 respectively). This residual management plan is prepared in the event of site closure or partial site closure of this facility.

The basis of the requirement for the preparation of a Closure, Restoration, and Aftercare Management Plan (CRAMP) stems from the IPPC Directive (96/61/EC), which places a specific obligation on the regulator of an IPPC licensed site, to ensure that site closure is addressed as stated in Article 3:

"the necessary measures are taken upon definitive cessation of activities to avoid any pollution risk and to return the site of the operation to a satisfactory state"

This requirement is directly translated into Condition 14 of the operating IPPC licence (Register No. P0395-02). Note that the term CRAMP now replaces the term Residuals Management Plan (or RMP).

It has been estimated that, in the very unlikely event of site cosure involving complete cessation of all production activities at the Wyeth Nutritionals facility at Askeaton, an allowance of approximately € 2.2 million would be required to bring the site to an environmentally safe condition. It should be noted that a percentage of this cost relates to any potential soil and groundwater corrective action.

The second revision of the original CFAMP (dated August 19th, 2005) in 2007, in addition to updating the CRAMP to account for any changes in costs to the CRAMP, 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". The CRAMP was updated again in 2008 and 2009 to account for any changes on the site.

This is the fifth revision of the CRAMP and will account for any changes to the physical infrastructure on the site and costs to underwrite the CRAMP since the 2009 CRAMP update.



#### 1.0 INTRODUCTION

## 1.1. Introduction to the Facility

Wyeth Nutritionals Ireland was granted a revised IPPC licence, Register No. P0395-02, by the Environmental Protection Agency for the

"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"

on 24<sup>th</sup> January, 2004. This licence was amended on the 26<sup>th</sup> June 2006 by the amendment document titled 678 S82(11) and again in April 2008 to account for changes in fuel burning in the combined heat & power plant (CHP). The details of the amendments must be read in conjunction with the licence. This IPPC licence supersedes previous IPPC Licence Register No. P0395-01 for the site.

The Wyeth site is located in Askeaton, Co. Limerick. The Wyeth 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 (RFT) form in glass bottles and Tetra-Paks. Can manufacture also takes place on the site.

# 1.2. Requirement for a Closure, Restoration, Aftercare Management Plan (CRAMP)

In accordance with Condition 14 of the operating IPPC licence, Wyeth Nutritionals Ireland (WNI) is required to prepare a Residuals Management Plan (RMP, now replaced by CRAMP) comprising a fully detailed and costed plan for the decommissioning or closure of the site or part thereof. Condition 14 also required this plan be submitted to the EPA for approval. The IPPC licence states, as follows:

#### **Condition 14.1**

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

#### Condition 14.2

"Residuals Management Plan:

The licensee shall prepare, to the satisfaction of the Agency, a fully detailed and costed plan for the decommissioning or closure of the site or part thereof. This plan shall be submitted to the Agency for agreement within six months of the date of grant of this licence.

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

#### **Condition 14.3**

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

A scope statement for the plan.

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

14.3.3 A programme to achieve the stated criteria.

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

Details of costings for the plan and a statement as to how these costs will be underwritten.

The original Residuals Management Plan (RMP) for the site was completed and submitted to the Environmental Protection Agency (EPA) in August 2005.

Since completion of the 2005 RMP report, there have been little or no changes to operations on the site. The first operate of the RMP was carried out in 2006 and reflected the most Recent EPA Guidance Document entitled "Guidance Documents and Assessment Tools on Environmental Liabilities Risk Assessment and Residuals Management Plans incorporating Financial Provision Assessment (EPA Contract OEE-04-03) — Draft for Consultation, May 2005" (hereafter referred to the EPA Guidance Document 2005). This guidance was finalised and issued in 2006. The CRAMP was again updated in 2007, 2008 and 2009 to account for any changes at the site.

This update has been prepared for the site to consider any site changes and impacts (if any) on the 2009 CRAMP update and associated costs submitted in the 2009 CRAMP update in response to condition 14.2 above.

# 1.3. Site Closedown Scenario: Comments & Assumptions

To develop a fully detailed and costed CRAMP, it is necessary to present a number of assumptions regarding the mode and management of a hypothetical site shut down.

Site closure or partial closure is considered to include:

- Cessation of the IPPC licensed activity under Article 90 of EPA Act, 1992 amended by the POE (Protection of the Environment) Act 2003;
- Voluntary or involuntary liquidation of the company or organisation holding the IPPC licence which results in cessation of the activity;

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- Transfer of ownership under Article 91 of the EPA Act, 1992 amended by the POE (Protection of the Environment) Act 2003;
- Site closure as a result of corporate rationalisation or relocation;
- Partial closure;
- Mothballing.

Wyeth Nutritionals Ireland (WNI) is part of the Wyeth Corporation. Wyeth Corporation has been acquired by Pfizer Inc. in 2009. Pfizer and Wyeth began joint operations on October 16, 2009. The corporation operates under strict environmental policies and procedures. Therefore, it is assumed that any shutdown of the site will be a well-planned and well-resourced event. This implies that the shutdown date will be known well in advance and that both production schedules and raw materials purchasing will be planned with the shutdown already factored in. It also implies that Wyeth Nutritionals Ireland will have the resources in terms of both financial inputs and manpower to implement the CRAMP through completion – with no requirement for external financing or manpower other than for expert advice.

A general assumption is that the site cannot be sold as a going concern to a third party and that completion of the plan will result in a decommissioned and decontaminated site with no restrictions placed on future land use. In reality, the Wyeth Nutritionals Ireland site is extremely valuable asset with a current replacement value for the plant and equipment in excess of €800m. The assumption is made purely for the purposes of developing "worst-case" costs for site closure and decontamination.

The third general assumption is that all parts of the site are closed as part of one comprehensive CRAMP. No direct reference to partial closure is made in the CRAMP. Under a closure scenario involving a single plant or element of the site, the facility would still operate under its IPPC licence. The CRAMP and associated costs have been developed for a number of discrete programme stages arranged in a logical sequence to facilitate complete site closure. The actual steps to be carried out and their associated costs for any partial shut downs may be derived from the CRAMP by simply reviewing that part of the CRAMP which covers that specific activity or land-parcel.

It is a requirement of the IPPC licence that the CRAMP be reviewed and updated as necessary, on an annual basis as part of the Annual Environmental Report (AER). As part of this CRAMP preparation, site activities including planned activities for 2009 were reviewed.

#### 1.4. Structure of the CRAMP

The CRAMP is divided into sections addressing the various issues on decommissioning and residuals management. The overall structure is as follows:

Section 2.0 Site Assessment

Section 3.0 Criteria for Successful Decommissioning

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Section 4.0	Management of the CRAMP	
Section 5.0	Programme to Achieve Stated Criteria	
Section 6.0	Test Programme Implementation	
Section 7.0	Summary of Costs Associated with the Implementation of the CRAMP	
Section 8.0	Underwriting of the CRAMP	
Section 9.0	Review of the CRAMP	

**Section 2.0** provides an overview of the scope of the CRAMP in terms of the buildings, activities and issues, which are covered in this plan.

**Section 3.0** describes the proposed criteria to be used to demonstrate successful decommissioning and decontamination.

Section 4.0 outlines the responsibilities for management of the CRAMP.

**Section 5.0** describes the CRAMP in a project management style with definite stages and associated tasks. The CRAMP is considered in two main programmes, namely:

- Short Term Programme (STP):

  Decontamination of all above and below ground structures including management of residues arising.
- Long Term Programme (LTP): Management of long term residual soil and groundwater contamination.

**Section 6.0** describes the requirement (if any) for the preparation and implementation of a test programme for the CRAMP.

**Section 7.0** provides a summary of the costs associated with implementation of the CRAMP.

**Section 8.0** outlines the company's assurance to finance the implementation of the CRAMP to completion.

**Section 9.0** outlines the requirement and importance of reviewing the CRAMP.



#### 2. SITE ASSESSMENT

#### 2.1. Wyeth Nutritionals Ireland Site Description and History

Wyeth Nutritionals Ireland (WNI) was established in Askeaton, Co. Limerick in 1973. The entire site comprises approximately 14.5 hectares. 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.

The Wyeth Nutritionals Ireland facility is an integrated manufacturing facility which produces and distributes a range of infant nutritional products. Products are manufactured by compounding and homogenisation of liquid and powder milk. 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 a day.

The production part of the site comprises of 113 acres of the total 36 acre site area. A site layout plan is provided in the Appendix A. The main features of the production PRET-Wet Process
 RET-Krones Filling Room, and Room, and Recommendation of the R

- RFT-LAN/Barriquand Room
- RFT-Tetra-Pak Filing Line
- RFT-Packing Line/Warehouse
- Materials Handling
- Can Manufacturing Plant
- Batch Make-up and Dispensing
- Fat Blending
- Powder Plant Wet Process 1,2,2X, 3
- Evaporation/Drying

- Dry Blending Plant
- Canning Lines 2,3,4,5,6
- Pouch Filling Line
- Tote Bin Filling
- Tote Bin C.I.P Station
- Stickpack Filling Line
- Water Treatment Plant
- Wastewater Treatment Plant
- **Utilities Operations**
- Laboratory Operations
- Air Abatement Systems
- **CHP 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.

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#### 2.2. Site Evaluation & Issue Identification

It is considered that the Wyeth Nutritionals Ireland facility and associated activities in Askeaton are well characterised at this stage and all potential residues arising in the event of site shutdown, including hazardous wastes and non hazardous wastes have been identified and discussed in terms of management and costing in this CRAMP. Any other potential residues arising in the future can be incorporated into the annual review of the CRAMP.

With regard to programmes for production decontamination, it is considered that many such programmes are currently in place due to the strict cleaning regimes and regulatory and legislative requirements in force. These programmes can be utilised or adapted for use as part of CRAMP implementation.

Furthermore, site utilities (namely adequate water supply, nitrogen system etc.) required for decontamination and decommissioning procedures are considered to be readily available on-site for utilisation during implementation of the CRAMP.

Although there is a minor soil and groundwater contamination issue associated with the site, this issue would have no impact on the Gosure, Restoration, and Aftercare Management Plan (CRAMP) for this site as the source of contamination is outside the site boundary and therefore the site has no control over it. This issue is detailed in section 5.2 of this report.

# 2.3. IPPC Licence Compliance

Wyeth Nutritionals Ireland was granted a revised IPPC licence Reg. No. P0395-02 by the EPA on 24<sup>th</sup> January, 2004, for

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

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

This IPPC licence supersedes previous IPPC licence Register No. P0395-01 for the site.

A review of environmental control documentation demonstrated a high compliance level with IPPC licence specified emission limit values. Wyeth Nutritionals Ireland are committed to a WWTP improvement programme with the aim to achieve 100% compliance with IPPC license limits. Wastes arising at Wyeth Nutritionals Ireland, comprising both hazardous and non-hazardous wastes, are characteristic of a food processing operation.

During 2009, there were no major accidents on site.

The following non-compliances occurred on site during 2009:

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- Emission limit value for BOD at discharge point SW-1, set at 40 mg/l in the site's IPPC licence, was exceeded twice (measured BOD values were 54.94 mg/l and 60.25 mg/l);
- Emission limit value for ammonia at discharge point SW-1, set at 0 mg/l in the site's IPPC licence, was exceeded was exceeded once (measured ammonia value was 16 mg/l); and
- Emission limit value for particulate emissions to atmosphere are set at 50 mg/Nm<sup>3</sup> in the site's IPPC licence and this was exceeded once (measured particulates value was 52.3 mg/Nm<sup>3</sup>).

Complaints are reported to the EPA monthly (except in certain emergency or serious circumstances) and submitted as part of the Annual Environmental Report.

The Wyeth Nutritionals Ireland facility is operated in compliance with the IPPC licence and should the site be subject to closure/partial closure, Wyeth Nutritionals Ireland will apply the same level of dedication to implementation of the CRAMP as shown to IPPC licence compliance.

## 2.4. Assessment of Potential Risks

An initial screening and operational risk assessment was carried out on the site. The EPA's RMP Guidance Document 2005 provides a straightforward risk assessment decision matrix which can be used to classify sites according to Low, Medium and High Risk and thereby help in the preparation of an appropriate Residuals Management Plan and Financial Provision Requirements suitable for the site. Industries classified as high risk usually require both a Closure Plan and some form of Restoration and Aftercare Management Plan. Low Risk industries usually only require a Closure Plan.

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. Based on the guidance given in the EPA's Guidance Document 2005, the Wyeth Nutritionals Ireland site is classified in a 'High Risk Category' and will therefore require some degree of Restoration and Aftercare Management Plan. Such a requirement is addressed in this CRAMP.

The full operational risk assessment carried out for the site is detailed section 3 of the Environmental Liabilities Risk Assessment Report (ELRA).

This CRAMP designed for site closure incorporating decontaminating and decommissioning procedures will contain a hazardous element. However, as the site is dealing with processes, materials and wastes on a regular basis, it is anticipated that the facility and personnel involved in decommissioning will be capable of dealing with any hazardous element of the CRAMP, in terms of decommissioning and waste management.

The implementation of the CRAMP at Wyeth Nutritionals Ireland may in itself create environmental risks. Therefore it is recommended prior to decontamination and decommissioning operations that an environmental risk assessment is carried out on-

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site. This assessment will identify potential risks associated with implementation of the CRAMP, which may include but is not limited to the following:

- Inadequate bulk storage of wastes prior to off-site disposal;
- Inadequate bunding of liquid wastes prior to collection by waste contractors;
- Structural hazards (e.g. overhead/underground services);
- · Health and safety hazards.

It is recommended that a site safety plan be developed prior to the commencement of the decontamination and decommissioning process at Wyeth Nutritionals Ireland. Any other aspects of implementation of the CRAMP, which may involve specific health and safety issues, should be accompanied by a dedicated health and safety plan for that particular activity.

# 2.5. Scope of the CRAMP

Taking into consideration the site description, as previously detailed in Section 2.1, the scope of the CRAMP is proposed in two programmes:

The Short Term Programme (STP) will focus on the decontamination and decommissioning of most of the site activities related directly to production and the disposal of the residuals arising thereof

This will involve decommissioning of:

- all production buildings;
- all ancillary/utility areas; and
- all storage areas.

The STP will also involve the disposal of all residuals arising as a direct result of decommissioning. Here, the term 'residuals' is used to describe any materials that should not be left on the site following process decommissioning. Therefore this includes raw materials, wastes, finished product, intermediate product, tankage, etc.

In the case of Wyeth Nutritionals Ireland, it is proposed that a Long Term Programme (LTP) will be also required. This programme will focus on post decommissioning soil, groundwater assessment and treatment as appropriate.

## 2.6. Exclusions from the CRAMP

Completion of the CRAMP will occur when all potential sources of environmental harm have been either removed from the site or rendered harmless (assuming contained industrial use of the land). The costs of removing above and below ground structures – effectively returning the site to "green field" status have not been included.

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#### 3. CRITERIA FOR SUCCESSFUL DECOMMISSIONING

It is essential to define criteria for successful decommissioning to ensure appropriate management of the residuals and minimum impact to the environment. The criteria considered relevant to the Wyeth Nutritionals Ireland facility should include the following:

- Confirmed removal of all hazardous substances;
- Agreement from the EPA on the Long Term Programme (LTP);
- Decontamination of soil and/or groundwater (as necessary).

The above criteria can be achieved as follows:

- 1. <u>Decontamination Procedures</u>, including the following:
  - Procedures to ensure appropriate decontamination of all process equipment according to site developed instructions and standards;
  - Procedures to ensure appropriate decontamination of all pipelines, ancillary works and utility systems according to manufacturer recommendations;
  - Specification of such decontamination/cleaning materials required in the procedures;
- 2. <u>Materials and Waste Management/Disposal Operations</u>, to include the following:
  - Documented and fully costed reports to ensure that all raw materials and finished product have been dispatched from the site that are not considered waste and so have a monetary value;
  - Documented and fully costed reports on the disposal of hazardous waste including full certification required under appropriate legislation;
  - Documented and fully costed reports on the disposal of non hazardous wastes including all certification required under the Waste Management Act and operating IPPC licence;
  - Clearance and final disposal documentation for any asbestos found on the site;



- 3. Remediation Programmes, as appropriate, should include the following to ensure successful decommissioning:
  - If contamination is found to be present, remediation of site soil and groundwater to pre-determined, risk based, remedial goals, agreed with the Agency and verified by a programme of groundwater monitoring post corrective action;

#### 4. EPA Compliance:

- Continued compliance with the operating IPPC licence during decommissioning operations;
- Completion on any requirements raised in an EPA Closure Audit in the event of cessation of activities;
- 5. <u>Documentation Management is an important criterion in successful decommissioning for validation and verification of all decommissioning and residuals management operations.</u>

Note that, with respect to the above criteria, the costs and time to complete decommissioning should not exceed that estimated in the most up-to-date revision of the Closure, Restoration, Aftercare Management Plan in place at the time of decommissioning.

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### 4. MANAGEMENT OF THE CRAMP

The overall responsibility and management of the CRAMP will be undertaken by designated members of site management lead by the Environmental Health and Safety (EHS) Manager. The personnel selected to form CRAMP including financial management, environmental management etc. All decontamination procedures, decommissioning operations and residuals management, as required under this CRAMP will be authorised by the group members. In addition, a person will be nominated to conduct all necessary communications with relevant authorities and ensure the appropriate information transfer.



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#### 5. PROGRAMMES TO ACHIEVE STATED CRITERIA

## 5.1. Short Term Programme

#### 5.1.1. Introduction

The short term programme (STP) encompasses the decommissioning and decontamination operations associated with all above and below ground structures, and subsequent management of all residues arising as a result of such activities, in the short and medium term.

The structure of the STP of the CRAMP is based on a logical sequence of events (project milestones) that would occur in the event of a shutdown, similar in logic to an annual maintenance shutdown. However, STP completion involves the removal of all wastes and materials from the site that could pose a residual threat to the environment. All remaining structures/buildings would be in a steady-state and safe condition.

The STP would involve below ground structures, primarily in-ground sumps, bunds, and drains, only in terms of decontamination of internal surface areas i.e. emptying and flush/rinse etc. Issues associated with removal of such structures, disposal of resulting residuals and assessment of soil/groundwater contamination are dealt with in the Long Term Programme (LTP).

The STP is constructed in a Project Management style format with a number of stages, each with a set of specific tasks that involve the management of residual waste. The individual stages are in a logical sequence, however, some overlap in terms of timeframes is expected. Each stage includes the following elements:

- Tasks to complete the stage;
- · Cost:
- Time to complete;
- Plant status at completion of stage.

STAGE NO	STAGE
1	Production decommissioning, including transfer of residuals to on-site storage.
2	Removal of excess residuals from Stage 1 (including raw materials, wastes and final product) from site.
3	Treatment of bulk liquid wastes in WWTP.
4	Removal of production related hazardous and non-hazardous waste.

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STAGE NO	STAGE
5	Contract cleaning of bulk storage.
6	Decommissioning of site utilities, administration buildings and WWTP.
7	Removal of residual hazardous materials.
8	Documentation and certification of decommissioning and decontamination.

The individual stages proposed are set out as follows. A timetable is included in Appendix C.

# 5.1.2. Stage 1: Production Decommissioning, Including Transfer of Residuals to On- Site Storage

## Preface to Production Decommissioning

This stage will involve decommissioning of the Powder Plant (including the Can Manufacturing Plant) and the Ready to Feed Plant. As each of the production operations are staffed with separate production teams, it is possible, in a complete shutdown situation to decommission the production plants in parallel.

## Task 1: Transfer of raw material and products to appropriate site storage.

At this stage it is assumed that all blending and sterilisation steps are finished. Therefore, to fully complete the production run, allow for packing of product into bottles and cans, sterility testing and release by quality control department.

Residuals management will involve the following:

- Labelling product and transfer to packing line/warehouse for palletising;
- Isolation and purging of conveyors and transfer lines;
- Remove drums of laquor and thinners to the drum storage area;
- Transfer of raw material drums to the warehouse;
- Transfer of product samples and documentation to a designated off-site storage area where they can be stored for a minimum of 7 years.

The estimated quantities of residues generated at this point are contained in Table 5.1.5.1 and 5.1.5.2.

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### Task 2: Transfer of production liquid wastes.

Production liquid waste (which will be categorised as a strong effluent) will be transferred at a controlled rate to the WWTP for treatment. Laquers and thinners will be transferred to the flammable materials storage area.

Table 5.1.5.1 summarises the residuals expected to arise. Transfer lines from production/bulk storage will be isolated and purged to transfer pipe volumes of production liquid waste back to bulk storage.

#### Task 3: Transfer all production solid wastes to storage.

This task will include the specific transfer of hazardous and non-hazardous solid waste to appropriate storage on-site, as follows:

- Transfer of all properly labelled drums of hazardous and non-hazardous waste –
  including drums of packaging material, pallets, plastic, plastic scoops, and ink glue to
  the warehouse;
- Transfer of hazardous empty drums, lined bins, etc. to the waste storage compound;
- Removal of the carbon bed, cation and anion multimedia beds from the de-ionising plant to appropriate drums and transfer to the waste storage compound;
- Removal of all Heating, ventilation and air condition (HVAC) system HEPA filters from all HVAC units and transfer to the warehouse; and
- Removal of non-hazardous general skip waste (e.g., packaging not product contaminated) to dedicated general waste receptacles.

The remaining residuals are summarised in Table 5.1.5.1 (Hazardous) and Table 5.1.5.2 (Non-hazardous).

#### Task 4: Decontamination

All liquid streams produced here are classified as either "strong effluent" or "weak effluent". Strong effluent is generated from the washings of interior of vessels. Strong effluent is composed of nitrogen, phosphoric blend, organic material from vessel internals and hydrogen peroxide. These are discharged to Industrial Bulk Containers (IBCs) and stored in the designated waste storage area. They can be released in a controlled manner to the Waste Water Treatment Plant (WWTP) where they will be treated.

Weak effluent will consist of floor washings. Floor washings are comprised of caustic based detergent at 0.2% solution, and 'oxonia' active. Weak effluent can be pumped directly to the WWTP. It is estimated that it will take approximately 1 week to clean each production area as the process is decommissioned.

This task specifically includes:

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- Execution of Clean in Place (CIPs) for all equipment associated with each of the production steps including rinse checking. This process will involve the use of acid, caustic, condensate, deionised water and steam;
- Nitric acid and sodium hydroxide utilised for CIP in plant 1 and 2. They are recovered
  and reused in plant 2 until their strength drops below a set point. They are then
  discharged to a drain;
- Oil and fat blending tanks are steam cleaned;
- Cleaning of production building materials in contact with any product or raw material;
   and
- Purging and cleaning of transfer and conveying lines.

#### Task 5: Isolate from steam, compressed air & other utilities available.

There are no specific residuals associated with this stage.

## Task 6: Isolate from HVAC, nitrogen storage, refrigeration plant, CHP plant and air abatement.

This stage will include isolation from HVAC system, nitrogen storage, refrigeration plant, deionised water plant, air abatement systems and CHP plant.

#### Task 7: Shutdown of Air emissions abatement units.

The cyclone and bag house abatement units attached to the dryers can now be shutdown. Residues arising from the air abatement units are detailed in the next task (Task 8).

# Task 8: Transfer resulting wastes to drum storage (where required), bottle storage or to bulk tanks.

This task will include the specific transfer of resulting hazardous and non-hazardous waste to appropriate storage on-site, as follows:

- Draining of oil and fat residues from transfer lines, drum and transfer to drum storage area;
- Removal residual powder from the cyclones by vacuum;
- Removal of filter bags from bag house dryers and storage; and
- Removal of product and intermediate samples and obsolete chemicals from laboratories and production areas to drum storage area.

#### Plant Status at Completion of Stage 1

Following successful completion of Stage 1 (Tasks 1 - 8), the plant status is as follows:

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- All site production equipment decontaminated and in a "safe to work" (and environmentally secure) state;
- All production related residuals transferred to bulk storage or warehouse; and
- All auxiliary systems decommissioned and working mediums oils, fats, vitamins, minerals, laquers, etc. removed from production buildings to storage.

#### **Time to Complete**

It is estimated that Stage 1 would take approximately 2-3 weeks to complete utilising the full compliment of production and maintenance staff at Wyeth Nutritionals Ireland. Where necessary, external contractors will assist in the decommissioning and decontamination operations.

#### **Budget Cost Estimate**

As described in Section 1.2 it is assumed that the shutdown is a well-planned and resourced event and all costs in terms of manpower will be allocated to normal plant running costs for the period in question. However, it is anticipated that 50 external technical staff will be required for three weeks to complete specific aspects of decommissioning. This results in a cost of €240,000. Additionally, plant and equipment hire will be required for various decommissioning procedures, at an estimated cost of €100,000.

# 5.1.3. Stage 2: Removal of Excess Residuals from Stage 1 (including Raw Materials, Wastes & Final Product) from Site

## Task 1: Dispatch of finished product from final production

The Wyeth site is an integrated manufacturing facility which produces infant nutritional products in their final dosage. The site produces approximately 39 million kg of infant formula per annum. Once product leaves the site it is ready to be placed directly on the open market. It is therefore assumed that there will be no finished product remaining once production ceases. Intermediates can be shipped to other sites for final processing, formulation and packaging. Based on inventory data supplied to the Agency for the IPPC licence review of 2003, approximate maximum quantities to be dispatched during site decommissioning are summarised in Table 5.1.3.1. As the production volume is constant, this inventory has not significantly changed since 2003.

Table 5.1.3.1 Inventory of Intermediate Materials

Material	Storage Tanks
Process 1 Intermediate liquid	6 x 10,000 litres
	2 x 30,000 litres
	1 x 40,000 litres

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Material	Storage Tanks
Process 2, 2X Intermediate liquid	4 x12,000 litres
	6 x 45,000 litres
	1x 65,000 litres
Process 3 Intermediate liquid	3 x 23,000 litres 4 x 65,000 litres

#### Task 2: Shipping of excess raw material and solvents off-site.

The following table approximates the raw materials on-site at any one time, which will require shipment off-site. As the production volume is constant, this inventory has not significantly changed since 2003.

Table 5.1.3.2 Inventory of Raw Materials

Material	Quantity and different	Storage
Solid Reagents (dry powders)	375 formes	25 kg bags 1000 kg bulk bags
Liquid Reagent	446 tonnes	Bulk storage
Laquer and Thinners of	8.2 tonnes	25 litre metal drums
Acid/base <sup>Coff</sup>	141 tonnes	Bulk Storage 1000 litre IBCs

Raw material purchase is planned on a schedule directly related to the planned production schedule. As the date for plant shutdown will be known in advance, it is assumed that stocks of raw materials will be reduced accordingly. However for the purposes of the CRAMP, it is assumed that the planned reduction in stocks reduces the inventory by 80% at shut down and that the remainder is shipped from site as a hazardous waste. Treating the material as a hazardous waste is a "worst case" scenario. In reality there will be alternative routes for this material including:

- Return of raw material to suppliers;
- Transfer of materials to other Wyeth sites;
- Use of some acids and bases in the wastewater treatment plant;

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Transfer of materials for reuse as animal feed.

All of the above routes would result in considerable costs savings when compared to the "hazardous waste" route. Based on an 80% reduction in inventory prior to shutdown, Table 5.1.3.3 summarises the raw materials, which will still be on-site and require off-site disposal.

Table 5.1.3.3 Residual Materials Remaining

Material	Quantity	Storage
Solid Reagents (dry powders)	75 tonnes	25 kg bags 1000 kg bulk bags
Liquid Reagents	89 tonnes	Bulk storage
Laquer and Thinners	1.6 tonnes	25 litre Metal drums
Acid/base	28 tonnes	Bulk Storage

Costs (both unit and total estimates) are provided in Table 5.1.5.1.

#### Plant Status at Completion of Stage 2

The warehouse, bulk storage and drum storage areas will be clear of raw materials.

### **Time to Complete**

The residuals set out in Table 5.1.3.3 should all be removed over an 8 - 10 week period, allowing for documentation (including inventory lists) and arranging shipments.

#### **Budget Cost Estimate**

The costs associated with Task 1 are not considered as it is assumed that shipping costs will be absorbed as part of the net value of the intermediates and products.

The estimated costs, both unit costs and total estimates, for the disposal of the residuals from Task 2 are presented in Table 5.1.5.1.

## 5.1.4. Stage 3: Treatment of Bulk Liquid Wastes in the WWTP.

The production related bulk liquid wastes generated from decommissioning and decontamination operations during Stage 1 will be treated in the WWTP.

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As previously described in Stage 1, all "weak effluent streams" generated during the shut down will be treated in the on-site WWTP. Strong effluent streams, which are readily biodegradable, will be treated at a controlled rate in the WWTP.

It is estimated that site shutdown will generate approximately 10,000 m<sup>3</sup> of wastewater. This quantity is based on production data reviewed for the purposes of the CRAMP study.

#### Plant Status at Completion of Stage 3

All bulk liquid wastes treated in WWTP.

#### **Time to Complete**

The time to complete will be determined by the WWTP throughput. It is estimated that onsite treatment of bulk liquid wastes in the WWTP will require 3 - 5 weeks. This is based on the assumption that it takes 10 days for process waste to pass through the WWTP. It is also assumed that treatment will start one week following the commencement of the shut down period.

#### **Budget Cost Estimate**

It is assumed that the WWTP operation is included with normal production related costs and therefore there is no net residual cost for this stage.

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## 5.1.5. Stage 4: Removal of Production-related Hazardous & Non-hazardous Wastes.

Task 1: Create inventory of all waste to be disposed with correct classification (e.g., hazardous, non-hazardous).

At this stage, all hazardous and non-hazardous waste arising from production related decommissioning is confined to dedicated site storage and is quantified.

The gross inventory of hazardous waste anticipated to be disposed is detailed in Table 5.1.5.1. It is assumed that all hazardous wastes will be incinerated. A footnote to Table 5.1.5.1 explains the basis behind the figures presented. Disposal costs of approximately €1,200 per tonne are based on the price charged by the site's hazardous waste management company in 2009.

The gross inventory of anticipated non-hazardous wastes arising for disposal is detailed in Table 5.1.5.2. It is assumed that all non-hazardous wastes will be recycled, composted or landfilled. Disposal costs of average price of €114 per tonne of non-hazardous waste are based on prices charged by the site's waste management companies in 2009.

Table 5.1.5.1 Anticipated Hazardous Waste Inventory

ITEM	DESCRIPTION  DESCRIPTION  Solid Raw Materials  Liquid Raw Material	Tonnes	Total cost @ 1,200 per tonne (€)
1	Solid Raw Materials	75	90,000
2	Liquid Raw Material	89	106,800
3	Acids/bases	28	33,600
4	Waste solvent for incineration	2.4#	2,880
5	Laboratory smalls (COD vials)	0.38	456
6	Contaminated Drums (oil, solvent)	60	72,000
7	Waste Material for Recovery	10*	12,000
8	Other Waste Material for Incineration	5**	6,000
	TOTAL (approximate)	269.78	323,736

<sup>#</sup> laquer drum washings

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<sup>\*</sup>Includes batteries and an estimate of and any other small waste stream arising

 $<sup>^{\</sup>star\star}$  Includes aerosols, medical waste, and any other small waste stream arising



	T		
ITEM	DESCRIPTION	Tonnes*	Total cost @ €114 per tonne
			(€)
1	Recycled sludge	1,566.7	178,604
2	General waste	307	34,998
3	Timber and wood packaging	347.4	39,604
4	Metal	319.9	36,469
5	Cardboard and plastic packaging	311.5	35,511
6	Tailings	153.9	17,545
7	Vegetable oil	58,.1	6,623
8	Glass	Other 112 9.9	1,129
9	Paper Paper	8.9	1,015
	Out of the		

**Table 5.1.5.2 Non-Hazardous Waste Disposal Cost Estimate** 

3,083.30

351,496

## Task 2: Contact disposal companies.

Total

Following compilation of the hazardous and non-hazardous inventories, the administrative function of contacting disposal companies will be undertaken to arrange waste disposal operations. Although existing arrangements may be in place, Wyeth will ensure waste companies are licensed and will comply with all relevant waste management legislation.

#### Task 3: Remove waste from site.

Licensed waste disposal contractors will remove the specified waste from the site in accordance with the conditions of the operating IPPC licence and all relevant legislative requirements.

#### Plant Status at Completion of Stage 4

All wastes in dedicated storage removed off-site by licensed waste contractors.

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<sup>\*</sup> Amounts based on levels of waste for half a year, (RMP is expected to take 6 months to implement) figures estimated from recent year AER's properties at the state of the st



#### **Time to Complete**

This stage will be carried out, following a lag time of approximately 2 weeks, in parallel to the decommissioning stages. Wastes arising on-site will be transferred for appropriate storage in the drum store and warehousing areas. This waste will then be quickly removed by licensed waste management contractors for incineration or landfill, to ensure waste storage areas have sufficient storage space. It is expected that this stage will take 6 weeks.

#### **Budget Cost Estimate**

Tables 5.1.5.1 and 5.1.5.2 summarise the anticipated costs associated with removal and disposal of wastes.

#### 5.1.6. Stage 5: Contract Cleaning of Bulk Tanks, Sumps and Bunds.

This stage is started when bulk storage vessels or tanks begin to be emptied and with all virgin and waste contents removed for return or disposal. At the site, there are approximately 35 above ground, external bulk storage tanks. These tanks are associated with production (nitric tank, vegetable oils and fats) and the associated utilities (e.g. hydrochloric and caustic storage tanks). In addition there are approximately 15 bunds, nine small sumps and one very large sump. A specialist company will be contracted to provide a comprehensive cleaning service for all tanks and pipelines including the collection of any residual sludge. Residual material will be drummed and disposed of off site by specialist waste contractors. Amounts generated have been included in table 5.1.3.3

## Plant Status at Completion of Stage 5

All bulk storage, bunds and sumps decontaminated by specialist cleaning contractors and residual materials dispessed of in environmentally sound manner.

#### Time to Complete

It will take approximately 12 weeks to complete this stage, assuming that one tank per day, 3 bunds per day and 5 sumps per day can be cleaned. This stage can start after two weeks into Stage 3 – Treatment of bulk liquid wastes.

#### **Budget Cost Estimate**

The pricing provided by a cleaning contractor in Dublin in 2009 is €1,500 a day for tank cleaning and €1,000 a day for sump or bun cleaning. In the worst case scenario, it would take a day to clean a  $200\text{m}^3$  tank, and approximately 3-5 sumps or bunds could be cleaned in a day. Therefore, in this report a flat rate price of €1,500 per tank and €350 per sump or a bund is used.

- Tanks €1,500 x 35 = **€52,500**
- Sumps € 350 x 9 + € 2,000 x 1 = € 5,150

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- Bunds € 350 x 15 = € 5,250
- Total € 62,900

## 5.1.7. Stage 6: Decommission of Site Utilities, Administration Buildings and WWTP.

This stage of decommissioning will apply to the following site utilities and contractor compounds, plus site administration buildings and the site wastewater treatment plant (WWTP):

- 1. Nitrogen storage
- 2. Deionised water plant
- CHP 3.
- Boiler house (duty & standby boilers) Spection buildeses only any other use.
- Refrigeration plant
- Compressed air plant
- 7. Maintenance
- Laboratories
- Contractor compounds
- 10. Administration buildings
- 11. Water treatment plant
- 12. Wastewater Treatment Plant (WWTP)
- 13. Fire suppression system
- 14. Firewater utilities
- 15. LPG Plant

#### CHP, Boiler house, deionised water plant, refrigeration plant and nitrogen storage

With regard to the decommissioning of CHP, boiler house, deionised water plant, refrigeration plant, compressed air plant and the nitrogen storage, the following tasks will apply:

- Task 1: Decommissioning of the nitrogen storage system and purge with air;
- Task 2: Transfer of waste oils and machining waste from the maintenance building to the drum storage area;

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- **Task 3:** Cleaning of deionised water system and removal of resins to hazardous waste storage;
- **Task 4:** Cleaning of refrigeration system;
- **Task 5**: Removal and transfer of ammonia from the compressors;
- Task 6: Isolation and shut down of compressed air plant;
- **Task 7:** Removal of oil from the compressors, and desiccant from the dryers;
- **Task 8:** Isolation and shutdown of the stand-by boiler and associated utilities (demineralisation plant);
- **Task 9:** Isolation of gas, steam and electricity supply followed by shutdown of the CHP plant; and
- **Task 10:** Return of waste oils to licensed waste contractor for recovery.

The following points should be taken into consideration for this stage of decommissioning:

- 1. The pressure swing adsorption unit for nitrogen production can be decommissioned when the final cambing of product has taken place;
- 2. It is assumed that the deionised water plant, refrigeration plant, nitrogen storage system and boilers have a capital value and thus no residuals management is considered; and
- 3. An electrical contractor may be required to decommission some of the electrical equipment. This is subject to discussion between the owners of the CHP plant and Wyeth.

### Refrigeration

There is a chilled water plant on site. There are 6 compressors, associated with the chilled water plant, which contain ammonia. The compressors contain an estimated quantity of 1.6 tonnes of ammonia. The ammonia from the closed loop refrigeration system will be removed by a specialist contractor.

#### **Cryogenics**

The liquid nitrogen storage can store 19 tonnes of liquid nitrogen. It is anticipated that a specialised company will be contracted for decommissioning.

#### Laboratories

It is assumed that laboratory instruments can be sold on as assets, with decommissioning costs associated primarily with expired chemicals and laboratory waste disposal.

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#### **Contractor Compounds**

Wyeth Nutritionals Ireland will be responsible for ensuring the decommissioning of the contractor compounds on-site. Additional contractors will be required for the decommissioning process. It is anticipated that there will be no residuals associated with this operation.

#### **Administration Buildings**

At this stage, it is assumed that only partial administration facilities will be required for the remaining site decommissioning operations and the successful completion of the RMP. The only anticipated residuals associated with decommissioning of the administration buildings include waste electrical and electronic equipment (WEEE). Present figures indicate approximately 300 PCs and 100 printers at the facility, which would require disposal. Removal and disposal of fluorescent tubing is considered in Stage 7.

#### **Water Treatment Plant**

There is on-site storage for 757m³ of treated water, once the plant requirement is reduced below this level decommissioning of the water treatment plant can begin.

The primary tasks in decommissioning the Water Treatment Plant would involve the following:

- Task 1: Flush and isolate the feed lines;
- Task 2: Treat remaining raw water through treatment stages;
- **Task 3:** With submersible primps or equivalent, pump the sludge in the clarifier to the WWTP;
- Task 4: Remove the sand from the filters and resin bed from the softener;
- **Task 5**: Remove the any remaining sodium hypochlorite;
- **Task 6:** Power clean the system and discharge effluent to the sewer; and
- **Task 7:** Dispose of residual treatment chemicals (alum, polyelectrolyte, sodium hypochlorite), salt, sand and resin.

#### Wastewater Treatment Plant (WWTP)

Production and subsequent decommissioning will generate the majority of the effluent to be treated in the on-site WWTP. Therefore, the WWTP may be reduced in loading rate to an acceptable minimum to allow functioning over the remaining decommissioning phase. It is anticipated that equipment, vessel, pipeline and tank washing generated effluent over the remaining decommissioning period will allow the functioning of the WWTP. Therefore, the WWTP will be the last process to undergo decommissioning.

It is assumed that the final effluent will be monitored throughout the decommissioning period for compliance with the operating IPPC licence as normal.

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The primary tasks in decommissioning the WWTP would involve the following:

Task 1: Flush and isolate WWTP feed lines;

Task 2: Treat remaining raw effluent through treatment stages;

**Task 3:** With submersible pumps or equivalent, pump balance tank and sequencing batch reactor (SBR) contents to the sludge dewatering plant, and drain supernatant to tankers for off-site treatment in an activated sludge wastewater treatment plant;

Task 4: Power clean SBR and repeat Task 3;

Task 5: Decommission de-watering facilities; and

**Task 6:** Dispose of de-watered sludge.

#### **Fire Suppression System**

The fire suppression system at Wyeth Nutritionals Ireland contains 20,000 litres of FM200 agent. While FM200 is not categorised as an ozone depleting substance it does have global warming potential. The system is maintained by a specialist contractor. The gas can be recovered from the system prior to its decommissioning and reused by the contractors. This system will be one of the last systems to be decommissioned and can only be removed when all potential fire sources have been eliminated from the site.

#### **Budget Cost Estimates**

The cost of the gas removal will be covered by the resale value of the system.

#### **Fire Water Utilities**

There are two firewater tanks on the site. In addition there is a water storage tank associated with the water treatment plant and a water tank which contains the water supply for the sprinkler system. The water contained in the storage tank associated with the water treatment plant will be used during the final processing. The remaining water can be discharged to the River Deel provided that it is uncontaminated. In the worst case, it can be discharged to the WWTP.

#### LPG Plant

LPG tanks can be isolated and removed by Calor. Calor also lease the tanks to Wyeth and will remove the tanks at no additional cost.

#### Plant Status at the Completion of Stage 6

All site utilities, with the exception of limited electrical supply, effectively decommissioned.

#### Time to Complete

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Utility decommissioning should not start until cleaning (Stage 5) has been completed. The WWTP would be the final facility to be decommissioned. An overall estimate of the time to decommission all utilities is 6 weeks.

#### **Budget Cost Estimates**

The estimated cost to hire an electrical contractor to decommission some of the electrical equipment and to have the decommissioning work certified by the ESB is €26,300. The remaining residual management and disposal costs are detailed in the following sections:

#### Refrigerants

Following decommissioning, the disposal of gas will be coordinated by approved waste management contractors. This is a worst case scenario. The disposal cost of €16 per kg is only charged if, when a sample of the gas is analysed, the gas is not fit for recovery. In the case when the gas can be recovered, there is no charge. Table 5.1.6.1 provides a cost estimate based on €16 per kg.

Table 5.1.6.1 Cost Estimates for Ammonia Gas Removal and Recovery

Compound	kg	Disposal Cost (€)
Ammonia	1,600 control of the	25,600
Total	Cost (approximate)	25,600

#### **Laboratory Waste**

It is anticipated that following decommissioning of site laboratories there will be expired chemicals and general laboratory waste requiring disposal. A PC sum of €33,760 is provided for waste removal and subsequent disposal.

#### Waste Electrical & Electronic Equipment

The worst case scenario would involve disposal of all PCs and printers at the Wyeth Nutritionals Ireland facility. There are approximately 300 PC's and 100 printers, with present disposal costs at €80 per PC and €14 per printer, giving a total cost of €25,400 for adequate disposal.

#### Waste oils

Heavy fuel oil (HFO) storage tank was emptied of HFO during 2009 and Wyeth Nutritionals does not plan to use HFO as a fuel in the foreseeable future, therefore this tank will remain empty. However, the tank and associated pumps and pipework were not cleaned during 2009. Costs for cleaning of the HFO tank and associated pumps and pipework are accounted for in section 5.1.6.

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#### Water treatment plant

The decommissioning costs for the Water Treatment Plant are as follows:

- 1. The clarifier, sand filters, softener, chlorination and storage tank: allow €10,000 per tank, 6 tanks. Total estimate: €60,000
- 2. The total sand filter tank volume is approximately 9 m³ and total softener volume is 10m³. It is assumed for the purposes of the CRAMP that the sand and resin are non-hazardous and so will be diverted to landfill at an approximate cost of €150 per tonne, with an overall costs estimated at €1,200.

This gives a total budget cost estimate for the Water Treatment Plant is €61,200.

### **WWTP**

The decommissioning costs for the WWTP are as follows:

- Effluent collection sump, balance tank, two SBRs, buffer tank, picket fence sludge thickener, sludge dewatering plant: allow €10,000 per tank, 6 tanks. Therefore estimate: €60,000
- 2. Dewatered sludge composting: Total balance tank volume is approximately 1,800 m³ and total SBR volume is 5,000m³. Based on 2007 waste data, Wyeth disposes of approximately 3000 tonnes of sludge on an annual basis from the WWTP by composting, at €100 per tonne, with an overall costs estimated at €300,000.

This gives a total budget cost estimate for the WWTP of €360,000.

### 5.1.8. Stage 7: Removal of Residual Hazardous Materials

This stage applies to the situation where there may be specific residuals associated with the building structure and plant equipment that may not be removed during an annual maintenance shutdown. This includes PCBs, radioactive wastes and fluorescent tubes but does not include for actual concrete that may be contaminated.

#### Task 1: Remove identified hazardous materials (asbestos etc).

Wyeth Nutritionals commissioned Safeway Environmental Ltd. to complete an Asbestos Survey Report during 2009. This survey was completed in March 2009 and the Survey Report lists the following asbestos materials present on site:

- Boiler Room:
  - Compressed flange gaskets to pipe work, plant and equipment throughout;
  - Compressed flange gasket debris to high level walkway;
  - Mastic sealer to casing of Boiler #2;

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- o Galbestos cladding (part) to external walls and roof of boiler room;
- Compressed flange gaskets to pipe work, plant, equipment located outside the boiler room and on top of the boiler room;
- Compressed flange gaskets to pipe work in old oil pumping shed;
- Old style fire doors throughout Offices, Laboratories and production areas;

#### Main Plant Area:

- Galbestos cladding (part) to Dryer #1;
- Galbestos cladding (part) to Dryer #2;
- o Galbestos cladding (part) to Dryer #3;
- o Galbestos cladding internally within Pipe Bridge;
- Galbestos cladding internally within Old Tank Farm;
- o Galbestos cladding to roof over man production and canning area;
- Compressed flange gaskets to pipe work and equipment within Old Tank farm;
- Compressed flange gaskets to pipe work and equipment throughout Dryer #2;
- Compressed flange gaskets to pipe work and equipment throughout Dryer #3.
- Compressed flange gaskets to pipe work and equipment throughout Dryer #4:
- Compressed flange gaskets to pipe work supplying Heating / Ventilation equipment throughout factory;
- Bitumen mastic beneath floor tiles on Production Offices;
- Old style fire doors throughout Offices, Laboratories and production areas:

#### • High Rise Warehouse:

- Compressed flange gaskets to pipe work supplying Heating / Ventilation equipment throughout High Rise Warehouse Area;
- RTF Building:

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 Compressed flange gaskets to pipe work supplying Heating / Ventilation equipment throughout the first floor plant room areas.

An approximate estimate of €400,000 is given for removal and disposal of Asbestos materials. This estimate is based on the middle of the pricing range provided by an asbestos removal specialist company, who provided a range of €200,000 to €600,000. The exact costs would depend on the multitude of factors related to asbestos disposal options, asbestos accessibility, ease of removal, etc. The exact costs can only be determined upon the site visit and a thorough assessment of identified asbestos materials.

There are no PCB sources on the Wyeth Nutritionals Ireland site.

#### Task 2: Remove and dispose of radioactive material and fluorescent tubing.

It is difficult to estimate the number of fluorescent tubes that exist on the site - 5000 is an approximate figure. There are also UV lamps, used in the sterilisation processes on site which may be classified as hazardous. Based on the approximate weight of 300 grams per fluorescent tube, €1,400 per tonne of WEEE charged by the Irish Lamp Recycling Ltd. in 2009 and allowing 50% buffer, a budget of €3,150 is allowed for lamp disposal.

The site holds a licence from the Radiological Protection Institute of Ireland (RPII) for a radioactive source (100 grams of thorium pitrate). The site is waiting for the RPII to advise on the correct disposal route. However, the disposal is not expected to incur any costs.

## Plant Status at Completion of Stage 7

All hazardous residual materials removed off-site.

## Budget Cost Estimate

The overall cost estimate to removal asbestos material and fluorescent tubing from the site is €403,150.

#### Time to Complete

An overall estimate of the time required to decommission and remove all residual hazardous materials off-site is 6 weeks.

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# 5.1.9. Stage 8: Documentation and Certification of Decommissioning and Decontamination

Throughout implementation of the CRAMP, documentation will be generated to track the progress. All residues removed from site will be recorded and final clearance certificates will be prepared as required under the terms of the IPPC licence and as required under relevant waste management regulations. Environmental documentation must be retained by the company for a period of 7 years, financial and health and safety data must be retained for much longer. Arrangements for secure storage must be made as one of the final tasks of the decommissioning process.

A full report on the outcome of the CRAMP will be prepared and submitted to the EPA.



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## 5.2. Long Term Programme

#### 5.2.1. Introduction

Soil and groundwater investigation work has been completed on behalf of Wyeth by URS 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 Wyeth site is located on a gently sloping coastal 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 surrounding land use is predominantly agricultural, consisting mainly of pasture land.

Bedrock beneath the site has been mapped as Waulsortian limestone by the Geological Survey of Ireland (GSI). This limestone comprises tesh, massive, blue grey, fine to coarsely crystalline, occasionally cherty, unaltered fossiliferous limestone. According to the GSI 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 throwledge of the groundwater by site personnel supports this data.

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

Groundwater monitoring results indicate that there is 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 appears to be from the river outwards into the surrounding limestone aquifer and this reverses during low tide conditions.

Table 5.1 contains a summary of the more historical aspects of releases to ground and groundwater on the site. The incidents summarised in Table 5.1 have been detailed in previous versions of the CRAMP.

Table 5.1: 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.

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Date	Incident & Effects	Current Status		
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.		
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 overground 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.		
1 - A - ''	In April 2007 major ion recults were within their normal concentration ranges with the			

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. Wyeth have confirmed that there have been no leaks in the sewer system since that time.

Wells 202 and 203 were resampled in July 2007. Surface water from the River Deel was also sampled in July as a result of the 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.

Major ion and microbial concentrations in groundwater from wells 101 and 202 were again elevated in October 2007 and December 2007, which as stated previously is likely to be a result of influent water flow from the river to the groundwater.

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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 Wyeth's wastewater treatment plant be sampled during quarterly monitoring rounds.

A decrease in major ion concentrations and microbial concentrations was recorded 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.

Overall, a decrease in major ion concentrations and microbial concentrations was recorded in March 2009, relative to November 2008.

There appears to be negative impact on the groundwater quality adjacent to the River Deel in terms of COD and bacteriological quality, due to the Limerick County Council sewage discharge to the River Deel from their sewage treatment facility within the Wyeth 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.

Wyeth Nutritionals run a continuous programme of pipeline testing and repairs.

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

## 5.2.2. Characterisation of Potential Source areas of Chemical Release

Following the site closure, investigations of potential source areas of chemical release would be carried out by undertaking an intrusive investigation close to areas of potential concern. Undertaking a post site closure investigation also guarantees that data is collected at a point in time that marks the end of chemical use/transfer/storage on the site. The intrusive investigation would focus primarily on the subsoils (<5 m thick).

The existing groundwater database from the existing site bedrock wells is comprehensive. Therefore only a relatively limited groundwater investigation will be needed.

The budget required to complete a comprehensive investigation of potential source areas, including soil drilling, laboratory analysis, drains survey, risk assessment and reporting is estimated to be €11,000.

## **5.2.3.** Design/implementation source area soil remediation programme (as appropriate)

Significant shallow soil contamination could continue to leach to groundwater, effectively acting as an ongoing source of groundwater contamination. If such contamination is discovered during the post-closure investigation, it would have implications on the potential future use of the site. Therefore the results of the post-closure investigation study will be used to establish whether specific corrective action will be required. Risk

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based decision making will be used to quantitatively evaluate the appropriate levels of residual contamination that can be left in place.

Based on the currently available data, significant shallow soil contamination is unlikely. For the purposes of this CRAMP, it has been assumed that no significant, long-term residual contamination beneath the Wyeth site exists and no groundwater interception and treatment will be required.

Annual modifications to the CRAMP may alter this assumption if, in the meantime, further investigations of potential soil contamination are completed.

## 5.2.4. Management of corrective action programme with post remediation monitoring

Following the site closure, a period of groundwater monitoring will be required.

In a site closure and decommissioning situation, the scope of the groundwater monitoring programme would be a variation on the current monitoring programme underway at Wyeth and would be based on the most up-to-date data available on the quality of groundwater at that time.

Assuming a total of two years monitoring, until final closure and surrender of the IPPC licence, groundwater monitoring and data assessment/reporting costs for the existing five wells at Wyeth Askeaton are estimated to be €13,000 per year, totalling €26,000 over 2 years.

In the event that the EPA require further characterisation of groundwater based on the findings of the soil investigation, it is assumed that a further four bedrock wells would be required. Estimated cost for drilling a well is €5,500, and additional monitoring costs are estimated to be €1000 per well per year. The total additional cost is estimated to be €30,000 over 2 years.

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#### 6. TEST PROGRAMME

Following completion of all decontamination and decommissioning operations on-site, all documentation will be compiled (as previously detailed in Section 3.0) and submitted to the EPA and relevant authorities. It is assumed that this will be sufficient to demonstrate successful implementation of the decommissioning plan. Furthermore, in relation to the successful implementation of the LTP, it is also assumed that any ongoing soil/groundwater remediation and/or monitoring programmes will be accompanied by associated monitoring data. This monitoring data will demonstrate any contaminant levels and/or ongoing performance of treatment systems, will be submitted to the EPA and relevant authorities and will demonstrate the completion of the programme. A certificate of completion will be issued on completion of the CRAMP.



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## 7. SUMMARY OF COSTS ASSOCIATED WITH THE CRAMP

This section briefly summarises the costs presented in Sections 5.1 and 5.2 of this report. The summary is presented in Table 7.1 and includes all costs identified during the analysis of the Short Term and Long Term Programmes.

**Table 7.1 Summary of CRAMP Costs** 

ITEM	DESCRIPTION	COST (€)
STP.1	Production decommissioning	340,000
STP.4	Production related hazardous waste disposal	323,376
	Production related non-hazardous waste disposal	351,496
STP.5	Cleaning of bulk storage	62,900
STP.6	Decommission site utilities, including:-	
	Decommission & certification of electrical work	26,300
	Disposal of laboratory waste	33,760
	Disposal of ammonia gas	25,600
	WEEE disposal costs	25,400
	Decommissioning of water treatment plant	61,200
	Decommissioning of WWTP	360,000
STP.7	Disposal of residual hazardous materials	403,150
	SUB TOTAL STP (approximate)	2,013,182
	is on of	
LTP	Investigation for potential contamination sources	11,000
	Management of groundwater corrective action	56,000
	Carse	
	SUB TOTAL LTP (approximate)	66,000
	ODAMO TOTAL (approximate)	0.070.400
	CRAMP TOTAL (approximate)	2,079,182

In conclusion it has been estimated that, in the event of site closure involving complete cessation of all production activities by Wyeth Nutritionals at Askeaton, an allowance of approximately  $\in$  2.1 M would be required to confirm the site to an environmentally safe (inert) condition.

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## 8. UNDERWRITING THE CRAMP – FINANCIAL INSTRUMENT

It is imperative to demonstrate the successful underwriting of the CRAMP. Appendix B contains a copy of a correspondence from Pfizer International, ultimate owner of Wyeth Nutritionals, confirming that liabilities associated with decommissioning will be underwritten by Pfizer Inc., and funded from Pfizer Inc. central funds.



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### 9. REVIEW OF THE CRAMP

The summary of costs associated with the CRAMP, as presented in Section 7.0 of this report, are estimates only and are based on the information and data available at the time of compilation of the report. It is anticipated that these costs will vary as time progresses and will depend on factors, including the following:

- · Site conditions;
- Legislative developments;
- Advances in remediation technology;
- Inflation.

Therefore, it is important that the CRAMP is reviewed and updated to reflect the current site situation. In addition, IPPC licence requirements specify the CRAMP report must be reviewed on an annual basis as part of the Annual Environmental Report.



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Appendix A - Site Sensitivity Assessment

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#### 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 timestone 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 (<44m³ / 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 Wyeth 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 by draulically 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 it to an 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

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#### **Wyeth Nutritionals Ireland**

Askeaton, Co. Limerick Ireland 061 392168 tel 061 392440 fax

Wyeth

Ms Regina Campbell.
Office of Environmental Enforcement,
Environmental Protection Agency,
Regional Inspectorate,
Inniscarra,
Co. Cork.
August 22, 2005

Dear Ms. Campbell,

In compliance with condition 14.2 of our Integrated Pollution Control Licence ref. 678, WNI are required to prepare and submit to the Agency for agreement a fully detailed and costed Residual's Management Plan for the decommissioning or closure of the site or part thereof.

The plan for WNI was submitted to the Agency on 19th August, 2005. As regards our commitment to comply with Section 4 of the Plan, the Company [licensee] undertakes to activate, execute and fund its cost, in the very unlikely event of site closure at Askeaton. The Company shall obtain all relevant permissions prescribed by Local and/or National Authorities and shall comply with all requirements of such permissions and with all Building regulations and statutory requirements (if any) required for the undertaking at Askeaton. The Company shall materially comply with all applicable statutory requirements and the integrated Pollution Control License issued by the Environmental Protection Agency in relation to environmental controls and the prevention of pollution in connection with the undertaking at Askeaton.

Trusting this is to the satisfaction of the Agency. Should you have any queries please do not hesitate in contacting me.

Yours sincerely,

Wyeth Nutritionals Ireland is a business name of AHP Manufacturing bv, a company incorporated (Reg. No. 80067) with limited

liability in The Netherlands

Registered in Ireland – No. E3277

Managing Directors:

William J. Noonan Ploos van Amstel (Dutch) Paul J. Jones (U.S.A.) Eileen M. Lach (U.S.A.) Jack M. O'Connor (U.S.A.)



Appendix C - Gantt Chart

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## **Figure: Timetable for Decommissioning Process**

ID	Stage	W	W	W	W	W	W	W	W	W	W	W	W	W	W	W	W	W	W	W	W	W	W	W	W	W	W
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26
1	Production Decommissioning		_																								
2	Removal of Excess Materials			_	_	_	_	_	_	_	_	_		other i	se.												
3	Treatment of Bulk Liquid Wastes					_						airposes	orld or a	<b>,</b>													
4	Removal of Production Wastes			_						Foris	Spection right out	net reev															
5	Cleaning							_	Conser	TO,	_			_				_			_						
6	Decommissioning WWTP & Utilities.																										
7	Removal of Residual Hazardous																										
8	Documentation																										

Where W = week



# Transfer of Licence Application Form

# ATTACHMENT F(b) Environmental Liability Risk Assessment



ELRA Update 2010 Liabilities
Environmental Liabilities
Risk Assessment 2010

04 May 2010 Final

Issue No 2 49340715 /



**Project Title:** ELRA Update 2010

**Report Title:** Environmental Liabilities Risk Assessment 2010

49340715 **Project No:** 

Report Ref:

Status: Final

**Client Contact Name:** Brian Shiel

**Client Company Name:** Wyeth Nutritionals

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# **Document Production / Approval Record**

Issue No: Name **Signature** Date **Position** 2 Prepared Klara Kovacic 04/05/2010 Project Manager by Checked Peter Hassett 04/05/2010 Department Head, and Transactions & approved Compliance by

# **Document Revision Record**

Issue No	Date	Details of Revisions		
1	04/05/2010	Original issue		
2	04/05/2010	Final issue		



#### LIMITATION

URS has prepared this Report for the sole use of Wyeth Nutritionals in accordance with the Agreement under which our services were performed. No other warranty, expressed or implied, is made as to the professional advice included in this Report or any other services provided by us. This Report may not be relied upon by any other party without the prior and express written agreement of URS. Unless otherwise stated in this Report, the assessments made assume that the sites and facilities will continue to be used for their current purpose without significant change. The conclusions and recommendations contained in this Report are based upon information provided by others and upon the assumption that all relevant information has been provided by those parties from whom it has been requested. Information obtained from third parties has not been independently verified by URS, unless otherwise stated in the Report.

Where assessments of works or costs required to reduce or mitigate any environmental liability identified in this Report are made, such assessments are based upon the information available at the time and are subject to further investigations or information which may become available. Costs may therefore vary outside the ranges quoted. No allowance has been made for changes in prices or exchange rates or changes in any other conditions which may result in price fluctuations in the future. Where assessments of works or costs necessary to achieve compliance have been made these are based upon measures which, in URS's experience, could normally be negotiated with the relevant Peritum thinking teditied for an authorities under present legislation and enforcement practice, assuming a pro-active and reasonable approach by site management.

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# 1. INTRODUCTION

# 1.1. Background

Wyeth Nutritionals Ireland (WNI) was granted an IPPC licence, Register No. P0395-02, by the Environmental Protection Agency on 24<sup>th</sup> January 2004. This licence was amended on the 26<sup>th</sup> 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 Wyeth site is located in Askeaton, Co. Limerick. The Wyeth 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 ligence requires the licensee to arrange for the preparation of an Environmental Liabilities Risk Assessment (ELRA) covering the Wyeth Nutritionals Ireland (WNI) Askeaton site. The ELRA must address liabilities arising from past and present activities and must be completed by an independent and appropriately qualified consultant. Furthermore, the financial provision for the completed ELRA must be reviewed annually and agreed with the EPA.

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 and 2009 to account for any changes in risk in the previous years.

This is the fifth revision of the ELRA and will account for any changes in risk since the 2009 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 unnotice 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 Pisk 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 Wyeth Nutritional Ireland 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 Wyeth 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 Wyeth Nutritionals Ireland at their Askeaton sites including Phase I and Phase II assessments, IPPCL compliance audits, hydrogeological investigations, Air Dispersion Modelling and Closure Restoration and Attendare Management Plans. We are currently monitoring groundwater at the site on a total fund that the site of the sit

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## 2. OVERVIEW OF WYETH

# 2.1. The Company

Wyeth Nutritionals Ireland (WNI) is part of the Wyeth Corporation. Wyeth Corporation has been acquired by Pfizer Inc. in 2009. Pfizer Inc. and Wyeth Corporation began joint operations on October 16, 2009. The company operates a strict environmental policy.

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

Wyeth Nutritionals Ireland (WNI) was established in Askeaton Co. Limerick in 1973 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 Wyeth plant.

The WNI 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 in 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

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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 1<sup>st</sup> quarter 2005.

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

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# 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 2005 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 aquiters 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).
- **Pollution 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</li>
- 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 Wyeth 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 WNI.

#### 3.3. **Environmental Sensitivity**

A sub-matrix for environmental sensitivity for the WNI 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
- Skot inspection buttores only any other use. 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

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Table 3.2 - Environmental Sensitivity Sub-Matrix

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

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

Scores in Table 3.2 appropriate for WNI are underlined in bold font typeface. Based on the above Environmental Sensitivity Sub-Matrix, the total environmental attribute score for Wyeth 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'.

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## 3.4. Pollution Record

The pollution 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 minor non-compliances (< 5 non-compliances in 12 month period) are classified as being **Minor Non-Compliant** and have a score of 2. 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 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 3.

As part of the preparation of the ELRA, documentation relating to IPPC licence compliance, in particular monitoring reports to the ERA were reviewed for 2003, 2004, 2005, 2006 and 2007. This documentation review demonstrated a high compliance level with IPPC licence specified emission limit values. In 2007 there were zero exceedances of emission limit values with respect to believe emissions or emissions to water. Wastes arising at Wyeth Nutritionals Ireland, comprising largely non-hazardous wastes, are characteristic of a food processing operation.

Another aspect of IPPC licence compliance relates to environmental complaints. Wyeth Nutritionals Ireland have had noise and dust complaints. In 2007, there was one odour complaint and one noise complaint. Complaints are reported to the EPA monthly (except in certain emergency or serious circumstances) and submitted as part of the Annual Environmental Report

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.

2009, there were no major accidents on site.

The following non-compliances occurred on site during 2009:

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- 1. Emission limit value for BOD at discharge point SW-1, set at 40 mg/l in the site's IPPC licence, was exceeded twice (measured BOD values were 54.94 mg/l and 60.25 mg/l); and
- 2. Emission limit value for ammonia at discharge point SW-1, set at 10 mg/l in the site's IPPC licence, was exceeded was exceeded once (measured ammonia value was 16 mg/l).
- 3. Emission limit value for particulate emissions to atmosphere are set at 50 mg/Nm<sup>3</sup> in the site's IPPC licence and this was exceeded once (measured particulates value was 52.3 mg/Nm<sup>3</sup>).

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 the above, a Pollution Record score of '3' is assigned to WNI.

#### 3.5. Risk Category

The proceeding subsections of this section has determined the:

Complexity Score (G4) = 3

Rection Putposes Environmental Sensitivity Score = 3

Pollution 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 Wyeth Nutritionals Site?

Table 3.3 - Risk Category

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

The Wyeth 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 WNI.

# 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 Wyeth Nutritional Ireland 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 Wyeth Nutritional 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, WNI 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. Only three such exceedances occurred in 2009.

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 more 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	e 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 overground 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 penerated 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. Wyeth 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.

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.



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 Wyeth'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.

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 Wyeth 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 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 2010. Also there are new secondary bunds around four 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 Wyeth 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. Assuming that the decrease of contaminants continues, the total cost of this management strategy is estimated to lie in the region of €13,000 per annum over the next year. These costs are not significant in terms of total site financial turn-over.

# 5. HIGH RISK FACILITY – SITE SPECIFIC ELRA

# 5.1. General

For High Risk facilities such as WNI, 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 WNI. 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 appotential 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:

- 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 WNI 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 WNI.

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

Table 5.2: Risk Classification Table - Occurrence

Rating/ Score	Category	Description the tree to the contract the con	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 nazard 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

# 5.2.3. Risk Classification Severity Assessment

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

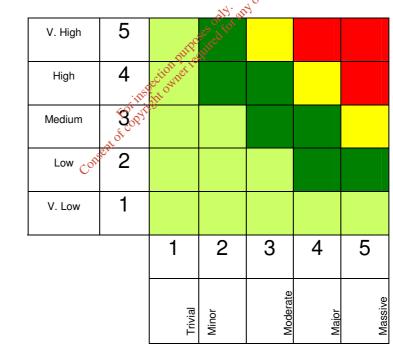


Rating/ Score	Category	Description	Cost of Remediation (€)
1	Trivial	No damage or negligible change to the environment	<1,000
2	Minor	Minor impact/localised or nuisance	1,000-10,000
3	Moderate	Moderate damage to the environment	10,000-100,000
4	Major	Severe damage to the environment	100,000- 500,000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

Table 5.3: Risk Classification Table - Severity Criteria

## 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 stick matrix.



# Occurrence

# Severity

# 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 associallocated for the implementation of each risk mitigation measure.



# 5.3. Identification of Risks at WNI

Through a combination of site visits and utilising information supplied by WNI 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 7.4 illustrates the Risk Register.

Table 5.4: - WNI 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 Stanker 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	Site Closure Conservation
13	Blocking of dryer cyclone
14	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 WNI 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 Surposes only any off Surposes only any off	No previous incidents in 33 years of WNI 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	Three IPPCL ELV breaches in 2009. 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.

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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 hupposes only any of the required for any of	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.	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 complete. All solvent transfers handled on a concrete surface.	3	Solvent containing materials, including toluene, with vulnerable and regionally important aquifer beneath the site. Maximum possible amount of spillage is 1000 litres.
6	Parking of ISO tankers	Accidental release of food oils from ISO tanker	Potential pollution of soil and groundwater	1	No previous incidents in 33 years of WNI	2	Large quantity of product loss possible.



Table 5.5 – Risk Assessment

Risk ID	Process	Potential Hazard	Environmental Effect	Occurrence Rating	Basis of Occurrence	Severity Rating	Basis of Severity
		parking areas.	immediate to storage areas.	, di	operation.  The tanks are built to withstand a drop and rough handling during the transport.		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).  Red Transport of the contract of the co	Authorized for any	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 covered by the end of 2010. Improvements included replacement of some pipes and manholes and some pipes were brought	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
					above ground.		
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 putposes only any off	No previous incidents in 33 years of WNI operation. There are new secondary bunds around all four mixed process tanks.	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 were fitted with high level alarms and automatic fill shut off.  All process storage tanks are bunded since 2008.	3	Large release directly to ground & groundwater or surface water possible however, good management of the process tanks and secondary containment and improved instrumentation.
10	All processes	Loss of containment of contaminated	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.



Table 5.5 – Risk Assessment

Risk ID	Process	Potential Hazard	Environmental Effect	Occurrence Rating	Basis of Occurrence	Severity Rating	Basis of Severity
		firewater					
11	All processes	Contamination of by-product sold as animal feed	Health effects on animals or humans.	1 purposes only any off	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 Wyeth facility, the financial exposure from any contamination event, regardless of risk, could be significant.
12	Site Closure	Residual environmental pollution. Accidental release of potentially polluting substances. Mis-management of waste.	Various Control	1	Proposed/expected lifetime of production building, etc.	5	Costs associated with Site closure – See RMP
13	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. Wyeth are currently considering continuous monitoring of the dryers.		
14	Various	Odorous Fugitive Emissions	Odour Nuisance	2 of the lot and off	Only one odour complaint received in recent years.	1	Localised impact



# 5.4. Assessment of Risks at WNI

# 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.	5	3	15
12	Residual environmental pollution. Accidental release of potentially polluting substances. Mismanagement of waste.  Wastewater treatment plant overloading and so failure of biological treatment  Contamination of byproduct sold as animal feed	1 use only other use	. 5	5
2	Wastewater treatment plant overloading and so that failure of biological treatment 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	1	3	3

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Table 5.6 Risk Register ranked by Risk Score

Risk ID	Description	Occurrence	Severity	Overall
	hazardous chemicals in yard areas during transport (e.g., chlorine based disinfectants, detergents, thinners, coating laquor)			
3	Release of gas oil to ground or surface water	1	3	3
1	Wastewater treatment plant overflow	1	3	3
14	Odorous Fugitive Emissions	2	. 1	2
13	Blocking of cyclones resulting in dust deposition	2 offer us	1	2
6	Accidental release of food oils from ISO tanker parking areas.	2 offer face of the face of th	2	2

# 5.4.2. Risk Matrix

Risk Matrix

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

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5 V. High 4 High 3 Medium 2 13,14 2 Low 6 1, 3, 4, 10, 11 13 1 V. Low 5, 8, 9 1 2 3 4 5 Moderate Massive Major Severity

**Table 5.7** – Risk Matrix (specific to WNI)

ned is a high level risk.
Yellow is a medium level risk, partial of the first of th

Table 5.7 above indicates that 13 risks are low level risks and do not require immediate action. However, there is a need for continuing awareness and monitoring on a regular basis.

#### 5.5. **Risk Prevention, Mitigation and Management**

The risk assessment and categorisation phase identified one risk in the yellow zone which requires mitigation and management action. Mitigation and management actions identified and implemented for this risk should be a matter of priority.

Table 5.8 illustrates the recommended risk mitigation measures identified during this assessment. Such measures are currently under way at WNI or have been planned as part of the company's Environmental Management Programme.



Table 5.8 Risk Mitigation Form

Risk ID	Process	Potential Hazard	Risk Score before Mitigation	Possible Mitigation measures	Time to Complete	Revised Risk Score
7	Process effluent and domestic effluent drainage	Failure of underground pipelines or sumps	15	Ongoing CCTV and hydrostatic survey in place. Survey of entire site and all required repairs planned to be completed by the end of 2010.	1 year	15
2	Operation of Wastewater Treatment Plant	astewater overloading and so failure		Improvement programme for control of emissions to water not implemented in to date due to high costs. This programme may be re-considered in the future. The operation of WWTP is currently considered to be of sufficiently high standard.	Undefined.	6



Risk ID No. 7 is assigned medium level risk due to the remaining portion of underground drainage scheduled for repair and given the sump failure incident in May 2008. The testing & repair programme should be completed by end 2010.

#### 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 WNI facility were calculated through the preparation and costing of the RMP (refer to Site Specific RMP prepared for WNI).

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 and as revised through consideration of risk mitigation measures (refer to Table 5.8):

- 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 WNI facility the worst case scenario was calculated. Table 5.10 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 5.10 – 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 (€) B	Most Likely Cost (€) = A x B
7	Failure of underground and overground pipelines or sumps.	5	50 to 100	3	10,000 to 5. 100,000	100	100,000	100,000
11	Contamination of by-product sold as animal feed	1	0 to 5	4 other	100,000- 500,000	5	500,000	25,000
10	Loss of containment of contaminated firewater	1	0 to 5 purpos	fired 4	100,000- 500,000	5	500,000	25,000
1	Wastewater treatment plant overflow	1	0 to 5 purpose of the first of	3	10,000- 100,000	5	100,000	5,000
3	Release of gas oil to ground or surface water	1 Conser	0 to 5	3	10,000 to 100,000	5	100,000	5,000
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	10,000- 100,000	5	100,000	5,000
5	Accidental spillage of drummed solvents and laquor in the waste storage compound. Protective drain blocked with silt.	1	0 to 5	3	10,000- 100,000	5	100,000	5,000



Risk ID	Potential Hazard	Occurrence Rating	Likelihood of Occurrence Range (%)	Severity Rating	Cost Range (€)	Worst Case Probability (%)	Worst Case Severity (€) B	Most Likely Cost (€) = A x B
9	Overfilling of process storage tanks	1	0 to 5	3	10,000- 100,000	5	100,000	5,000
2	Wastewater treatment plant overloading and so failure of biological treatment	2	5 to 10	2	1,000 to 10,000	10	10,000	1,000
8	Failure of over ground secondary containment.	1	0 to 5	softing 3	1,000 to 10,000	5	10,000	500
6	Accidental release of food oils from ISO tanker parking areas.	1	0 to 5 he	2	1,000 to 10,000	5	10,000	500
13	Blocking of cyclones resulting in dust deposition	~	6.005 to 10	1	0 to 1,000	10	1,000	100
14	Odorous Fugitive Emissions	2 Canso	5 to 10	1	0 to 1,000	10	1,000	100
12	Residual environmental pollution.  Accidental release of potentially polluting substances.  Mis-management of waste.	1	0 to 5	5	500,000 to 1,500,000	5	1,500,000	2.1 million (*)

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.

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(\*) 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).

Consent of copylight owner required for any other use.

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#### 6. FINANCIAL PROVISION

# 6.1. Current Financial Provisions

There are two financial provisions that are relevant to this study that are in currently in place at WNI:

- 1. Wyeth is 'self-insured', i.e., any costs will be covered by trading revenue, against all liabilities;
- WNI has provided the EPA with a letter of financial guarantee relating to meeting the requirements of a Residuals Management Plan. The RMP includes for residual soil and groundwater contamination that may be present at cessation since the RMP must be updated annually. This letter is provided as Appendix B;

#### 6.2. Assessment of WNI Financial Provision

The environmental liabilities identified and assessed in this report (refer to Section 5) are unforeseen or unanticipated events that could occur suddenly but with only short to medium term impact likely. The exceptions to this are:

- 1. Risk ID 7: Underground pipeline or sump failure. The hazard event can either be unforeseen and sudden (e.g., the darrary 2006 incident described in Section 4), or gradual. However, if the hazard event is gradual, the current risk assessment and testing programme should limit the timeframe over which the event occurs, i.e, a leak, thus limiting the resulting impact;
- 2. Risk ID 3: Release of petroleum product release to ground. Again, there are two ways of looking at this risk. The associated hazard event can be an unforeseen or sudden, e.g., there is a sudden tank failure and/or bund failure. There could also be a gradual hazard event associated with oil storage through historical oil storage over time that may be present but not identified. However, current groundwater monitoring data for groundwater beneath the site does not suggest any significant oil product contamination;
- 3. Risk ID 13: Site Closure. This risk is a well defined event and has been described and costed in the revised Residuals Management Plan for the WNI site.

Having consideration for the 'most likely' costs calculated in Table 5.10, and the above discussion on the types of risk involved, a comparison of existing financial provisions presented in Section 6.1 above may be made with the suggested financial provisions contained in the tables provided in Section 5 of the EPA Guidance Document. Extracts from Table 5.3 of the EPA Guidance Document is compared with existing Financial Provisions (FP) at WNI in Table 6.1.



Table 6.1 - Assessment of WNI Financial Provision

Table 5.3 of EPA Guidance  – Recommended & Appropriate FP	Existing WNI Financial Provision	Comment			
Short-Medium Term Unknown Liabilities: - Insurance	Self-insured, i.e, cover expenditure with available cash flow	Wyeth worldwide has revenue and profit at the billions level.			
Short term unknown liabilities, subsidiary operations of large reputable parent organisation: - Parent Company Guarantee	WNI Guarantee Letter (Appendix B).	This letter was written to include underwriting the RMP. Note that this letter must get parent company approval before issue.			
Known Closure Restoration and Aftercare Liabilities: - Cash Deposits	WNI Guarantee Letter (Appendix B).	This letter was written to include underwriting the RMP.  Note that this letter must			
	although different,	get parent company approval before issue.			
Therefore, it is unlikely that WNt requires any additional financial provisions beyond those detailed in Section 6.1.  Consent of Co					

Wyeth Nutritionals\49340659 Wyeth Nutritional RMP ELRA 09\DURP0001/KK/KK **04** May 2010

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#### 7. CONCLUSIONS

The Wyeth Nutritional Ireland site at Askeaton is well defined in terms of historic and current environmental impacts. The site has been subject to Phase I and II due diligence audits, and is subject to an on-going monitoring programme for releases to air and water as well as surveillance of groundwater.

The overall site sensitivity to environmental liabilities is moderate to low. This has been concluded based on a detailed assessment provided in Section 5.

There was no significant historic environmental liability identified at the site.

The current environmental management programme on the site has reduced the risk of the development of new significant environmental liabilities to a low level.

No scenarios have been identified which could result in environmental liabilities that would threaten the financial solvency of Wyeth Nutritionals Ireland.

The Wyeth parent company guarantee has confirmed corporate commitment to underwrite any required environmentally related remedial works resulting from the activities of Wyeth Nutritionals Ireland.

Appendix B contains a copy of a correspondence from Pfizer International, ultimate owner of Wyeth Nutritionals, confirming corporate commitment to underwrite any required environmentally related remedial works, resulting from the activities of Wyeth Nutritionals Ireland.



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 timestone 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 (<44m³ / 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 Wyeth 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 by draulically 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 it to an 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

#### **Wyeth Nutritionals Ireland**

Askeaton, Co. Limerick Ireland 061 392168 tel 061 392440 fax

Wyeth

Ms Regina Campbell.
Office of Environmental Enforcement,
Environmental Protection Agency,
Regional Inspectorate,
Inniscarra,
Co. Cork.
August 22, 2005

Dear Ms. Campbell,

In compliance with condition 14.2 of our Integrated Pollution Control Licence ref. 678, WNI are required to prepare and submit to the Agency for agreement a fully detailed and costed Residual's Management Plan for the decommissioning or closure of the site or part thereof.

The plan for WNI was submitted to the Agency on 19th August, 2005. As regards our commitment to comply with Section 4 of the Plan, the Company [licensee] undertakes to activate, execute and fund its cost, in the very unlikely event of site closure at Askeaton. The Company shall obtain all relevant permissions prescribed by Local and/or National Authorities and shall comply with all requirements of such permissions and with all Building regulations and statutory requirements (if any) required for the undertaking at Askeaton. The Company shall materially comply with all applicable statutory requirements and the integrated Pollution Control License issued by the Environmental Protection Agency in relation to environmental controls and the prevention of pollution in connection with the undertaking at Askeaton.

Trusting this is to the satisfaction of the Agency. Should you have any queries please do not hesitate in contacting me.

Yours sincerely,

Wyeth Nutritionals Ireland is a business name of AHP Manufacturing bv, a company incorporated (Reg. No. 80067) with limited

Registered in Ireland - No. E3277

liability in The Netherlands

Managing Directors:

William J. Noonan Ploos van Amstel (Dutch) Paul J. Jones (U.S.A.) Eileen M. Lach (U.S.A.) Jack M. O'Connor (U.S.A.)



# Transfer of Licence Application Form

# ATTACHMENT F(c) Financial Provision in respect of costs/liabilities



# <u>Financial Provision</u> Licence Register No. P0395-02

The Wyeth facility located at Askeaton, Limerick, County Limerick (the "Facility") is owned by Pfizer (NEW PIP) Holdings, an indirect wholly-owned subsidiary of C.P. Pharmaceuticals International B.V. ("CPPI/CV"). Pfizer (NEW PIP) Holdings is an unlimited company established in Ireland and registered in the Companies Registration Office [Registered Number 490938]. . C.P. PHARMACEUTICALS INTERNATIONAL C.V. is a Dutch limited partnership (*commanditaire vennootschap*) formed and established under the law of the Netherlands and for all purposes represented by and acting through its general partners, Pfizer Manufacturing LLC, a company organized under the laws of the State of Delaware, United States of America, with address at 235 East 42<sup>nd</sup> Street, New York, New York 10017, United States of Delaware, United States of America, with address at 235 East 42<sup>nd</sup> Street, New York, New York 10017, United States of America, in their capacity as general partners of such C.V.

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

CPPI/CV is a partnership ("commanditaire vennotischap") that owns a large number of affiliates and subsidiaries in a number of different countries, whose number may change from year to year. CPPI/CV operates a holding function. Certain affiliates of CPPI/CV also carry on the business of manufacturing pharmaceutical, animal health, consumer health and nutritional products. CPPI/CV sultimate parent company is Pfizer Inc. (New York, USA). CPPI/CV has recorded net profits in excess of \$13 billion (USD) in 2009.

In the event of a decision to decommission the Facility, the Facility's Residual Management Plan ("RMP") would be prepared for activation. The actions detailed in the RMP would begin upon cessation of manufacturing at the Facility and preparation for closure. Any shutdown of the Facility would be planned and fully funded. Production schedules and raw materials purchasing would be planned with shutdown factored in. The Facility will have the resources in terms of both financial inputs and manpower to implement the RMP through to completion.

In the event of a shutdown of the Facility and, therefore, activation of the RMP, and upon default of the Facility to undertake its obligations in connection with the RMP, CPPI/CV undertakes that it will, by itself or through one of its subsidiaries (including Pfizer (NEW PIP) Holdings), arrange and pay for the completion to the satisfaction of the EPA of all works relating to closure, remediation and aftercare to ensure compliance with the conditions of the licence.

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.

In the event of sale of the Facility or Pfizer (NEW PIP) Holdings, CPPI/CV undertakes to continue this undertaking until such time as the EPA shall have approved the transfer of the licence, as applicable, or until the new owner shall have entered into a financial security agreement to the satisfaction of the EPA.

We confirm that this letter is intended to constitute a legally binding obligation on CPPI/CV, its successors and assigns, and shall be subject to the exclusive jurisdiction of the Courts of Ireland and subject to the laws of Ireland.

The RMP's financial provisions will be reviewed on an annual basis, and will be communicated to the EPA in the Annual Environmental Report, as required by the Licence.

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of C.P. Pharmaceuticals Intern	
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By:	od od
Title: Senior Vice President	Collect at.
Dated: November 2010	dufgses only, any other use.
	in the capacity of general partner for and on behalf
Pfizer Manufacturing LLC,	in the capacity of general partner for and on behalf
of C.P. Pharmaceuticals International	national G.V.
of C.P. Pharmaceuticals Internation	cent of con
By:	- Grish
Title: Senior Vice President	
Dated: November 2010	

Draft form of Guarantee to be furnished in respect of funding for expenditure for costs/liabilities. Signed copy to be provided when it becomes available.



### C.P. PHARMACEUTICALS INTERNATIONAL C.V.

ANNUAL ACCOUNTS 2008/2009

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#### GENERAL PARTNERS' REPORT

#### General information

Enclosed are the consolidated accounts for the 12 months ended 30 November 2009 of C.P. Pharmaceuticals international C.V. ("CPPI CV or the Partnership") and its subsidiaries together with our review of the Partnership's performance during the year and expectations for 2010. The term "Partnership" includes the Partnership and its subsidiaries on a consolidated basis.

C.P. Pharmaceuticals International C.V. is a partnership ("Commanditaire Vennootschap") that owns a large number of subsidiaries in a number of different countries, whose number may change from year to year. The Partnership operates as a holding function. The Partnership also carries on the business of manufacturing pharmaceutical, animal health, consumer health and nutritional products.

The Partnership's ultimate parent company is Pfizer Inc. (New York, USA).

Pfizer inc. is a research-based, global pharmaceutical company that discovers, develops, manufactures and markets leading prescription medicines, including vaccines, for humans and animals, as well as consumer health and nutritional products. Pfizer's longstanding value proposition has been to prove that its medicines cure or treat disease, including symptoms and suffering, and this remains Pfizer's core mission. Pfizer has expanded its value proposition to also show that not only can its medicines cure or treat disease, but that they can also markedly improve health systems by reducing overall healthcare costs, improving societies' economic well-being and increasing effective prevention and treatment of disease. Pfizer generates revenue through the sale of its products, as well as through alliance agreements by co-promoting products discovered by other companies.

#### Financial information

The Partnership and its subsidiaries on a consolidated basis showed an improved performance in 2008/2009 with its products in the aggregate performing well despite the challenge of operating in a weak global economy.

The Partnership's performance was impacted specifically in 2008/2009 by:

- An increase in revenues (USD 1.3 billion) as a result of improved performance in Pfizer products and additional revenue from legacy Wyeth products
- Other expenses decreased in 2008/2009 to USD 5.6 billion (2007/ 2008: USD 6.9 billion) on account of a fall in restructuring expenses
- General and Administrative expenses decreased in 2008/2009 largely due to a fall in service and management fees.

The Partnership's consolidated sales increased to USD 37.6 pillion (2007/ 2008: USD 36.3 billion) and the net profit for the year has increased to USD 13 billion (2008: USD 10 billion). Dividends of USD 3.7 billion were paid out during 2009. There was no dividend paid bill to its partners subsequent to the year end.

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The Partnership has elected not to present a separate statement of consolidated cash flows. Accordingly, a copy of the consolidated statements of Pfizer Inc. for the year ended 31 December 2009, in which the consolidated cash flows statement of C.P. Pharmaceuticals International C.V. is incorporated, is deposited at the Chamber of Commerce of Rotterdam, The Netherlands.

#### Forward-looking information and factors that may affect future results

This report from time to time contains such forward-looking statements that set forth anticipated results based on plans and assumptions. The Partnership cannot guarantee that any forward-looking statement will be realized, although the Partnership believes it has been prudent in its plans and assumptions. Achievement of future results is subject to risks, uncertainties and inaccurate assumptions. Should known or unknown risks or uncertainties materialize, or should underlying assumptions prove inaccurate, actual results could vary materially from past results and those anticipated, estimated or projected.

Among the factors that could cause actual results to differ materially are the following:

- the success of research and development activities;
- decisions by regulatory authorities regarding whether and when to approve drug
  applications as well as their decisions regarding labeling and other matters that could
  affect the availability or commercial potential of our products;
- the speed with which regulatory authorizations, pricing approvals, and product launches may be achieved;
- success of external business development activities;
- competitive developments, including the impact on our competitor position of new product
  entrants, in-line branded products, generic products, private label products and product
  candidates that treat diseases and conditions similar to those treated by our in-line
  products and product candidates;
- the ability to successfully market both new and existing products;
- difficulties or delays in manufacturing;
- trade buying patterns;
- the ability to meet generic and branded competition after the loss of patent protection for our products and for competitor products;
- the impact of existing and future regulatory provisions on product exclusivity;
- trends toward managed care and health cost containment;
- legislation or regulations in markets affecting product pricing, reimbursement or access;
- contingencies related to actual or alleged environmental contamination;
- claims and concerns that may arise regarding the safety or efficacy of in-line products and product candidates;
- significant breakdown, infiltration or interruption of information technology systems and infrastructure:
- legal defense costs, insurance expenses, settlement costs and the risk of an adverse decision or settlement related to product liability, patent protection, governmental investigations, ongoing efforts to explore various means for resolving asbestos litigation and other legal proceedings;
- the ability to protect patents and other intellegal to protect patents and other patents and other patents are patents and other patents and other patents are patents and other patents are patents and other patents are patents and other patents and other patents are patents are patents and other patents are patents and other patents are patents are patents and other patents are patents and other patents are p
- Interest rate and foreign currency exchange rate fluctuation Audit
- governmental laws and regulations affecting operations, including tax applications of dated

changes in accounting principles;

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 any changes in business, political and economic conditions due to the threat of future terrorist activity in the U.S. and other parts of the world;

growth in costs and expenses;

- changes in our product, segment and geographic mix; and
- the impact of acquisitions, divestitures, restructurings, product withdrawals and other unusual items, including the ability to realize the projected benefits of our acquisition of Wyeth and of our cost reduction initiatives.

#### Personnel related information

The average number of employees of the Partnership and its consolidated subsidiaries in 2008/2009 amounted to 46,306 (2007/2008: 48,673).

#### Wyeth Acquisition

In response to the challenging operating environment Pfizer has taken keys steps to strengthen it's position and become a more diversified healthcare organization. The most important of these steps was the acquisition of Wyeth on October 15, 2009. All of the outstanding equity of Wyeth was acquired in cash-and-stock transaction, valued based on the closing market price of Pfizer common stock on the acquisition date, at \$50.40 per share of Wyeth common stock, or a total of approximately \$68 billion, of which the Partnership contributed approximately \$33 billion. The assets acquired and liabilities assumed from Wyeth have been recorded at their estimated fair values as of the acquisition date. The goodwill deducted from Partners Capital Accounts relating to the Wyeth acquisition amounted to \$1.7 billion.

Wyeth's core business was the discovery, development and manufacture and sale of prescription pharmaceutical products, including vaccines, to humans. Other operations of Wyeth included the discovery, development, manufacture and sale of consumer health products (over the counter products), nutritionals and animal health products.

#### Cost-Reduction Initiatives

During 2009, Pfizer continued the cost-reduction and transformation initiatives which were designed to increase efficiency and streamline decision-making across the company. Since the acquisition of Wyeth, Pfizer has focused on achieving an appropriate cost structure for a combined company which captures synergies company-wide. These targeted savings are expected to be achieved through the closing of duplicative facilities and other site rationalization actions, including research and development facilities, manufacturing plants and sales offices.

#### information regarding financial instruments

#### Financial Risk Management

The overall objective of the Partnership's financial risk management program is to seek a reduction in the potential negative earnings effects from changes in fore the potential negative earnings effects from changes in fore the potential negative earnings effects from changes in fore the potential and interest rates arising in our business activities. The Partnership manages these financial exposures attending operational means and by using various financial instruments. These practices the process of the partnership manages these financial exposures attending to the potential of the potential instruments. These practices the process of the potential instruments are processed in the potential of the potential negative earnings are processed in the potential neg

tetas or (mai valori pagos). KPNG sautosomen**Rabe\5**  Foreign Exchange Risk – A significant portion of the Partnership's revenues and earnings are exposed to changes in foreign exchange rates. The Partnership seeks to manage its foreign exchange risk in part through operational means, including managing same currency revenues in relation to same currency costs, and same currency assets in relation to same currency liabilities.

Foreign exchange risk is also managed through the use of foreign currency forward-exchange contracts. These contracts are used to offset the potential earnings effects from mostly intercompany short-term foreign currency assets and liabilities that arise from operations. The Partnership also uses foreign currency forward-exchange contracts and foreign currency swaps to hedge the potential earnings effects from short and long-term foreign currency investments and loans and intercompany loans.

In addition, under certain market conditions, the Partnership protects against possible declines in the reported net assets of our Japanese Yen, Swedish Krona, U.K. pounds and certain Euro functional-currency subsidiaries. In these cases, the Partnership uses currency swaps or foreign currency debt.

The Partnership's financial instrument holdings at year-end were analyzed to determine their sensitivity to foreign exchange rate changes. The fair values of these instruments were determined as follows:

- foreign currency forward-exchange contracts and currency swaps—net present values;
- foreign receivables, payables, debt and loans—changes in exchange rates.

In this sensitivity analysis, the Partnership assumed that the change in one currency's rate relative to the U.S. dollar would not have an effect on other currencies rates relative to the U.S. dollar. All other factors were held constant.

If there were an adverse change in foreign exchange rates of 10%, the expected effect on net income related to our financial instruments would be immaterial.

Interest Rate Risk - The Partnership's U.S. dollar interest-bearing investments, loans and borrowings are subject to interest rate risk. The Partnership is also subject to interest rate risk on euro investments and short-term currency swaps. The Partnership invests and borrows primarily on a short-term or variable-rate basis. From time to time, depending on market conditions, the Partnership will fix interest rates either through entering into fixed rate investments and borrowings or through the use of derivative financial instruments such as interest rate swaps.

The Partnership's financial instrument holdings at year-end were analyzed to determine their sensitivity to interest rate changes. The fair values of these instruments were determined by net present values.

In this sensitivity analysis, the Partnership's used a one hundred basis point change (decreased 1% from the rate of the yield of the financial instrument) in interest rates for all maturities, All other factors were held constant.

In 2009 and 2008, if there were an adverse change of one hundred basis points in interest rates, the expected effect on net income related to our financial insular figure and the immaterial.

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#### Research and development information

The discovery and development of safe, effective new products, as well as the development of additional uses for existing products, are necessary for the continued strength of our businesses. The opportunities for improving human and animal health remain abundant as scientific innovation increases daily into new and more complex areas and as the extent of unmet madical needs remains high. Prizer's product lines must be replanished over time in order to offset revenue bases when products lose their exclusivity, as well as to provide for growth.

As the world's largest privately funded blomedical operation, and through its global scale, Pfizer is developing and delivering innovative medicines that will benefit patients around the world. Pfizer will continue to make the investments necessary to serve patients' needs and to generate long-term growth.

Pfizer will continue to focus on reducing attrition as a key component of Pfizer's R&D productivity improvement affort. For several years, Pfizer has been revising the quality hurdles for candidates entering development, as well as throughout the development process. As the quality of candidates has improved, the development attrition rate has begun to fall. Three new molecular entities and multiple new indication programs for in-line products advanced into Phase 3 development during 2009. While a significant portion of R&D is done internally, Pfizer will continue to seek to expand our pipeline by entering into agreements with other companies to develop, license or acquire promising compounds, technologies or capabilities. Co-development, alliance and license agreements and acquisitions allow Pfizer to capitalize on these compounds to expand our pipeline of potential future products.

#### Future developments

While Pfizer Inc's, and consequently the Partnership's, revenues and income will continue to be tempered in the near term due to patent expirations and other factors, we will continue to make the investments necessary to sustain long-term growth. The Partnership remains confident that Pfizer has the organizational strength and resilience, as well as the financial depth and flexibility, to eucosed in the long term. However, no assurance can be given that the industry-wide factors or other significant factors will not have a material adverse effect on our business and financial results.

From 2010 to 2015, Pfixer intends to create a fully aligned manufacturing and supply organization from the combined networks of Pfixer and Wyeth, aliminating excess capacity, in order to better align production with market demands.

In addition, we are expecting to initiate a consolidation project to reduce the number of existing and new US owners of the Partnership by combining ownership interests where possible, using various approaches. This project is expected to have a positive effect on the equity of the Partnership.

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# CONSOLIDATED BALANCE SHEET AS AT 30 NOVEMBER 2009

(efter appropriation of results for the year)

66 T 200	i demografia de la ligra podes e descriza e descriza de la 1964 de 1965 de 1965 de 1965 de 1965 de 1965 de 196	30 November 2009	30 November 2008
(USD'000)			
	Note		
Fixed assets			
Intangible fixed assets	3	23,730,274	9,095,014
Tangible fixed assets	4	11,395,963	6,296,872
Financial fixed assets	5	15,431,147	15,580,867
		50,557,384	30,972,753
Current assets			
Stocks	6	6,516,808	2,797,031
Receivables	7	46,903,292	42,525,959
Cash and banks	8	389,309	240,843
		53,809,409	45,563,833
		ther	
TOTAL ASSETS	only any	104,366,793	76,636,586
	oses difor		
Partners Capital Accounts	Philipolitic 9	60,861,875	51,292,308
Minority interest	Winer 10	3,719,085	3,578,760
Provisions Col. High	11	4,538,317	2,215,607
Long term liabilities	12	1,310,579	814,969
Stocks Receivables Cash and banks  TOTAL ASSETS  Partners Capital Accounts  Minority interest  Provisions Long term liabilities  Current liabilities	13	33,936,937	18,634,942
TOTAL LIABILITIES		104,366,793	78,536,586
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# CONSOLIDATED STATEMENT OF INCOME FOR THE PERIOD 1 DECEMBER 2008 UNTIL 30 NOVEMBER 2009

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(USD'000)		,	
	Note		
Net turnover	15	37,568,384	36,291,021
Cost of goods sold	16	(5,622,105)	(6,200,986)
Gross margin		31,946,279	30,090,035
Research and development expenses		1,866,143	1,859,627
Selling expenses		9,373,571	8,739,628
General and administrative expenses	17	1,640,048	2,702,317
Other expenses	18	5,619,344	6,968,255
Total operating expenses		18,499,106	20,269,827
Operating result		13,447,173	9,820,208
Other operating income	19	net 15 <sup>©</sup> 613,343	327,529
Net financial income	23. V	1,060,600	959,675
Profit from ordinary operations before tax	20ses of for	15,121,116	11,107,412
Tax on result from ordinary operations	recipiti	(1,864,550)	(512,126)
Share in results from participating interests of	25	17,429	47,740
Profit from ordinary operations after tage		13,273,995	10,643,026
Operating result Other operating income Net financial income Profit from ordinary operations before tax Tax on result from ordinary operations Share in results from participating interests the profit from ordinary operations after tax Minority interest Net profit for the year		(179,273)	(196,341)
sent of			
Net profit for the year of		13,094,722	10,448,685

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# CONSOLIDATED STATEMENT OF RECOGNISED INCOME AND EXPENSE FOR THE PERIOD 1 DECEMBER 2008 UNTIL 30 NOVEMBER 2009

COLICIA DE COLICIA DE COMPONIMENTO DE COMPONIMENTO DE COMPONIMENTO DE CONTRESE CONTRESE CONTRESE DE CO	2008/2009	2007/2008
(USD'000)		
Consolidated net result after taxes attributable to the		
company	13,094,722	10,446,685
Translation differences on foreign participating interests	2,644,479	(2,529,566)
Actuarial gains/(losses)	(794,582)	(373,913)
Tex on actuarial gains/(losses)	274,220	144.351
Goodwill booked directly to equity	(1,959,104)	(669,120)
Adjustments to financial instruments valuation	251,943	
Total of items recognized directly in equity of the		**************************************
company as part of the group equity	416,956	(3,428,248)
Total recognized gains and (losses) relating to the year	13,511,678	7,018,437

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# NOTES TO THE CONSOLIDATED ANNUAL ACCOUNTS

#### General

The Partnership performs a holding function. The Partnership also carries on the business of manufacturing pharmaceutical, animal health, consumer health and nutritional products. The ultimate parent company of the Partnership is Pfizer Inc., New York, USA.

The Partnership and it subsidiaries are engaged in research and development, manufacture and/or distribution of human/pharmaceutical, and animal healthcare products, as well as consumer and nutritional products for sale to third parties and affiliated companies in both home and export markets.

The reporting currency of the Partnership is US dollar (USD).

#### Change in accounting in principles

Until 30 November 2008 receivables and liabilities were carried at face value. With respect to receivables a provision was accounted for if deemed necessary. As of 30 November 2008 receivables and liabilities are (in accordance with RJ 290) carried at amortised cost using the effective interest method. With respect to receivables impairment losses are taken into account. This change in accounting principles has no effect on the partners capital accounts and result after tax of 2008/2009 and 2007/2008.

#### Applicable standards

The financial statements are prepared on the basis of the legal requirements as set out in part 9 of Book 2 of the Netherlands Civil Code. With respect to the employee retirement plans and postretirement benefits the financial statements have been prepared in accordance with SFAS 158, which is allowed according to RJ271 'employee benefits'.

Application of Section 402, book 2 of the Netherlands Civil Code (BW)

The financial information of the Partnership is included in the consolidated financial statements. For this reason, in accordance with Section 402, Book 2 of the Netherlands Civil Code, the single profit and loss account of the Partnership exclusively states the share in the result after taxation of companies in which participating interests are held and the general result after taxation.

#### 2. Summary of significant accounting policies

#### General

If not stated otherwise, assets and liabilities are shown at nominal value.

An asset is disclosed in the balance sheet when it is probable that the expected future economic benefits that are attributable to the asset will flow to the entity and the cost of the asset can be reliably measured. A liability is disclosed in the balance sheet when it is expected to result in an outflow from the entity of resources embodying economic benefits and the amount of the obligation can be measured with sufficient reliability.

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Income is recognised in the profit and loss account when an increase in economic potential related to an increase in an asset or a decrease of a liability has arisen, the size of which can be estimated with a sufficient reliability. Expenses are recognized when a decrease in the economic potential related to a decrease in an asset or an increase of a liability has arisen, the size of which can be estimated with sufficient reliability.

If a transaction results in a transfer of future economic benefits and or when all risks relating to assets or liabilities transfer to a third party, the asset or liabilities is no longer included in the balance sheet. Assets and liabilities are not included in the balance sheet if economic benefits are not probable or cannot be measured with sufficient reliability.

The income and expenses are accounted for in the period to which they relate. Revenue is recognized when the Partnership has transferred to the buyer the significant risk and rewards of ownership of the goods.

The preparation of the financial statements requires the management to form opinions and to make estimates and assumptions that influence the application of principles and the reported values of assets and liabilities and of income and expenditure. The actual results may differ from these estimates. These estimates and the underlying assumptions are constantly assessed. Revisions of estimates are recognized when facts and circumstances indicate the need for change. Those changes will be reflected in our financial statements in the period when those related facts and circumstances change or, for estimates involving such items as useful lives, they are reflected prospectively.

#### Consolidation principles

The consolidated financial statements include the financial data of the Partnership and its group companies and other companies controlled by the Partnership. Control exists when the Partnership has the power, directly or indirectly, to govern the financial and operating policies of an entity so as to obtain benefits from its activities. Group companies exclusively acquired with the view to resale are exempted from consolidation.

The financial statements of subsidiaries are included in the consolidated financial statements from the date that control commences until the date that control ceases.

Intra-group balances, and any other unrealized income and expenses arising from intra-group transactions, are eliminated in preparing the consolidated financial statements. The group companies are consolidated in full with minority interest presented within group equity separate from parent's equity. Minority interests in the profit or loss of the group should be presented as an item of income and expense on the face of the profit and loss account.

In October and November 2009 the Partnership acquired (after the acquisition of Wyeth Inc. by Pfizer Inc.) a number of Wyeth companies. Since the acquisition decompanies are included in the consolidated balance sheets of these companies are included in the consolidated balance sheet of these companies are included in the consolidated balance sheet of these companies are included in the consolidated balance sheet of these companies are included in the consolidated balance sheet of these companies are included in the consolidated balance sheet of these companies are included in the consolidated balance sheet of these companies are included in the consolidated balance sheet of the second of the second of the consolidated balance sheet of the consoli

For a detailed summary of the consolidated group companies, please refer to note 31 - Principal subsidiary companies.

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#### Principles for the translation of foreign currencies

#### Foreign currencies

Transactions denominated in foreign currency are translated into the relevant functional currency of the group companies at the exchange rate applying on the transaction date. Monetary assts and liabilities denominated in foreign currency are translated into the functional currency at the balance sheet date at the exchange rage applying on that date. Non-monetary assets and liabilities in foreign currency that are stated at historical cost are translated into U.S. Dollars at the applicable exchange rates on the transaction date. Translation gains and losses are taken to the profit and loss account as expenditure.

#### Foreign operations

The assets and liabilities of foreign operations including goodwill and fair value adjustments arising on consolidation are translated into U.S. Dollars at exchange rates applying on the reporting date. income and expenses of foreign operations are translated into U.S. Dollars at the exchange rate on the transaction date.

Translation gains and losses are taken to the reserve for translation differences. If a foreign operation is totally or partially sold, the amount in question is transferred from the reserve for translation differences to the profit and loss account.

Hedging of the net investment in foreign operations

Exchange rate differences arising on retranslation of a foreign currency liability accounted for as a hadge of a net investment in a foreign activity are taken directly to shareholders' equity, in the reserve for translation differences, insofar as the hedge of effective. The non-effective part is taken to the profit and loss account as expenditure.

#### Financial Instruments

Financial instruments include investments in shares and bonds, trade and other receivables, cash items, loans and other financing commitments, trade and other payables.

Financial instruments also include derivative financial instruments (derivatives) embedded in contracts. These derivatives shall be separated from the host contract and accounted for as a separate financial instrument if

- The economic characteristics and risks of the embedded derivative are not closely related to the economic characteristics and risks of the host contract;
- A separate instrument with the same terms as the embedded derivative would meet the definition of a derivative; and
- The combined instrument is not measured at fair value with changes in fair value recognised in

If derivatives embedded in contracts are not separated from the host contract, they are recognised in accordance with the host contract. Document to which our report dated

Financial instruments, including derivatives separated from the host contracts, are/initially recognised at fair value. If instruments are not carried at fair value through profit and post ithem any directly attributable transaction costs are included in the initial measurement.

After initial recognition, financial instruments are valued in the manner described below.

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#### Financial instruments held for trading

Financial instruments (assets and liabilities) that are held for trading are carried at fair value and changes in the fair value are recognised in the profit and loss account. In the first period of recognition, attributable transaction costs are charged to the profit and loss account. However, changes in the fair value of available for sale securities are recognized in Partners Capital Accounts. In case the fair value of available for sale securities is lower than the historical cost price, the change is directly recognized in the income statement.

#### Purchased loans and bonds

Purchased loans and bonds which the company intends to hold to maturity (and is capable of doing so), are measured at amortised cost using the effective interest method, less impairment losses.

Other purchased loans and bonds are carried at fair value provided they are listed on a stock exchange. Changes in the fair value are recognised in the profit and loss account. Unlisted purchased loans and bonds are carried at amortised cost using the effective interest method, less impairment losses.

#### Loans granted and other receivables

Loans granted and other receivables are carried at amortised cost using the effective interest method, less impairment losses.

#### Other financial commitments

Financial commitments that are not held for trading purposes are carried at amortised cost using the effective interest rate method.

Derivative Financial Instruments and Hedging Activities

Foreign Exchange Risk

A significant portion of our revenues, earnings and net investments in foreign affiliates is exposed to changes in foreign exchange rates. We seek to manage our foreign exchange risk, in part, through operational means, including managing expected same-currency revenues in relation to same-currency costs and same-currency assets in relation to same currency liabilities. Depending on market conditions, foreign exchange risk also is managed through the use of derivative financial instruments and foreign currency debt. These financial instruments serve to protect net income and net investments against the impact of the translation into U.S. dollars of certain foreign exchange-denominated transactions. The derivative financial instruments primarily hedge or offset exposures in euro, Japanese yen and U.K. pound.

All derivative contracts used to manage foreign currency risk are measured at fair value and are reported as assets or liabilities on the consolidated balance sheet. Changes in fair value are reported in earnings or deferred, depending on the nature and purpose of the financial instrument (offset or hedge relationship) and the effectiveness of the hedge relationships, as follows:

We defer on the balance sheet the effective portion of the gains or losses on foreign currency forward-exchange contracts and foreign currency swaps that are designated as cash flow hedges and reclassify those amounts, as appropriate, into earlings as same period or periods during which the hedged transaction affects earnings.

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- We defer in a separate component of equity foreign exchange gains and losses, to the extent of change in the foreign exchange spot rates, related to foreign currency swaps designated as hedges of our net investments in foreign subsidiaries and reclassify those amounts into earnings upon the sale or substantial liquidation of our net investments.
  - The periodic net swap payments are recognized in earnings over time and any change in the difference between the foreign exchange spot rate and forward rate is recognized in earnings immediately.
- We recognize the gain and loss impact on foreign currency swaps designated as hedges of our net investments in earnings in three ways: over time— for the periodic net swap payments; immediately to the extent of any change in the difference between the foreign exchange spot rate and forward rate; and upon sale or substantial liquidation of our net investments—to the extent of change in the foreign exchange spot rates.
- We defer on the balance sheet foreign exchange gains and losses related to foreign exchangedenominated debt designated as a hedge of our net investments in foreign subsidiaries and reclassify those amounts into earnings upon the sale or substantial liquidation of our net investments.
  - Any ineffectiveness is recognized immediately into earnings. There was no significant ineffectiveness in 2009, 2008 or 2007.

#### Interest Rate Risk

Our interest-bearing investments, loans and borrowings are subject to interest rate risk. We seek to invest and loan primarily on a short-term or variable rate basis; however, in light of current market conditions, we currently borrow primarily on a long-term, fixed-rate basis. From time to time, depending on market conditions, we will change the profile of our outstanding debt by entering into derivative financial instruments like interest rate swaps.

We entered into derivative financial instruments to hedge or offset the fixed interest rates on the hedged item, matching the amount and timing of the hedged item. The derivative financial instruments offset U.S. dollar, euro and U.K. pound fixed-rate debt.

All derivative contracts used to manage interest rate risk are measured at fair value and reported as assets or liabilities on the consolidated balance sheet. Changes in fair value are reported in earnings, as follows:

We recognize the gains and losses on interest rate swaps that are designated as fair value hedges in earnings upon the recognition of the change in fair value of the hedged risk. We recognize the offsetting earnings impact of fixed-rate debt attributable to the hedged risk also in earnings.

Any ineffectiveness is recognized immediately into earnings. There was no significant ineffectiveness in 2009, 2008 or 2007.

#### Intangible fixed assets

Intangible fixed assets other than goodwill acquired are capitalized and amortized against income over the estimated useful life of the underlying asset, not exceeding 20 years. Goodwill is directly taken to Partners Capital Accounts. In case of a disinvestment within a period of five years the remaining part of the goodwill (calculated with a depreciation rate of 20% per year) is charged to the profit and loss account.

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#### Tangible fixed assets

Tangible fixed assets are stated at cost. With the exception of land, tangible fixed assets are depreciated over their estimated economic lives by the straight line method.

#### Financial fixed assets

Participations are carried at cost or lower where no significant influence (less than 20% of the voting rights) is exercised over business and financial policy realizable value.

Participations where significant influence is exercised over business and financial policy (20% or more of the voting rights) are carried at net asset value. The net asset value is calculated on the basis of the accounting principles of C.P. Pharmaceuticals International C.V.

In case the net equity of such a participation is a negative amount, a provision is created and booked against (long term) receivables from subsidiaries or affiliated companies, and the remaining amount is recognized as a provision.

The accounting policies for other financial fixed assets are included under the heading 'financial instruments'.

#### impairment or disposal of fixed assets

The company states intengible, tangible and financial fixed assets in accordance with accounting principles generally accepted for financial reporting in the Netherlands. Pursuant to these principles, assets with a long life should be reviewed at each balance sheet date to determine whether there is any indication of impairment. If any such indication exists the assets' recoverable amount is estimated. The recoverable amount is calculated as the present value of estimated future cash flows, discounted at the effective interest rate.

If the book value of an asset exceeds the recoverable amount, an impairment is charged to the result equal to the difference between the carrying amount and the recoverable amount. Assets for sale are stated at the carrying amount or lover market value, less selling costs.

#### Stocks

Stock is valued at cost or market value, if lower. Cost is determined as follows:

- raw materials and supplies at average or latest actual cost
- finished goods and semi-finished goods at average actual cost.

When valuing inventories, account is taken of any value adjustments occurring on the balance sheet date.

#### Receivables

The principles for the valuation of trade and other receivables are described under the heading 'financial instruments'.

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#### Partners Capital Accounts

Financial instruments that are designated as equity instruments by virtue of the economic reality are presented under partners capital accounts. Payments to holders of these instruments are deducted from the shareholders' equity as part of the profit distribution.

Financial instruments that are designated as a financial liability by virtue of the economic reality are presented under liabilities. Interest, dividends, income and expenditure with respect to these financial instruments are

#### Revaluation reserve

Revaluation reserve relates to value increase of securities available for sale that are valued at fair value. A revaluation reserve is recorded for each individual asset and is not higher than the difference between book value according to historical cost price and book value at fair value. If an asset is disposed of, the related revaluation reserve is released to profit and loss account. Within the calculation of the revaluation reserve the amount for deferred tax assets is offset against the effective tax rate.

#### Winority Interest

The minority interests are valued at net asset value, which is determined in accordance with the accounting principles of C.P. Pharmaceuticals International C.V.

#### **Provisions**

A provision is recognized if

- ned for The company has a legal or constructive obligation, arising from a past event; and
- If there is a probable outflow of resources and
- The amount can be estimated reliably

#### Deferred taxes

Insofar as valuations of assets and liabilities for tax purposes differ from their carrying amounts, and this results in deferred tax liabilities, a provision is formed for these liabilities, calculated at the tax rates that are expected to apply the period when the liability is settled. Deferred tax assets are only recognized if it is probable that sufficient taxable profit will be available to realize such assets.

#### Employee benefits

#### Employee retirement plans

Retirement plans are provided for employees of all major group companies. The nature of such plans varies according to the legal and fiscal requirements and the economic conditions of the country in which the employees are employed. Generally, the plans provide defined benefits based on employees' years of service and average or final remuneration. Plan assets principally comprise marketable securities and property holdings. Retirement plans to which employees contribute and non-contributory plans are generally funded by payments bendent trusts. Valuations of plans are carried out by independent actuaries. KPMG Audit

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Postretirement benefits other than pensions

Some group companies provide certain postretirement health care and life insurance benefits to retirees, the entitlement to which is usually based on the employee remaining in service up to retirement age and the completion of a minimum service period. The expected costs of these benefits are accrued over the periods employees render service to the group. These plans are not funded. A provision is included in the annual accounts, which is sufficient to cover the present value of the expected postretirement benefit obligation based on current assumptions. Valuations of these obligations are carried out by independent actuaries.

#### Other Provisions

Pfizer and the Partnership are involved in various patent, product liability and environmental litigations and claims, and other legal proceedings that arise from time to time in the ordinary course of their business. The Company records accruals for such contingencies to the extent that management concludes that their occurrence is probable and the related liabilities can be estimated. The Company considers many factors in making these assessments. Because litigation and other contingences are inherently unpredictable and excessive verdicts do occur, these assessments can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions.

Long term and current liabilities

The principles for the valuation of long term and current liabilities are described under the heading 'financial instruments'.

Net turnover

Net turnover is stated net of returns, commissions, discounts and value added tax.

Revenues

Revenue Recognition – the Partnership records revenue from product sales when the goods are shipped and title passes to the customer. At the time of sale, the Partnership also records estimates for a variety of sales deductions, such as rebates, discounts and incentives, and product returns. When the Partnership cannot reasonably estimate the amount of future product returns, we record revenues when the risk of product return has been substantially eliminated.

Deductions from Revenues — Gross product sales are subject to a variety of deductions that are generally estimated and recorded in the same period that the revenues are recognized.

Specifically:

The majority of the Partnership's pharmaceutical rebates are contractual or legislativelymandated and the Partnership's estimates are based on actual invoiced sales within each period, both of these elements help to reduce the risk of variations in the estimation process. Some European countries base their rebates on the government's unbudgeted pharmaceutical spending and the Partnership uses an estimated allocation factor based on historical payment against its actual invoiced sales to project the expected level of reimbursement. The Partnership obtains third party information that helps monitor the adequacy of these accruals.

Provisions for pharmaceutical returns are based on a calculation at each market that incorporates the following, as appropriate: local returns splitter and practices; returns as a percentage of sales; an understanding of the reasons in the returns; estimated shelf-life by product; an estimate of the amount of time between shipment and returns of laguitime.; and any other factors that could impact the estimate of future returns, supportantly and product recalls, or a changing competitive environment, as appropriate.

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- The Partnership provision for chargebacks (primary reimbursements to wholesalers for honoring contracted prices to third parties) closely approximates actual, as we settle these deductions generally within two to three weeks of incurring the liability.
- The Partnership records sales incentives as a reduction of revenues at the time the related revenues are recorded or when the incentive is offered, whichever is later. The Partnership estimates the cost of its sales incentives based on its historical experience with similar incentives programs.
- Taxes collected from customers and remitted to governmental authorities are presented on a net basis; that is, they are excluded from revenue.

Alliances - The Partnership has agreements to co-promote pharmaceutical products discovered by other companies. Revenues are earned when the Partnership's co-promotion partners ship the related product and title passes to their customer. Alliance revenue is primarily based upon a percentage of the Partnership's co-promotion partners' net sales. Generally, expenses for selling and marketing these products are included in Selling expenses.

#### Other revenues

Other revenues are accounted for in the period to which they relate. These are a combination of government grant rebates and third party miscellaneous income.

#### Research and development expenses

Research and development (R&D) costs are expensed as incurred. These expenses include the costs of the Partnership's proprietary R&D efforts as well as costs incurred in connection with the Partnership's third-party collaboration efforts. Before a compound receives regulatory approval, the Partnership records milestone payments made by to third parties under contracted R&D arrangements as expense when the specific milestone has been achieved. Once a compound receives regulatory approval, we record any subsequent milestone payments in Patents, trademarks and other intangible fixed assets and, unless the assets are determined to have an indefinite life, the Partnership amortizes them evenly over the emaining agreement term or the expected product life cycle, whichever is shorter. The Partnership has no third-party R&D arrangements that result in the

Pension and Post Retirement Plans and Defined Contribution Plans

The Partnership provides defined benefit pension plans and defined contribution plans for the majority of its employees worldwide.

The accounting for benefit plans is highly dependent on actuarial estimates, assumptions and calculations, which result from a complex series of judgments about future events and uncertainties. The assumptions and actuarial estimates required to estimate the employee benefit obligations for the defined benefit and postretirement plans, include discount rate; expected salary increases: certain employee-related factors, such as turnover, retirement age and mortality (life expectancy); expected return on assets; and healthcare cost trend rates. The assumptions reflect the historical experiences and best judgment regarding future expectations that have been deemed reasonable by management. The judgments made in determining the costs of our benefit plans can materially impact the results of operations.

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The Partnership adopted the provisions of Statement of Financial Accounting Standards (SFAS) No. 158, Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans (an amendment of Financial Accounting Standards Board (FASB) Statements No. 87, 88, 108 and 132R). SFAS requires the Partnership to recognize on its balance sheet the difference between benefit obligations and plan assets of benefit plans. In addition, the Partnership is required to recognize as part of partners capital accounts, net of tax, gains and losses due to difference between the actuarial assumptions and actual experience (actuarial gains and losses).

#### Share in Results from participating interests

The share in the result of participating interests consists of dividends received from participations carried at cost, the share of the group in the result of participating interests carried at net asset value and the result of divestitures.

#### Texation

The taxation on result comprises both taxes payable in the short term and deferred taxes, taking account of local jurisdictional tax law and non-deductible costs. No taxes are deducted from profits if and insofar as profits can be offset against unrecognized losses from previous years.

Tax credits on losses are recognized if these can be offset against profits in previous years and this results in a tax rebate. In addition, taxes may be benefited if and insofar as may be reasonably expected that losses can be offset against future profits.

#### Determination of fair value

A number of accounting principles and disclosures require the determination of fair values, for both financial and non-financial assets and liabilities. For measurement and disclosure purposes, the fair value is determined on the basis of the following methods. Where applicable, detailed information concerning the principles for determining the fair value are included in the section that specifically relates to the relevant asset or liability.

#### Financial assets

The fair value of financial assets is determined on the basis of the listed closing (bid) price as at reporting date. The fair value of investments held to maturity is only determined for the benefit of the disclosures.

#### Trade and other receivables

The fair value of trade and other receivables is estimated at the present value of future cash flows.

#### Derivatives

The fair value of forward exchange transactions is based on the quoted market price, if available. If there is no market price available, the fair value is estimated on the basis of the expected cash flows discounted at the current interest rates, including a margin for discounting the relevant risks.

#### Non-derivative financial obligations

The fair value of non-derivative financial commitments is only determined for disclosure purposes and is calculated on the basis of the net present value of future repayments and interest payments, discounted at the market interest rate, including a margin of the reporting date. For financial leases, the market interest rate is determined further formula agreements.

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# 3. Intangible fixed assets

	Patents, Trademarks and Other
(USD'000)	
<u>At cost</u>	
Balance beginning of year Acquired New in consolidation (Wyeth) Disposals	20,917,621 231,312 16,104,159 (1,215,882)
Translation differences	1,013,161
Balance end of year	37,050,371
Accumulated amortization	
Balance beginning of year Amortization for the year Disposals Translation differences  Balance end of year  Impairment  Balance at beginning of year Disposals  Balance end of year  Net book value as at 30 November 2009 Net book value as at 30 November 2008	10,712,062 1,994,654 (25,212) <u>638,593</u>
Balance end of year CILY and	13,320,097
Impairment authorized to	
Balance at beginning of year Disposals	(1,110,545) 1,110,545
Balance end of year	-
Net book value as at 30 November 2009	23,730,274
Net book value as at 30 November 2008	9,096,014

The amortization on intangible fixed assets is included in other expenses.

Amortization in %

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# 3. Intangible fixed assets (confd)

Intangible fixed assets can be specified as follows:

GOOD TEST A TO COMPANY TO THE THE TOTAL PROPERTY OF THE THE THE TOTAL PROPERTY OF THE TO	Gross carrying amount	Accumulated amortization	Net book value
(USD'000)			
Developed Technology rights	32,092,073	(12,278,924)	19,813,149
Brands	4,513,691	(867,256)	3,646,435
Licence agreements	181,998	(27,225)	154,773
Trademarks	65,704	(62,617)	3,087
Other	196,905	(84,075)	112,830
Balance end of year	37,080,371	(13,320,097)	23,730,274

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### 4. Tangible fixed assets

(USD'000)	Land and buildings	Machinery and equipment	Under construction	Other	Total
(002000)					
At cost					
Balance beginning of year	4,769,165	6,146,272	803,147	444.328	12,162,912
Movement in consolidation	3,049,049	347,563	68.043	1,299,494	4,764,149
Acquired	363,001	250,266	32.702	18.092	664,051
Disposals	(468,496)	(528,935)	(81,825)	(145,222)	(1,224,478)
Translation differences	351,597	453,121	59,210	32,757	896,685
Balance end of year	8,064,316	6,668,277	881,277	1,649,449	17,263,319
Accumulated depreciation					
Balance beginning of year	1,566,980	3,919,885	-	379,175	5,866,040
Movement in consolidation	(27,240)	(63,363)	4 other use.	(8,188)	(98,791)
Depreciation for the year	174,085	19,270	at its	286,368	479,723
Disposals	(207,734)	(523,794)	athe,	(46,050)	(777,578)
Translation differences	106,319	268,075	-	23,568	397,962
Balance end of year	1,612,410	3,620,073	-	634,873	5,867,356
Net book value as at		Street.			***************************************
30 November 2009	6,451,908	011 43,048,204 3,048,204	881,277	1,014,576	11,395,983
Net book value as at	NAMES THE STREET OF THE STREET	S	Annacia descriptions and an analysis of the second	ACADINEOUS CONTRACTION	**************************************
30 November 2008	3,202,186	2,228,387	803,147	65,163	6,298,872
Depreciation in %	£013%	3%	***	14%	

The amortization on tangible fixed assets is included in the selling and other expenses.

In movement in consolidation at cost the tangible fixed assets of the acquired Wyeth companies are included.

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#### S. Financial fixed assets

	<b>Participations</b>	Participations	Long term	Long term	Deferred	Other	Total
	stated at net	stated at cost	investments	loans	income and		
	equity				other texes		
(USD'000)							
Beginning							
Balance	68,361	656,707	9,344,772	1,208,163	3,053,515	1,253,349	15,580,867
Additions	-	599,640	6,993,505	75,363	1,371,732	35,965	9,076,205
Share in result	17,429	-	-		-	-	17,429
Movement in							
consolidation	-	-	•	-	(1,253,524)	• -	(1,263,524)
Disposals	(128)		(5,706,789)	-		-	(5,708,917)
Transfers to short							
term	-	-	(633,837)	(873,414)	•		(1,507,251)
Currency			•				
translation							
adjustment			-	-	70,632		70,632
Movement from							
provision	-				(332,381)		(332,381)
Repayments				್ದಲ.	, , ,	(414,009)	(414,009)
Other	10,362	-	-	at il	(12,869)	(97,397)	(99,904)
Ending	94,024	1,256,347	9,997,881	408,112	2,897,105	777,908	15,431,141
Balance	SERVICE PRODUCTION CONTRACTOR SERVICES	TACABAN METANGARAN PROPERTY OF THE PROPERTY OF	Maria Maria	OCCUPATION AND PROPERTY OF THE PARTY OF THE	unsured manufacturates	wasanin kanana	omenine and a second
			are sould, sur				

#### As at 30 November 2009 the following participations are stated at net equity:

Capaugel Healthcare Limited, India (28%)
Consumer Health Products (Minority Interests) Company, United Kingdom (49%)
Pitzer Chile S.A., Chile (34%)
Pitzer Limited, Telwan (49%)
Pitzer Pharmaceutical India Pvt. Ltd. (28%)
Pitzer Pharmaceuticale Ltd, China. (35%)
Pitzer Physic Limited, Singepore (30%)

Pilzar Private Limited, Singapore (30%)
Pharmacia South Africa (Pty) Ltd. South Africa (39%)
Warner-Lambert South Africa (Proprietary) Limited, South Africa (34%)
Yusafarm D.O.O., Serbia (50%)

As at 30 November 2009 the following participations are stated at cost:

Pfizer Corporation Austria GmbH, Austria (19%)
Pfizer Inc. (0.0049%)
Pfizer OTC Seteiligungs GmbH (3%)
Pharmacla Limited, United Kingdom (19%)
Pravo Investment, Co., Isle of Jersey (49.9%) - voting rights in this participation are less than 20%, therefore stated at cost.
Wysth Consumer Healthcare LY (0.4%)
Wilt Healthcare Limited (14%)

VIIV Healthcare Limited (14%)

The additions in participations at cost mainly represent the joint venture with VIIV Healthcare Limited amounts to USD 599 million.

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#### 5 Financial fixed assets (cont'd)

Long term investments are mainly securities available-for-sale stated at fair value with a maturity date of more than one year. The fair value of the securities amounts to USD 9.9 billion (2007/2008: USD 9.0 billion). During 2009 a re-positioning of the long term investment portfolio took place in order to avail of higher USD interest rates. New long term bonds of USD 6.9 billion were purchased as part of this and, in addition, long term investments of USD 5.5 billion were sold to fund this exercise. During 2009 USD 634 million of long term investments with remaining maturity of less than 1 year were transferred to short term investments.

Long term loans concern loans and advances to banks and to other parties.

The deferred income taxes represent the recognized available tax loss carry-forwards, including current portion of deferred income tax receivable of USD 1.97 billion (2007/2008: USD 2.1 billion).

The other financial fixed assets mainly include deferred charges and deposits advances.

#### 6. Stocks

	30 November 2009	30 November 2008
Raw and auxiliary materials Semi-finished goods Finished products  7. Receivables  Foliation for the control of	Ollis	
Raw and auxiliary materials	MY 2017 669,885	455,047
Semi-finished goods	3,487,641	1,326,984
Finished products	2,359,282	1,015,000
ition Verices	6,516,806	2,797,031
(USD'000)	30 November 2009	30 November 2008
Short term loans and investments	10,249,553	21,707,074
Frade accounts	8,440,615	5,048,716
Accounts receivable from Participations	857,014	930,335
Accounts receivable from Partners	2,026,883	2,071,572
Accounts receivable from Affiliated Companies	22,165,394	11,658,682
Other	3,163,833	1,109,580
	<b>15,803,29</b> 2	42,525,955

Short term loans

KPMG Audit The line short term loans and investments include securities at a frainmealue offclusore problition (2007/2008: USD 20.9 billion).

billion in their becompumposes RPMC Action and Rage 25

#### 7. Receivables (cont'd)

Other

The line 'Other' includes the following:

	30 November 2009	30 November 2008
(USD'000)		
Prepaid expenses	441,245	182,310
Deposit advances	227,030	169,096
Prepaid taxes	1,318,277	283,825
Forward exchange contracts	332,330	395,752
Interest rate swaps	110,488	1,111
Cross currency swaps	734,463	77,486
• •	3,163,833	1,109,580

3,163,833 1,109,580

8. Cash and banks

The balance as at 30 November 2009 consists of on demand payable cash and banks.

9. Partners Capital Accounts of the Partnership annual accounts for the year ended 30 November 2009. ended 30 November 2009.

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### 10. Minority interest

The minority interest represents the share of third parties in the shareholders' equity of the following entities:

Pfizer Australia Holdings Pty Limited (31%)
Pfizer Limited, India (39%)
Pfizer Holding Italy S.P.A. (20%)
Pharmacia International B.V., The Netherlands (19%)
Pfizer Pharmaceutical LLC (42%)
Pfizer S.A., Spain (40%)
Warner-Lambert (Europe), United Kingdom (44%)
Wyeth Lederle S.P.A. (49%)
Other entities (total amount of the minority share is less than USD 100 million)

Minority interest can be specified as follows:

	2008/2009	2007/2008
(USD'000)		
Balance beginning of year  Additions Disposals Currency translation difference Dividends paid Share in result Pension effect Tax effect Goodwill recorded directly to capital Other movements Balance end of year	3,578,760	3,221,487
Additions	426,522	643,891
Disposals	(65,172)	84,181
Currency translation difference	195,498	(565,138)
Dividends paid	(378,629)	• • • •
Share in result	179,273	196,341
Pension effect	(1,229)	(3,302)
Tax effect	236	1,300
Goodwill recorded directly to capital	(73,493)	-
Other movements Control	(142,681)	
Balance end of year	3,719,085	3,678,760

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#### Provisions

	30 November 2009	30 November 2008
(USD'000)	•	
Deferred income taxes	3,269,932	1,215,899
Pensions and similar obligations	1,201,356	734,518
Other provisions	67,029	265,190
	4,638,317	2,215,607
Deferred income taxes		
	A STANCE OF THE PROPERTY OF TH	2008/2009
(USD'000)		
Beginning balance		1,215,899
Movement in consolidation	୍ଦ•	2,428,414
Current year provision	ar ils	(107,937)
Movement to Financial fixed assets	othe	(332.381)
Currency translation adjustment	Mr. oth	150 903
Other movements	diot	(84,968)
Ending balance		3,269,93
The deferrals with a residual term of one year and le	ess amount to USD 203 millio	on (2007/2008: U
Beginning balance Movement in consolidation Current year provision Movement to Financial fixed assets Currency translation adjustment Other movements Ending balance The deferrals with a residual term of one year and le		

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#### 11. Provisions (cont'd)

Pensions and similar obligations

The Partnership provides defined benefit pension plans and defined contribution plans for the majority of its employees.

The Partnership uses a measurement date as at November 30. As a result of recent global financial market conditions, the actual annual rate of return on assets held in the Partnership's pension plans has increased from (20.7%) to 14%.

The following table shows the expected versus actual rate of return on plan assets and the discount rate used to determine the benefit obligations for the partnership qualified pension plans:

	2009	2008	
	%	%	_
Expected annual rate of return	8.5	8.5	%
Actual annual rate of return	14,2	(20.7)	
Discount rate	63	5.4	

The assumption for the expected long-term rate of return-on-assets in Partnership pension plans, which impacts not periodic benefit cost, was maintained at 8.5% for 2009. In early 2009, in order to reduce the volatility of plan funded status and the probability of future contribution requirements, a shift was made from an explicit target asset allocation to asset allocation ranges. No further changes to the strategic asset allocation were made in 2009 and therefore, we maintain the 8.5% expected long-term rate of return-on-assets in 2009. The Partnership assumption for the expected return-on-assets reflects the actual historical return experience and the long-term assessment of forward-looking return expectations by asset classes which is used to develop a weighted-average expected return based on the implementation of the targeted asset allocation in the respective plans. The expected return is applied to the fair market value of plan assets at each year end.

The Partnership's discount rates are set by benchmarking against investment grade corporate bonds rated AA or better including where there is sufficient data, a yield curve approach.

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### 11. Provisions (contd)

Pensions and similar obligations (cont'd)

# A) Components of Net Periodic Benefit Costs and Other Amounts Recognized in Partners Capital Accounts and Minority Interest

CHEATHER STATEMENT AND AN APPLICATION OF THE ACCORDING TO MAKE A CHECK CONTROL	Pension Benefits 2008/2009	Postretirement Benefits 2008/2009	Pension Senefits 2007/2008	Postretirement benefits 2007/2008
(USD'000)				,
Net Periodic Cost				•
Service cost	143,529	127	190,241	115
Interest cost	216,111	1,100	248,985	1,004
Expected return on plan assets	(288,784)		(331,229)	-
Net amortisation of unrecognised:				
Prior service costs (gains)	(6,233)	42	(3,101)	47
Transition amount (asset)/obligation	23	53	25	59
Plan (galna)/losses-net	30,953	231	35,034	187
Curtaliments and settlements-net	4,780		5,121	-
Special termination benefits	6,344	, USC	24,681	•
Net periodic cost	108,723	0 <sup>1</sup> 1,553	170,757	1,412
Other changes recognized in partners capital accounts	29. 3	Ki		
and minority interest	793,630	952	378,615	(1,400)
Total recognized in net periodic benefit costs and	36,91			
partners capital accounts and minority interest	31(1) 1900,353	2,505	549,372	12
partners capital accounts and minority interest  Defined Contribution Plan Data  Net periodic pension cost-employer contributions  Plan Data	not to			
Net periodic pension cost-employer contribution	(*)		•	
required based on service rendered	24,623		27.636	

The decrease in the 2009 pension benefit plans' net periodic benefit cost compared to 2008 was largely driven by the increase in interest rates set at the beginning of the year and ongoing restructuring and certain acquisition-related activities, which was partially offset by lower expected returns on plan assets.

The following table presents the amount in partners' capital accounts and minority interest expected to be amortized into 2010 net periodic benefit costs:

nemente con chianne suitante resistante resista de la consecución de la consecución de consecuci	Pension	Postretirement	
(USD'000)	Plan	Plan	
Actuarial losses	62,626	205	
Prior service cost/(credit) and other	(7,383)	112	
Total	KPN <b>45</b> 245ud		
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#### 44. Provisions (cont'd)

Pensions and similar obligations (cont'd)

#### 8) Actuarial Assumptions

Discount rates, projected rates of remuneration growth and expected rates of return on plan assets vary for the different plans as they are determined in the light of local conditions. The following table provides the weighted-average actuarial assumptions:

	Pension benefits 2008/2009	Postretirement benefits 2008/2009	Pension benefits 2007/2008	Postretirement benefits 2007/2008
Weighted-average assumptions used to determine benefit obligations:				
Discount rate	5.1%	9.5%	5.6%	8.5%
Rate of compensation increase	3.6%	-	3.2%	-
Weighted-average assumptions used to determine				
net periodic benefit cost:				
Discount rate	5.6%	8,6%	5.3%	8.0%
Expected return on plan assets	6.7%	other in	7.2%	-
Rate of compensation increase	3.2%	oliv -	3.3%	-

The assumptions above are used to develop the benefit obligations at fiscal year-end and to develop the net periodic benefit cost for the subsequent iscal year. Therefore, the assumptions used to determine net periodic benefit cost for each year are established at the end of each previous year, while the assumptions used to determine benefit obligations were established at each year-end.

The net periodic benefit cost and the penefit obligations are based on actuarial assumptions that are reviewed on an annual basis. The Parmership revises these assumptions based on an annual evaluation of long-term trends, as wall as market conditions, that may have an impact on the cost of providing retirement benefits.

The expected rates of return on plan assets for the Partnership pension and postretirement benefits plans represent its long-term assessment of return expectations, which the Partnership will change based on significant shifts in economic and financial market conditions. The 2009 expected rates of return for these plans reflect our long-term outlook for a globally diversified portfolio, which is influenced by a combination of return expectations for individual asset classes, actual historical experience and its diversified investment strategy. The historical returns are one of the inputs used to provide context for the development of our expectations for future returns. Using this information, the Partnership develop ranges of returns for each asset class and a weighted-average expected return for its targeted portfolio, which includes the impact of portfolio diversification and active portfolio

The effect of a one percentage point increase/ (decrease/ of test) of service and interest cost components is approximately USD 0.2 million/ (USD 0.1 million) and of the postetirement benefit obligation approximately USD 2.2 million/ (USD 1.8 million) obligation approximately USD 2.2 million/ (USD 1.8 million).

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# 11. Provisions (cont'd)

Pensions and similar obligations (cont'd)

# C) Obligations and Funded Status

Defined Benefit Pension Plans	Pension Benefit	Postretirement Benefit	Pension Benefit	Postretirement Benefit
(USD'000)	2008/2009	2008/2009	2007/2008	2007/2008
Change in Benefit Obligation (DBO)				
Benefit obligation at beginning of year	4,017,877	11,289	6,146,791	14,878
Service cost	142,368	127	190,241	115
Interest cost	214,486	1,100	248,985	1,604
Employee contributions	10,965	_	20,113	
Plan amendments	(2,425)	-	12,505	•
Plan net (gains)/losses	899,744	(373)	(669,713)	1,173
Foreign exchange impact	522,733	4,133	(812,965)	(5,274)
Acquisitions/(divestitures)	8,983	-	214,558	•
Curtsilments	(24,012)	چ.	(58,526)	
Setilements	(42,072)	at it.	(36,902)	
Special Termination Benefits	6,344	other -	24,881	
Benefits paid	(183,841)	(521)	(204,004)	(607)
Wyath movement in consolidation	221,083	-		
Other movements in consolidation	oses die	-	(1,057,887)	
Other movements in consolidation  Benefit obligation at end of year  (USD'000)  Changes in Plan Assets  Fair value of plan assets at beginning of year	5,790,213	15,755	4,017,877	11,289
eetigh.	er			
and and the contract of the co	Pension	Postretirement	Pension	Postretirament
For Wife	Benefit	Benefit	Bonefit	Benefi
(USD'000)	2008/2009	2008/2008	2007/2008	2007/2008
Changes In Plan Assets	marked Market Market State Control		PHYSICA NEW YORK MANNEYS S. R. S.	######################################
Fair value of plan assets at beginning of year	3,398,280		5,169,500	,
Actual return on plan assets	521,193		(1,058,719)	
Company contributions	350,699	521	359,310	607
Employee contributions	10,985	-	20,113	
Foreign exchange impact	398,989	-	(765,465)	
Acquialtions/(divestitures)	5,573		264,768	
Settlements	(42,072)	-	(36,902)	,
Senefits paid	(183,841)	(521)	(204,004)	(607)
Wyeth movement in consolidation	156,206		_	
Other movements in consolidation		•	(352,321)	
Fair value of plan assets at end of year	4,613,99	PMGI -	3,396,280 MG Audit	•
Funded Status		Doc	ument to which	our report dated
Plan assets in excess of/(less than) benefit obligation	(1,176,221)	(15,755)	(621,597) 1 OCT 2016	(11,289)
			refers.	iina aurooses
		KP	MG Accounte	ring N.V Page 32

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# 11. Provisions (cont'd)

Pensions and similar obligations (cont'd)

The unfavorable change in the pension benefit plans projected benefit obligations funded status from \$622 million underfunded in the aggregate as of November 30, 2008, to \$1,176 million underfunded in the aggregate as of November 30, 2009, was largely driven by a 0.4 percentage-point increase in the average rate of compensation increases, weakening of the U.S. dollar against the U.K. pound, euro and Japanese yen and the acquisition of Wyeth international pension plans. The Partnership funded its defined benefit plans to the extent that tax or other incentives exist and the Partnership has accrued liabilities on its consolidated balance sheets to reflect those plans that are not fully funded.

Amounts recognized in the consolidated balance sheet as of November 30 follow:

efont international monotocastical comments and control and contro	Pension Benefit 2008/2009	Postretirement Benefit 2008/2009	Pension Benefit 2007/2008	Postretirement Benefit 2007/2008
Non current assets (Footnote 5 - Others)	38,028		125,466	-
Current liabilities (Footnote 13 - Current Liabilities)	(27,783)	(865)	(23,257)	(577)
Non current liabilities (Footnote 11 - Provision)	(1,186,466)	(14,890)	(723,806)	(10,712)
Funded Status	(1,178,221)	(35,755)	(621,597)	(11,289)
production and makes in the section of the control		J	NAME AND COLUMN TO A STREET OF THE STREET OF	The state of the s

Amounts recognized in Partners Capital Accounts and minority interest as of November 30 follow:

он и порядком на на пот на постанова потпостанавления состойность на постанова и и постанова и постанова и пост Постанова на постанова	Pension	Postretirement	Pension	Postretirement
	SO Senefit	Senefit	Benefit	Benefit
, in the second	2008/2009	2008/2009	2007/2008	2007/2008
(USD'000) \$\frac{\sqrt{0}}{2}	Office			
Actuarial losses	1,936,604	4,708	1,142,031	3,983
Prior service cost/(credits) and other	(16,856)	1,177	(15,913)	948
Total	1,919,748	5,883	1,126,118	4,931

The actuarial losses primarily represent the cumulative difference between the actuarial assumptions and actual return on plan assets, changes in discount rates and plan experience. These actuarial losses are recognized in Partners Capital Accounts and Minority Interest and are amortized into income over an average period of 14.6 years.

For employee retirement plans with benefit obligation in excess of plan assets, the respective amounts at 30 November 2009 were benefit obligations of USD 1.5 billion (2007/2008: USD 1.5 billion) and plan assets of USD 859 million (2007/2008: USD 876 million).

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#### 11. Provisions (contd)

Pensions and similar obligations (cont'd)

#### D. Plan Assets

The following table presents the weighted-average long-term target asset allocations and the percentages of the fair value of plan assets for the pension benefit plans by investment category as of November 30:

<ul> <li>Control of the Control of the Control</li></ul>	Target Allocation	Percentage of P		
	2009	2009	2008	
Pension Senefit Plan:	***************************************			
Global equity securities	54.0%	49.9%	48.5%	
Debts securities	32.0%	33.8%	31.6%	
Alternative investments	14.0%	10.2%	11.2%	
Cash	0.0%	6.1%	8.7%	
Total	100%	100%	100%	

#### Other Provisions

The line Other provisions includes estimates of unpaid obligations that have been incurred but are not yet payable. Subsidiaries of the Partnership recorded provisions for litigation for the book year ending 30 November 2009. Provisions for the majority of litigation and product matters have been recorded by the ultimate parent company Pfizecting.

The movement of Other provisions was as follows:

COCCOSC TECCOSC COCCOSC COCCOS	TO THE REPORT OF THE PROPERTY
kof wide	2008/2009
(USD'000)	
Beginning balance Reserve utilized in 2009 Current year provision	265,190 (187,516) (10,645)
Ending balance	67,029

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# 12. Long term liabilities

procession-with contribution of the contributi	30 November 2009	30 November 2008
(USD'000)		
Long term debt	44,193	15,692
Other long term liabilities	1,266,386	799,277
	1,310,679	814,969
Other long term liabilities		
Other long term liabilities are comprised of the following:		
WASSISTANCE OR AND AND THE PROPERTY OF THE PRO	30 November 2009	30 November 2008
(USD'000)	2009	2000
Cross currency swaps	394,178	22,326
Interest rate swaps	, 6,464	7,087
Restructuring obligations	441,477	526,699
Legal related liabilities	16,095	17,861
Accrued post-employment benefits Assets retirement obligation	13,929 144,042	13,410 81,783
Accrued sales returns	9,123	5,800
Other long term obligations	241,078	124,311
didn'y rich	1,286,386	799,277
Cross currency swaps Interest rate swaps Restructuring obligations Legal related liabilities Accrued post-employment benefits Assets retirement obligation Accrued sales returns Other long term obligations  13. Current liabilities		,
13. Current liabilities	,	
CONT.	30 November 2009	30 November
(USD'000)	2009	2008
Short term loans / bank overdrafts	1,159,334	189,632
Trade accounts	2,979,984	1,001,101
Accounts payable to Partners	12, <b>158</b> ,175	2,781,790
Accounts payable to Participations	1,513,367	1,689,337
Accounts payable to Affiliated Companies	11,031,291	9,014,993
Income Taxes	769,059	588,083
Other accounts payable and accrued expenses including payroll taxes	25,727	3,570,006
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#### 13. **Current liabilities**

Other accounts payable and accrued expenses including payroll taxes

Other accounts payable and accrued expenses are comprised of the following:

THE RESIDENCE OF THE PROPERTY	30 November 2009	30 November 2008
(USD'000)		
Accrued employee expenses	813,779	680,006
Accrued expenses other	1,103,856	699,446
Restructuring obligations	418,891	665,399
Forward exchange contracts	252,369	913,386
Cross currency swaps	849,888	
Accrued grants	129,333	61,559
Accrued interest and royalties	<u>ي.</u> 124,742	7,617
Accrued inventory and sales rebates	3 <sup>3</sup> 291,762	168,881
Accrued taxes	199,818	55,699
Accrued legal and professional services	64,772	73,972
Accrued advertising and sales promotional expenses of the sales promotion of the sales pr	76,517	44,041
OSE PATE		
aut Pairie	4,325,727	3,370,006
Accrued grants Accrued interest and royalties Accrued inventory and sales rebates Accrued taxes Accrued legal and professional services Accrued advertising and sales promotional expenses the accrued advertising and sales promotional expenses the accrued advertising and sales promotional expenses.		
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#### 14. Financial instruments

#### General

During the normal course of business, the Partnership makes use of various financial instruments that expose the Partnership to market or credit risks. These concern financial instruments that are included on the balance sheet. The Partnership does not trade in financial derivatives and follows procedures and lines of conduct to limit the size of the credit risk with each counterparty and market. If a counterparty falls to meet its payment obligations to the Partnership, the resulting losses are limited to the fair value of the instruments in question. The contract value or principal amounts of the financial instruments serve only as an indication of the extent to which such financial instruments are used, and not of the value of the credit or market risks.

#### Foreign exchange risk

A significant portion of revenues, earnings and net investments in foreign affiliates is exposed to changes in foreign exchange rates. The Partnership seeks to manage its foreign exchange risk in part through operational means, including managing expected same currency revenues in relation to same currency costs, and same currency assets in relation to same currency liabilities. Depending on market conditions, foreign exchange risk is also managed through the use of derivative financial instruments and foreign currency debt. These financial instruments serve to protect net income and net investments against the impact of the translation into U.S. dollars of certain foreign exchange denominated transactions.

#### Interest rate risk

The interest rate risk is limited to possible changes in the fair value of loans taken up and granted. These loads have a fixed interest rate over the entire term. The loans are held to maturity. The Partnership's policy is therefore not to use derivative financial instruments to control interim or other interest rate fluctuations.

#### Credit risk

On an ongoing basis, the Partnership reviews the creditworthiness of counterparties to foreign exchange and interest rate agreements and does not expect to incur a loss from failure of any counterparties to perform under the agreements.

There are no significant concentrations of credit risk related to the Partnership's financial instruments with any individual counterparty.

In general there is no requirement for collateral from customers. However, derivative financial instruments are executed under master netting agreements with financial institutions. These agreements contain provisions that provide for the ability for collateral payments, depending on levels of exposure and the credit rating of the counterparty and the Partnership.

The fair value of most of the financial instruments stated on balance sheet, including account receivable securities, cash and cash equivalents and current liabilities, is close to the carrying amount.

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### 14. Financial instruments (contd)

The fair value of the other financial instruments stated on the balance sheet is approximately equal to the book value as per 30 November 2009 (and 30 November 2008).

#### Securities

// (CO)(CO)	Fair value 30 November 2009	Fair value 30 November 2008
(USD'000)		
Securities, assets, available for sale Securities, assets, held to maturity	18,381,592 610,241	28,165,055 1,737,420
	18,991,833	29,902,475

The fair values of securities, assets are included in financial fixed assets (long term) and other receivables (short term).

#### Derivatives

WILL AND DESCRIPTION AND AND AND AND AND AND AND AND AND AN	***************************************	17.00	and annex or manufacture to the contract of th	
	Est. fair	چې نو Est. fair	Contract	Contract
	Est. fair value	ອິດວ່ value	value	value
	30	30	30	30
	November	November	November	November
	2009	2008	2009	2008
(USD'000)	of its plat of			
Forward exchange contracts,	332,330			
asseis	332,330	395,750	32,381,375	22,469,863
Forward exchange contracts,				
debts	(252,369)	(913,385)	(32,308,326)	(23,135,072)
	79,981	(617,636)	73,049	(665,209)
Cross currency swaps, assets	734,463	77,486	95,687	198,210
Cross currency swaps, debts	(1,244,066)	(22,326)	3,049,230	2,452,605
	(509,603)	55,160	3,144,917	2,650,815

The fair values of forward exchange contracts are included in account

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# 14. Financial instruments (cont'd)

Cross currency swaps are included in long term investments and in other long term and current liabilities.

Chemical N. (1970) (School Matter) (Chemical New York) (Proposition of Proposition (Chemical New York) (Proposition (Chemical New York) (Proposi	Est. feir	Est. fair	Contract	Contract
	value	value	value	value
	30	30	30	30
	November	November	November	November
	2009	2008	2009	2008
(USD'000)			**************************************	
Interest rate swaps, assets	110,488	1,111	3,007,527	251,702
Interest rate swaps, debts	(6,464)	(7,087)	(157,527)	(116,702)
•	104,024	(5,976)	2,850,000	135,000

The fair values of interest rate swaps are included in other receivables and current liabilities.

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#### 15. Net turnover

#### Sector analysis

	. 2008/2009	2007/2008
(USD'000)	,	
Pharmaceutical products	37,568,384	36,291,021
	37,568,384	36,291,021
Geographical analysis		
THE CONTRACT OF THE CONTRACT O	2008/2009	2007/2008
(USD'000)		
America (USA, Canada and Mexico) Europe	18,168,607 12,147,162	17,770,008 11,366,648
Asia, Australia, New Zealand	6,458,730	6,101,201
Rest of world	793,885	1,053,164
-	37,568,384	36,291,021
Pasties and the state of the st	r	
	2008/2009	2007/2008
(USD'000)		
Affiliated companies	16.058.546	15,805,407
Participations	447,865	545,572
Third parties	21,061,973	19,940,042
(USD'000)  Affiliated companies Participations Third parties  Consent of control of the control	37,668,384	38,291,021
o disetti		

### 16. Cost of Goods Sold

Cost of Goods Sold decreased by USD 600 million to USD 5.6 billion (2007/2008 USD 6.2 billion).

### 17. General and Administrative Expenses

The decrease in general and administrative expenses in 2008/2009 is mainly due to a fall in service and management fees.

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#### 18. Other expenses

ANALYSIS MATERIAL PROGRAMMENT AND ANALYS	2008/2009	2007/2008
(USD 7000)		
Royalty expenses	2,989,648	3,023,000
Amortization of intangible assets	1,994,654	1,612,627
Loss on sale or liquidation of subsidiary		601,267
Restructuring expenses	164,500	1,182,351
Distribution expenses	236,984	249,548
Other expenses	233,558	299,462
	5,619,344	6,968,255

Restructuring expenses relate to site rationalisations in both R&D and manufacturing, and also the streamlining of organisational structures.

### 19. Other operating income

PRESIDENT CONTROL CONT	***************************************	2008/2009	2007/2008
(USD'000)		other	
Gain on sale of assets through a joint venture Other revenues	eses alfor as	423,937 189,406	327,529
	purpolities	813,343	327,520

Other revenues include USD 120 million of gain on sale of third party investment.

#### Wages and salaries and social charges 20.

EX.ES AND INTERPOLATION AND EXPONENTIAL TO ACT TO C.	2008/2009	2007/2008
(USD'000)		
Wages and salaries	3,271,529	3,151,617
Social charges	462,581	500,427
Pension charges	131,346	198,393
	3,865,456	3,850,437

Wages and salaries and social and pensions charges are included in the Research and development, Selling and General and administrative expenses.

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### 21. Average number of employees

equinament and an experiment of the control of the	2008/2009	2007/2008
America	7,891	8,850
Europe	19,847	22,304
Asla	15,267	14,205
Rest of the world	3,301	3,314
	48,303	48,873

Within the consolidated group of entities of C.P. Pharmaceuticals international C.V. in 2008/2009, 288 people were employed in The Netherlands (2007/2008: 345).

The number of employees which transferred to the consolidated group of entities of C.P.Pharmaceuticals International C.V at 30 November 2009 from the acquisition of Wyeth legal entities amounted to 9,291 and this was not included in the average number of employees disclosed in the above table.

#### 22. Stock options

Pfizer Inc. may grant stock options to employees, including officers. Options are exercisable after five years or less subject to continuous employment and certain other conditions, and generally expire 10 years after the grant date. Once options are exercisable, the employee can purchase shares of the Pfizer Inc. common stock at the market price of the date the option is granted. Former Pharmacia plans provided that, in the event of a change in control of Pharmacia, stock options already granted become immediately exercisable. The costs of the stock option plan are accounted for in the annual report of Pfizer Inc.

#### 23. Net financial income of

постатительного принципального принценного	2008/2009	2007/2008
(USD'000)		and the state of t
Interest income	1,275,682	1,626,734
interest expense	(487,936)	(615,811)
Foreign exchange gain/(loss)	272,854	(51,248)
	1,060,600	969,875

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### 24. Tax on result from ordinary operations

The applicable weighted average tax rate is 10.69% in 2008/2009 (2007/2008: 13.22%). The tax charge in the profit and loss account over 2008/2009 amounts to USD 1.8 billion (2007/2008: USD 512 million), or 12.71% of the result before taxes and mainly includes tax over the current year, local jurisdictional tax law, tax on non-deductible interest and other cost and deferred tax liability. The tax charge in the profit and loss account includes the following components:

ACTION OF THE PROPERTY OF T	2008/2009	2007/2008
(USD'000)		
Tax liability of current financial year after non-taxable		
income/expense	2,180,020	1,709,362
Deferred tax liability	(358,601)	(1,302,704)
Prior period correction	(40,469)	72,222
Other	83,600	33,246
	1,864,550	612,126

#### 25. Share in results from participating interests

4. SECURIO DE CODE CONCUENCIONO DE LA RECORDAN PERCENTA CONTRA DE PRESENTA MENANTA AL CONTRA DE PRESENTA DE LA CONTRA DEL CONTRA DE LA CONTRA DEL CONTRA DE LA CONTRA DEL CONTRA DE LA CONTRA DEL CONTRA DE LA CONTRA DE L	2008/2009	2007/2008
(USD'000)		
Net income from participations stated at net equity	17,429	47,740
gion retre	87,428	47,740

# 26. Cash flow statements

The Partnership has elected not to present a separate statement of consolidated cash flows. Accordingly, a copy of the consolidated statements of Pfizer Inc. for the year ended 31 December 2009, in which the consolidated cash flow statement of C.P. Pharmaceuticals International C.V. is incorporated, is deposited at the Chamber of Commerce of Rotterdam, The Netherlands.

#### 27. Transactions with participations and affiliated companies

In its normal course of business, the partnership buys and sells goods and services from and to various affiliated companies and companies in which it has participations in which the partnership has an interest of 50% or less. Generally, these transactions are conducted on a commercial basis under comparable conditions that apply to transactions with third parties.

In 2009, the purchase of services from participations amounted to USD 40 million. The sale of products to participations amounted to USD 448 million. As at 30 November 2009, the accounts receivable from participations amounted to USD 857 million, while amounts owed to participations amounted to USD 857 million, while amounts owed to participations amounted to USD 857 million, while amounts owed to participations amounted to USD 857 million.

also refers | Initials for Identification purposes EPMC: Access attacks N.V. Page 43 In 2009, the purchase of services from affiliated companies amounted to USD 2.6 billion and the sale of services to affiliates amounted to USD 487 million. The sale of goods to affiliated companies amounted to USD 16 billion. As at 30 November 2009, the accounts receivable from affiliated companies amounted to USD 22 billion, while amounts owed to affiliated companies amounted to USD 11 billion.

# 28. Contractual Obligations

Payment due under contractual obligations as of 30 November 2009, mature as follow:

	Total	Within 1 year	Over 1 to 3	Over 3 to 5	THE STREET WEST PROPERTY.
(USD'000)	produce of the Control of the Contro	***************************************	years	years	After 5
Long-term debts <sup>(a)</sup> Lease commitments and rent expense <sup>(b)</sup>	45,806 303,329	1,965 71.374	13,561 95,980	15,969 48,798	14,311 87,177
Purchase obligations and other <sup>(c)</sup>	1,182,019	419,836	376,117	156,907	229,159

Long-term debt obligation include both expected principal and interest obligations. The calculation of expected interest payments incorporate only current period assumptions for interest retest foreign currency translation rates and hadging strategies. Long term debt consists of senior unsecured notes, croating rate unsecured notes, foreign currency denominated notes and other borrowing and mortgages.

(b) Include operating and capital lease obligations.

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<sup>(</sup>o) Include agreements to purchase goods and services that are enforceable and legally blinding and includes amounts relating to advertising, information technology services and employee benefit administration services and potential milestones payments deemed reasonable likely to occur.

#### 29. Other contingencies

Certain subsidiaries participate in cash pooling arrangements with affiliates involving a series of cross guarantees between the parties.

The total exposure of the guarantees amounts to USD 199 million.

For the purposes of applying the exemption under Article 403, Book 2 of the Dutch Civil Code, the Partnership has assumed joint and several liability for all legal transactions carried out by:

C.E. Commerical Investments C.V., Netherlands Pfizer Animal Health B.V., Netherlands Prizer Animal Health S.V., Netherlands
Pfizer Asia Holdings B.V., Netherlands
Pfizer B.V., Netherlands
Pfizer Commercial Holdings Cooperatief U.A., Netherlands
Pfizer Global Holdings B.V., Netherlands
Pfizer Investments Netherlands B.V., Netherlands
Pfizer Netherlands B.V., Netherlands
Pfizer OTC B.V., Netherlands Pfizer OTC B.V., Netherlands
Pfizer Pharmaceuticals B.V., Netherlands Pharmacia B.V., Netherlands Pharmacia International B.V., Netherlands

The Partnership has guaranteed the liabilities (as defined by Section 5(c)(ii) of the Irish Companies (Amendment) Act, 1986) of the subsidiaries as listed below, in order to allow them avail of the exemption from filing their individual financial statements for the year ended 30 November 2009, as set out in Section 17 of the Irish Companies (Amendment) Act, 1986.

For its pection purposes only any AHP Finance Ireland Limited, Ireland CovX Technologies Ireland Limited, Ireland Fort Dodge Ireland Limited, Ireland FOT HEREITOR DIFFOR TO THE TOTAL TO THE TOTA Pfizer Biotechnology Ireland, Ireland Pfizer Biologics Ireland Holdings Limited, Ireland Pfizer Cork Limited, Ireland Pfizer Distribution Company, Ireland Pfizer Export Company, Ireland Pitzer Export Company, Ireland
Pitzer Finance International Limited, Ireland
Pitzer Global Tracting, Ireland
Pitzer Healthcare Ireland, Ireland
Pitzer Holding Ventures, Ireland
Pitzer Holdings Europe, Ireland
Pitzer International Holdings Limited, Ireland
Pitzer Investment Capital plc, Ireland
Pitzer Ireland Ventures, Ireland
Pitzer Ireland Ventures, Ireland Prizer Ireland Pharmaceuticals, freland
Prizer Ireland Pharmaceuticals, freland
Prizer Manufacturing Services, Ireland
Prizer Science and Technology Ireland Limited, Ireland
Prizer Service Company Ireland, Ireland
Prizer Shared Service, Ireland Pharmacia Ireland Limited, Ireland Warner Lambert Ireland, Ireland Wyeth Medica Ireland Limited, Ireland Wyeth Research Ireland Limited, Ireland

On 19 May 2009, CPPI CV issued a letter of comfort to Pfizer, Shared Services (PSS) whereby it pledged to provide whatever financial support is required to provide whatever financial support is required to at least 30 November 2010. In doing so, CPPI CV relieves Pfizer Ireland Pharmaceuticals of any obligation to cover the liabilities of Philadelle Shared Services which was previously agreed. - 1 oct 2010

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#### 30. Litigation and Proceedings

The Partnership and its subsidiaries from time to time are involved in various patent, product liability, consumer, environmental and tax claims and litigations, and additional matters that arise from time to time in the ordinary course of business. These include challenges to the coverage and/or validity of patents on products or processes and allegations of injuries caused by drugs or medical devices. The Partnership and its subsidiaries are also from time to time subject to environmental laws and regulations, and are also involved with or the subject of governmental or regulatory agency inquiries or investigations from time to time. Litigation is inherently unpredictable and excessive verdicts that are not justified by evidence can occur. The Partnership believes that it and its subsidiaries have valid defenses with respect to the legal matters pending against them and, taking into account insurance and reserves, the Partnership believes that the ultimate resolution of these matters will not have a material adverse impact on the financial condition, results of operations, or cash flows of the Partnership. It is possible, however, that cash flows or results of operations could be affected in any particular period by the resolution of one or more of these contingencies.

#### **Patent Metters**

Atorvastatin. Pfizer Ireland Pharmaceuticals ("PIP"), of which CPPICV is a partner, owns interests in worldwide patents covering Lipitor that are being challenged in lawsuits in Brazil, Bulgaria, Czech Republic, Georgia, Greece, Hungary, Korea, Mexico, Poland, Portugal, Romania, Russia, Slovakia, Spain, as well as in the United States.

On June 18, 2008, we announced that we had entered into an agreement with Ranbaxy Laboratories Ltd. (Ranbaxy) and certain of its affiliates to settle substantially all of the outstanding worldwide patent litigation between us involving Lipitor and Caduet. Under terms of the agreement, Ranbaxy will have a license to sell generic versions of Lipitor and Caduet in the U.S. effective November 30, 2011. In addition, the agreement provides a license for Ranbaxy to sell generic versions of Lipitor commencing on varying dates in seven other countries; Canada, Australia, Belgium, Netherlands, Germany, Sweden and Italy. The lawsuits between Ranbaxy and us regarding Lipitor and Caduet were dismissed, and Ranbaxy will no longer contest the validity and/or infringement of our patents for Lipitor and Caduet, in the U.S. and the other specified countries. The ongoing patent-infringement litigation between Ranbaxy and us relating to Lipitor will continue in other European countries including Spain, Portugal, and Romania.

In Spain, we have successfully defended challenges to the enantiomer patent. In late October 2009 the Court of Appeal affirmed the 2007 trial court decision upholding the enantiomer patent covering atorvastatin calcium and ordered Ranbaxy not to market until patent expiry in July 2010. Several other generic companies are seeking Supreme Court review of two appellate court decisions upholding the enantiomer patent. In addition, we joined a patent infringement action brought by our licensee Almirali against the generic companies Cinfa and Alter. In late October 2009, the trial court upheld the enantiomer patent covering atorvastatin calcium and ordered the defendants not to market until patent expiry in July 2010. Both Ranbaxy and Cinfa have appealed.

in Denmark, following the trial court's decision completely in Pfizer's favor finding that our basic atorvastatin patent is infringed by Ranbaxy's generic product and that our atorvastatin enantiomer patent is valid, the parties reached a settlement in April 2009 anding all pending litigation and Ranbaxy will not launch its generic product in Denmark patent of the expiration of our basic patent in November 2011, or any subsequent period of pediatric exclusivity, of any subsequent period are pediatric exclusivity.

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#### 30. Litigation and Proceedings (contd)

A preliminary injunction was obtained in Finland against Ranbaxy's generic atorvastatin product, and remained in place until the patent expired in February 2009. In March 2010 in Finland, we received a claim for damages from Ranbaxy in the amount of 30 million Euros—based on court ordered preliminary injunctions—which Ranbaxy alleges prevented it from entering the market until our atorvastatin commercial process patent expired in February 2009. In May 2010 there was a trial on infringement and validity of our patent and in June 2010 the court found the patent invalid and not infringed by Ranbaxy. We filled a notice of appeal and if we are ultimately unsuccessful on infringement or validity, a hearing on the damages to which Ranbaxy will be entitled due to the injunction will take place about a year from now.

Pending litigation in Belgium and Germany was dismissed pursuant to the settlement agreement with Ranbaxy discussed above.

The settlement agreement relates solely to Ranbaxy and does not apply to legal challenges to various Lipitor patents by or involving other generic manufacturers. In the previously reported patent infringement suit filed against Teva Pharmaceuticals USA, Inc. in the United States over their ANDA for generic atorvastatin, in July 2009 the parties entered into a settlement to resolve this litigation. In November 2008, Apotex Inc. (Apotex) notified us that it had filed an ANDA with the FDA seeking approval to market a generic version of Lipitor asserting the invalidity of our enantiomer patent and the non-infringement of certain later-expiring patents. Apotex is not challenging our basic patent. In December 2008, we filed suit against Apotex in the U.S. District Court in Delaware and Illinois asserting the validity and infringement of the enantiomer patent. Subsequently our action in Delaware was transferred to Illinois and consolidated with our pending action there. In May 2009, Matrix Laboratories Limited ("Matrix"), a subsidiary of Mylan inc. "Mylan"), notified us that it had filed an ANDA with the FDA seeking approval to market a generic version of Lipitor. Matrix asserts the non-infringement of our patent covering the crystalline form of atorvastatin and the non-infringement of two formulation patents. Matrix is not challenging our basic patent or our enanthomer patent. In June 2009, Pfizer filed actions against Matrix, Mylan and another Mylan subsidiary in the U.S. District Court for the District of Delaware and the Crystalline patent and two process patents. In November 2009, our action in West Virginia was transferred to Delaware and consolidated with our pending action there.

In October 2009, Dr. Reddy's Laboratories Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, Dr. Reddy's) and KUDCO Ireland, Ltd. and Kremers Urban LLC (collectively, KUDCO) notified us that they had filed abbreviated new drug applications with the FDA seeking approval to market generic versions of Lipitor. They essert the invalidity and/or non-infringement of our patent covering the crystalline form of atorvastatin and two other Lipitor patents. They are not challenging our enantlomer patent. In December 2009, we filed actions against Dr. Reddy's and KUDCO in the U.S. District Court for the District of Delaware asserting the infringement of our crystalline patent.

In July 2010, Actavis, Inc. and Actavis Pharma Manufacturing Pvt. Inc. (collectively "Actavis") notified us that they had filed an abbreviated new drug application with the FDA seeking approval to market a generic version of Lipitor. Actavis asserts non-infringement of our patent covering the crystalline form of atorvastatin and two other Lipitor patents, but has not challenged our enantiomer patent. In August 2010, we filed an action against Actavis in the U.S. District Operation the District of Delaware asserting the infringement of our crystalline patent.

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#### 30. Litigation and Proceedings (contd)

Caduet. In August 2009, Sandoz Inc., a division of Novartis AG (Sandoz), notified us that it had filed an abbreviated new drug application with the FDA seeking approval to market a generic version of Caduet. In that filing and in a declaratory judgment action brought by Sandoz in October 2009 in the U.S. District Court for the District of Colorado, collectively, Sandoz asserts the invalidity of our patent covering the atorvastatin/amlodipine combination, which expires in 2018, and the invalidity and non-infringement of three patents for Lipitor, which (including the six-month pediatric exclusivity period) expire between 2013 and 2017. Sandoz is not challenging our enantiomer patent for Lipitor. In October 2009, we filed suit against Sandoz in the U.S. District Court for the District of Delaware and the U.S. District Court for the District of Colorado asserting the infringement of the atorvastatin/amlodipine combination patent. In March 2010, the Colorado cases were transferred to Delaware, and we moved to have them consolidated with the Delaware case.

In December 2009, Mylan Pharmaceuticals, Inc. notified us that it had filed an abbreviated new drug application with the FDA seeking approval to market a generic version of Caduet. Mylan asserts the invalidity of our patent covering the atorvastatin/ amlodipine combination and the non-infringement of three patents for Lipitor, which (including the six-month pediatric exclusivity period) expire between 2013 and 2017. Mylan Pharmaceuticals, Inc. is not challenging our enanttomer patent for Lipitor. In February 2010, we filed suit against Mylan Pharmaceuticals, Inc. in the U.S. District Court for the District of Delaware asserting the infringement of the atorvastatin/amlodipine combination patent.

in Austria in October 2008 the Supreme Patent and Trademark Senate held that the use of Lek's product would infringe the Swiss-type use claim of our basic patent. This decision is final. Nullity actions against our atorvastatin enantiomer patent were prought by local generic companies in Georgia and Greece and we were successful in the previously reported nullity action in Cyprus. In Greece infringement suits continue against several companies and additional companies have launched generic atorvastatin and we brought actions against them. Infringement actions and nullity actions against our atorvastatin patents with Teye are still pending in Hungary as are nullity actions by Lek and Egis. Nullity actions were also brought by Egis against our crystalline atorvastatin patents in Poland in 2007 and in Bulgaria. Czech Republic, Russia and Slovakia in 2008 and Romania in 2008. Nullity actions brought by Ranbaxy against our enantiomer and amorphous process atorvastatin patents are still panding in Portugal and Romania. Ratiopharm and Mepha filled nullity actions against our enantiomer atorvastatin patent in Portugal in 2008 and Alter in 2009.

In Korea, in June 2008, the Patent Court affirmed the adverse 2007 patent office decision to invalidate Pfizer's atorvastatin enantiomer patent. Numerous generics are presently on the market. We appealed to the Supreme Court of Korea and that appeal was denied in 2010. In China the People's intermediate Court affirmed the invalidation of our atorvastatin crystalline patent and Pfizer is appealing that decision. In the Phillippines we filed patent infringement actions in 2008 and 2009 involving the enantiomer and crystalline patents.

The enantiomer patent in Brazil was challenged in March 2008 by a Brazilian generic association and remains pending. In a separate action, in August 2010 an appeals court ruled that the patent expiration date was July 2009 instead of December 2010. In Mexico the enantiomer patent was found invalid on November 9, 2009 by the patent office in response to the generics challenge. Pfizer appealed the decision on November 17, 2009 and obtained a stay order at the appeal court level, keeping the patent valid until final ruling. In 2008 a local part of the market. A preliminary injunction request on our enantiomer patent was granted in August 2009/MG Audit

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#### 30. Litigation and Proceedings (cont'd)

As previously reported, in the U.S., PIP was a plaintiff in a patent infringement lawsuit against Ranbaxy Laboratories Limited and Ranbaxy Pharmaceuticals Inc., which was decided in Pfizer's favor by the CAFC in 2006. The Court held that the basic patent was infringed, but also held a claim of the enantiomer patent invalid on technical grounds. Accordingly; in January 2007 we filled a reissue application with the U.S. Patent and Trademark Office (the Patent Office) and in March 2009, the U.S. Patent Office granted a reissue patent relating to Lipitor that corrects a technical defect in the calcium salt claim in the enantiomer patent. The reissued patent will have the same force and effect and same June 2011 expiration date (including the six-month pediatric exclusivity period) as the original enantiomer patent.

Amiodipine. In July 2009, the Canadian Federal Court in Toronto declared our amiodipine besylate patent invalid and, as a result, Health Canada granted marketing approval for several generic manufacturers' amiodipine besylate products. In July 2010 the Federal Court of Appeal affirmed the lower court's decision.

<u>Donepezil</u>. Certain of the Partnership's subsidiaries are parties, jointly with the patentee Elsal Co Ltd, in patent infringement litigations. These were ongoing in 2008 in Finland against Ratlopharm, in Norway against Krka, in Portugal against Merck, Ranbaxy, Krka, and several other generic companies, and in Spain since 2009 against Mylan; all remain pending.

Pfizer jointly with Eisal filed a main infringement action and a preliminary injunction in Spain against Mylan. The preliminary injunction was granted and Mylan's appear is scheduled for November 2010. The main action is ongoing.

Eletriptan. Certain of the Partnership's subsidiary/subsidiaries is a party in a patent Infringement litigation. In June 2010, we received notices from Apotex Inc. and Apotex Corp. (collectively, Apotex) and from Teva Pharmaceuticals USA, Inc. (Teva USA) that they had filed abbreviated new drug applications with the FDA seeking approval to market their generic versions of Relpax. Apotex and Teva USA assert the non-infringement of our patent covering the crystalline form of eletriptan, which expires in 2017. They have not challenged the basic patent, which expires in 2016. In July 2010, we filed actions against Acotex and Teva USA in the U.S. District Court for the Southern District of New York asserting the infringement of the crystalline patent.

Gabanentin. As previously reported, since 2000 Warner-Lambert has been involved in patent infringement suits against several generic manufacturers that have filed abbreviated new drug applications with the FDA asserting the invalidity and non-infringement of the low-lactam patent. The defendants have filed various summary judgment motions asserting invalidity and non-infringement on a number of grounds. In 2004 the court denied our requests for temporary restraining orders against these generics and several launched at-risk. In 2005, two non-infringement motions were decided in favor of the defendants, and Warner-Lambert appealed. In September 2007 the CAFC reversed the trial court's grant of summary judgment on one of the motions, and ordered the trial court to hold further proceedings. In March 2008, the Court granted our motion to amend our original complaints, to assert infringement based on defendants at risk launch and to demand damages. Certain of the Partnership's subsidiaries are parties to this action. A schedule has been set by the court, with the pretrial conference to be held in February 2011 Fact and expert discovery will go on through September 2010. Counterclaims in these suits as walks yearly is independent actions have been filed claiming that our attempts to enforce rights under these constitute ur fair competition and/or violations of the antitrust laws. These counterclaims and independent actions have been consolidated in the same federal court and are proceeding with a schedule parallel to the patent case, i.e., a pretrial conference is scheduled in February 2011.

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### 30. Litigation and Proceedings (contd)

Latanoprost. Certain of the Partnership's subsidiaries own interests in worldwide patents covering Xalatan (latanoprost). In Italy, in July 2009 through March 2010, we received summonses from Industriale Chimica Srl, Mylan Inc., Breath Ltd., Arrow Generics Ltd., Ratiopharm GmbH, Sifi Spa, Tubliux Pharma Spa, Alapis AVEE and Ratiopharm Italia challenging our latanoprost Supplemental Protection Certificate (SPC) in Italy. The cases are in their early stages. Both Sifi and Ratiopharm Italia launched at risk in April-May 2010 and preliminary injunction actions were initiated and are ongoing. The European patent underlying the Italian latanoprost SPC is the subject of an opposition by several generics at the European Patent Office, with a hearing scheduled on October 5-6, 2010. In February 2010 Alapis ABEE filed a cancellation action against our latanoprost SPC in Greece. In Finland, we filed a preliminary injunction action in July 2010 following a generic's request for a declaratory judgement of non-infringement of the SPC.

In Canada, two generic manufacturers are seeking to market their own latanoprost products and are challenging our Xalatan composition/use patent (expiring 2014) on grounds of non-infringement and invalidity. In December 2009 and April 2010, the Canadian Federal Court upheld the Xalatan product in the respective cases against Pharmascience and Apotex. Both generic manufacturers have filed appeals.

<u>Linezolid.</u> Certain of the Partnership's subsidiary/subsidiaries is a party in a patent infringement litigation. In December 2009, Teva Parenteral Medicines Inc. (Teva Parenteral) notified us that it had filed an abbreviated new drug application with the FDA seeking approval to market a generic version of Zyvox. Teva Parenteral asserts the invalidity and non-intringement of the basic Zyvox patent, which (including the six-month pediatric exclusivity period) expires in 2015, and another patent that expires in 2021. In January 2010, we filed suit against Teva Parenteral in the U.S. District Court for the District of Delaware asserting the infringement of the basic patent.

Pregabalin. Certain of the Partnership's subsidiaries own Interests in worldwide patents covering pregabalin. In March and April 2009, several generic manufacturers notified us that they had filed abbreviated new drug applications with the FDA seeking approval to market generic versions of Lyrica. Each of the generic manufacturers is challenging one or more of three patents for Lyrica: the basic patent, which expires in 2018, and two other patents, which expire in 2013 and 2018. Each of the generic manufacturers asserts the invalidity and/or the non-infringement of the patents subject to challenge. In April 2009, we filed an action against each of the generic manufacturers in the U.S. District Court for the District of Delaware asserting the infringement and validity of our patents for Lyrica. In October 2009, all of these cases were consolidated in the District of Delaware. The court has now issued a scheduling order for the cases, and set a two week trial beginning October 11, 2011. In March 2010, Mylan Pharmaceuticals Inc. (Mylan), the U.S. agent for Alphapharm Pty. Ltd. (Alphapharm), notified us that it had filed an abbreviated new drug application with the FDA seeking approval for Alphapharm to market a generic version of Lyrica and asserting the invalidity and noninfringement of the Lyrica basic patent, which expires in 2018. In March 2010, we filed suit against Mylan and Alphapharm in the U.S. District Court for the District of Delaware asserting the validity and infringement of the besic patent and we expect the action to be consolidated with the other pregabalin patent cases which include our action against Mylan/Alphapahrm on the pain patent.

In Canada, two generic manufacturers, Ratiopharm and Noviphari (Teva) served notices in July and October 2009, respectively, of regulatory submissions in the canada seeking approval to market generic versions of Lyrica which include challenges to rive patents under challenge are the basic patent, which expires in 2013, the pain patent which expires in 2017, two formulation patents and a use patent. We filed an action against Ratiopharm and Novipharm within the 45 day time period thus triggering a 24 month stay of approval of their regulatory submissions.

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#### 30. Litigation and Proceedings (cont'd)

Quinapril. Pfizer Ireland Pharmaceuticals ("PIP") owns interests in worldwide patents covering quinapril. In August, 2009, Apotex commenced an action in the Federal Court of Canada to impeach and/or invalidate two of our patents covering Accupril. Trial is estimated for August 2011.

Sildenafil. Certain of the Partnership's subsidiaries own interests in worldwide patents covering the use of cGMP PDE inhibitors, including sildenafil citrate (Viagra) and competitor PDE inhibitors (e.g., Cialis and Levitra). In October 2002, Pfizer Inc filed in the United States patent infringement actions against Bayer/GlaxoSmithKline and separately, against ICOS/Eli Lilly. In 2004, a worldwide settlement of all disputes with Bayer and GlaxoSmithKline over the patent was reached. In March 2010, the lawsuit Pfizer filed against Lilly/ICOS in 2002 was settled. In the reexamination, the claims to the use of sidenafil were allowed but the PDEv field of use claims stand finally rejected. Pfizer's appeal was heard in June 2009 and the Board of Appeals affirmed the rejection on February 12, 2010. On March 26, 2010, Pfizer submitted an amendment canceling the PDE-V field of use claims and requesting expedited issuance of the reexamination certificate for the sildenafil use claims. On May 13, 2010, the PTO issued a Notice of Intent to Issue an Ex Parte Reexamination Certificate for the sildenafil use claims. In Mexico, Protein, S.A. de C.V. (Apotex) is challenging the validity of the basic compound patent in response to our Infringement suit. Our preliminary injunction remains in force.

In March 2010, we brought a patent-infringement action in the U.S. District Court for the Eastern District of Virginia against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, Teva), which had filed an abbreviated new drug application with the FDA seeking approval to market a generic version of Viagra. Teva asserts the invalidity and non-infringement of the Viagra use patent, which expires in 2019, but is not challenging the basic patent, which expires in 2012.

In September 2007 the Canadian Federal Court united our Viagra use patent and entered an order preventing Apotex from launching a generic version of Viagra until expiration of the patent in 2014. In January 2009 the Canadian Federal Court of Appeal dismissed Apotex' appeal. A prohibition order remains in effect against Apotex for Viagra, however, Apotex has meanwhile filed an impeachment action to invalidate the Viagra use patent and our response was filed in June 2009. Novopharm also challenged the same two patents and in June 2009, the Canadian Federal Court issued a decision upholding our Viagra use patent. That decision has been appealed by Novopharm and we are awaiting a decision from the court. In the meantime, Novopharm has been prohibited from entering the market. In January 2010, Pfizer commenced an action against Mylan to prevent approval of its regulatory submission until expiration of the Viagra use patent. In May 2010, the Canadian Federal Court denied Pfizer's request for an order preventing Ratiopharm from obtaining regulatory approval for a generic version of Revatio. Ratiopharm obtained regulatory approval in Canada shortly thereafter.

Nullity actions were also brought against our sildenafil use patents in Czech Republic by Zentiva and Ratiopharm in 2007 and 2008, respectively. Actions were also brought in late 2008 in Latvia by Krka and in Russia by both Zentiva and Ratiopharm. All are currently pending. A nullity action was filed in Portugal against our basic compound patent in July 2009 and Pfizer was served by the court in July 2010.

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#### 30. Litigation and Proceedings (contd)

<u>Sutent</u> (<u>sunitinily malate</u>). Certain of the Partnership's subsidiary/subsidiaries is a party in a patent infringement litigation. In May 2010, Mylan notified us that it had filled an abbreviated new drug application with the FDA seeking approval to market a generic version of Sutent and challenging on various grounds the Sutent basic patent, which expires in 2021, and two other patents, which expire in 2020 and 2021. In June 2010, we filed suit against Mylan in the U.S. District Court for the District of Delaware asserting the infringement of those three patents.

Tolterodine. Certain of the Partnership's subsidiaries own interests in worldwide patents covering tolterodine. In February 2004 Teva notified us that it had filed abbreviated new drug applications with the U.S. FDA seeking approval to market a product containing tolterodine and asserting the non-infringement and invalidity of our patents relating to this product. In March 2004 Pfizer filed suit against Teva in the U.S. District Court for the District of New Jersey. In January 2007 Teva dropped its challenge to this patent and later the same day its wholly-owned subsidiary, Ivax, filed a challenge on substantially the same grounds. In Pfizer's ANDA lawsuit against Teva and Ivax for Infringement of Pfizer's basic compound patent for Detrol, the five day trial concluded in September 2009 and in January 2010, the court issued a decision in our favor, upholding the basic patent. The court entered an order preventing the FDA from approving Ivax's abbreviated new drug application for Detrol before the expiration of the basic patent in September 2012. Ivax and Teva have appealed the decision to the Federal Circuit Court of Appeals.

In October 2007, Teva notified us that it had filed an abbreviated new drug application with the U.S. FDA challenging on various grounds four patents related to Detroi LA, an extended release formulation of Detroi (tolterodine), and seeking approval to market a generic version of Detroi LA. In December 2007, we filed suit against Teva asserting the infringement of three of the patents relating to Detroi LA. In January 2008, Impax Laboratories inc. (Impax) notified us that it had filed an abbreviated new drug application with the FDA seeking approval to market a generic version of Detroi LA and challenging the same four patents as Teva. In March 2008, we filed suit against impax asserting the infringement of three of the patents. Trial is expected to be scheduled in 2010.

in March 2008 and May 2010, respectively, Sandoz Inc. (Sandoz) and Mylan Pharmaceuticals, Inc. (Mylan) notified us that they had filed abbreviated new drug applications with the FDA seeking approval to market generic versions of Detrol LA. They assert the invalidity and/or non-infringement of three formulation patents for Detrol LA, each of which (including the six-month pediatric exclusivity period) expires in 2020. They are not challenging the basic patent, which (including the six-month pediatric exclusivity period) expires in 2012. In June 2010, we filed actions against Sendoz and Mylan in the U.S. District Court for the District of New Jersey asserting the Infringement of two of the formulation patents for Detrol LA.

<u>Tigecvoline.</u> Certain of the Partnership's subsidiary/subsidiaries is a party in a patent infringement litigation. In October 2009, Sandoz notified Wyeth that it had filed an abbreviated new drug application with the FDA seeking approval to market a generic version of Tygacil. Sandoz asserts the invalidity and non-infringement of two of Wyeth's patents relating to Tygacil, including the basic patent, which expires in 2016. In December 2009, Wyeth filed suit against Sandoz in the U.S. District Court for the District of Delaware asserting infringement of the basic patent.

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#### 30. Litigation and Proceedings (cont'd)

#### **Product Matters**

Cox-2 Litigation

On October 17, 2008, the Company announced that it had reached agreements in principle to settle all the pending US consumer fraud purported class action cases and more than 90% of the known US personal injury claims. The proposed settlements of the U.S. consumer fraud purported class actions were approved by a federal court.

The remaining Cox-2 litigation facing the Company includes hundreds of claims alleging Stevens-Johnson syndrome and/or Toxic Epidermal Necrolysis as a result of the claimants' ingestion of Bextra. Indeed it was this serious skin issue which resulted in Bextra being withdrawn from the market in April of 2005. These claims are subjected to early settlement evaluation, and a reserve was established to address them. We have resolved hundreds of these claims, and we continue to evaluate and settle them where appropriate.

Pfizer Global Manufacturing

MPA Issue (Ireland)

CPPICV is a partner in AHP Manufacturing B.V. d/b/a Wyeth Medica Ireland ("WMI"). WMI manufactures, inter alia, Premarin (conjugated estrogens) Premarin MPA (conjugated estrogens plus medroxyprogesterone acetate ("MPA") - better known as Prempro in the U.S), and Totelle, a hormone replacement therapy (17β-estradiol plustringestone). In June 2003, WMI was served with a Statement of Claim in the Irish High Court @ Sublin by Schuurmans & Van Ginneken ("SVG"), a Netherlands-based molasses and liquid storage concern. SVG claims that it purchased sugar water allegedly contaminated with medroxyprogesterone acetate (MPA) from a WMI sugar water manufacturing effluent that was to have been disposed of by a third party. Plaintiff originally sought compensation in the amount of approximately €115 million for the contamination and disposal of molasses allegedly contaminated with MPA and for compensation on behalf of an unspecified number of its animal feed customers who are alleged to have used contaminated molasses in their livestock feed formulations. Quiring discovery in 2008, plaintiff further particularized its losses as totaling approximately €24 million, exclusive of interest and legal fees. WMI has provided plaintiff bank guarantees in the amount of €28.6 million as security for the amounts claimed by plaintiff in its Statement of Claim. Trial of this matter is likely to occur in the first quarter of 2011. WMI is also subject to a number of separate claims asserted by Dutch pig farming entities seeking damages relating to alleged contamination of pigs with MPA.

In November 2006, WMI was served with criminal summonses charging WMI with 18 violations of the Waste Management Act and WMI's Integrated Pollution Prevention and Control License in connection with five specifically identified shipments of MPA-contaminated sugar water waste from WMI's Newbridge, Ireland facility. The Company thereupon initiated proceedings in the Irish High Court in Dublin challenging the right of the Director of Public Prosecutions (DPP) and the Irish Environmental Protection Agency to prosecute the alleged violations of WMI's Integrated Pollution Prevention and Control License. WMI's challenge was denied by the High Court, and WMI then appealed the High Court's decision to the Supreme Court of Ireland. That appeal was subsequently

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### 30. Litigation and Proceedings (cont'd)

The criminal case was scheduled for trial in June 2010, but WMI reached an agreement to plead guilty to 4 strict liability charges. A hearing is scheduled for October 18, 2010 and the court will set penalties at that time. The maximum penalties under the relevant laws and regulations are IR£ 13 million per charge. In addition, a criminal conviction could form the basis of a determination that WMI is "unfit" to hold a license in Ireland. We have been advised that such a determination is highly unlikely in this case.

#### **Commercial Matters**

#### Polish NHF Margin/Customs Civil Suits

The Polish National Health Fund ("NHF") launched separate civil suits against some pharmaceutical companies, including Pfizer Polska Sp. z.o.o (in which CPPICV is a partner) and Pharmacia Polska Sp. z.o.o (together, the "Companies"), claiming that during the period of May 1, 2000 to April 9, 2002, the Companies inflated the declared customs values of imported medicines, thereby causing higher listed prices and, consequently, higher NHF reimbursement spend. According to the NHF, the declared customs values of imported medicines were inflated because they did not take into account discounts, rebates or similar mechanisms that the Companies received from their exporting affiliates. NHF seeks monetary damages of approximately \$4.1 million from Pfizer Polska and \$1 million from Pharmacia Polska, with the statutory interest. However, no specific mechanism for calculating these damages was provided.

These civil law suits represent a third prong of what became known as the Customs Margin Issue in Poland, arising in 2001, when the Polish government first began to investigate the industry's declared customs values of imported medicines. The other two prongs are based on VAT regulations (arguing that too much VAT was paid based on the inflated process and VAT tax settlement was not recorded correctly) and pricing regulations. The status of the pricing issue was addressed in a case against Sanofi-Aventis, where the court dismissed the Tax Chamber case based on lapsed statute of limitations. The status of the VAT issue was also addressed in a case against GSK and was resolved in GSK's favor. However, the Tax Chamber refuses to accept this GSK's ruling as precedent, and thus VAT still remain potential issues for other companies, including Pfizer and Pharmacia.

Both companies, Pfizer Polska Sp. z o.o. (Pfizer Poland) and Pharmacia Polska Sp. z o.o. (Pharmacia Poland), reached agreements with the NHF aimed at resolution of both cases, and settlements were executed on June 14, 2010 in both cases.

Under the settlements, NHF agreed to withdraw the actions brought against the Companies, and to waive the full claims, while Pfizer Poland agreed to pay PLN 1,413,500.00 (approximately 400,000 USD) and Pharmacia Poland agreed to pay PLN 3,000,000.00 (app. 900,000 USD) to the NHF. In the settlements, the parties agreed that the execution of the settlement exhausted any mutual claims of the parties that are covered by the court proceedings, as well as any existing or future claims arising from the reimbursement by NFZ or its predecessors, the Sickness Funds, of all medicines imported by the Companies from May 1, 2000 to April 9, 2002, regardless of the legal basis for such claims (including those arising from unlawful acts, unjust enrichment or price regulation.)

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also refers.

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# 30. Litigation and Proceedings (cont'd)

On June 15, 2010 NHF submitted motions to discontinue the proceedings in both cases (Pfizer Poland and Pharmacia Poland) to the court. In these applications NHF also waived the claims resulting from the margin case. On June 16, 2010 Pfizer Poland and Pharmacia Poland made the payments as determined in the settlements. The court issued orders dismissing the cases against Pfizer Poland and Pharmacia Poland on June 16, 2010 and June 21, 2010 respectively. Further, by the court's decisions dated July 9, 2010 and July 29, 2010, the June dismissals of the proceedings against Pfizer Poland and Pfizer Pharmacia respectively were confirmed to be final and binding.

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also refers

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# 31. Principal subsidiary companies

Unless stated otherwise, all subsidiary companies listed below are direct or indirect 100% owned, as of 30 November 2009. Subsidiary companies with a \* are new in the consolidation of 2009.

Legal Name		Country
Pfizer Saidal Manufacturing (70%)		Algeria
Pfizer Pharm Algerie SPA		Algeria
Pfizer Limitada		Angola
Pfizer S.R.L.		Argentina
Parke Davis Pty Limited		Australia
Pfizer Australia Pty. Ltd.		Australia
Catapult Genetics Pty Ltd		Australia
Catapult Genetics (Australia) Pty Ltd		Australia
Pfizer Australia Holdings Pty Limited (69%)		Australia
Pfizer Australia Superannuation Pty Ltd (69%)*		Australia
Pfizer ESP Pty Ltd (69%)*		Australia
Wyeth-Laderle Pharma GmbH *		Austria
Pfizer Animal Health S.A.		Belgium
Pfizer Manufacturing Belgium NV (Formerly known as Pharmacia NV/SA)		Balgium
Lothian Developments V SPRL		Belgium
Pfizer Service Company BVBA	ي. م	Belgium
Pfizer Financial Services NV/SA (Formerly known as Pharmacia Coordination C	entre NV/SA) (98%)	Belgium
Whitehall-Benefux SA"	o*	Belgium
vvyem Pharmaceuticate SA/NV "		Belgium
vyyern Ledena Vaccinas SA "		Belgium
Prizer Moldings Bermuda Limited		Sermuda
Searce Construir 6		Bermuda
Prizer ori U.O.O. Sarajevo "		Bosnia
Character Carell that		Srazil
First the Control of		Brazil
LEROFERONDS PRESS LIGHT.		Brazil
Discr Dhamacarticals Limited		Cayman Islands
Officer Intermediated Tradition (Changlant Limited) Comment		Cayitlati Islanus
Pfizer Financial Services NV/SA (Formerly known as Pharmacia Coordination C Whitehall-Benelux SA* Wyeth Pharmaceuticals SA/NV* Wiyeth Lederle Vaccines SA * Pfizer Holdings Bermuds Limited Searle Limited Pfizer BH D.o. Sarejevo * Herzegovina Pharmacia Brazil Ltda. Laboratorios Pfizer Ltda. Pfizer Prev - Sociedade de Previdencia Privada (99%), ne Pfizer Prev - Sociedade de Previdencia Privada (99%), ne Pfizer Pharmaceuticals Limited Pfizer International Trading (Sharighal) Limited) Rizer Suzhou Pharmaceutical Co., Ltd. (Formerly known as Upjohn Suzhou Pharmaceutical Co., Ltd. and alk/a Pharmacia (Suzhou) Ltd.) Pfizer Suzhou Animal Health Products Co., Ltd. (Formerly known as Upjohn Suzhou Pfizer Suzhou Animal Health Products Co., Ltd.)		China
Dizar Suzhan Obermensuiral Co. 1 td /Sorgariy bassa as Liniaha Suzhan		Visia
Pharmacautical Co. 1 td. and alkia Pharmacia (Surbout 1 td.)		China
Pfizer Suzhou Animal Hasilih Products (3) Ltd		Gillion .
(Formerly known as Upjohn Suzhou Animai Health Products Co., Ltd.)		China
Pfizer Pharmaceutical Wood Co., Let (Formerly known as Pharmacia Ltd. And P	hamacia (Wuxi) Ltd.)	China
Pilizer (China) Research and Development Co. Ltd.	( , , , , , , , , , , , , , , , , , , ,	China
Pfizer Healthcare Consultant (Shanghal) Co. Ltd.		
(Formerly known as Pfizer Health Management Co., Ltd)		China
Pfizer Finance Share Service (Dallan) Co., Ltd.		China
Pfizer Investment Co. Ltd. (Formerly known as Pharmacia & Upjohn (China) Ltd.	1.)	China
Pfizer S.A.	•	Costa Rica
Pfizer Zona Franca S.A.		Costa Rica
Pfizer Croatia d.o.o.		Croatia
Pfizer SPOL s.r.o.		Czesh Republic
Ayerst-Wyeth Pharmaceuticals LLC *		Delaware
Pfizer ApS ( )	3	Denmark
Pfizer Cia Ltda.		Ecuador
Pfizer Africa & Wilddle East Company for Pharmacouticals, Anima (Halling Che	micals S.A.E.	Egypt
Pfizer Egypt S.A.E. (99%) Pfizer Middle East for Pharmaceuticals, Animal Health and Chemicals S.A.E. (9	KPMG Audit	Egypt
Pfizer Wilddle East for Pharmaceuticals, Animal Health and Chemicals S.A.E. (9	Discoment to which our	rettemPteted
ruzer rusinia Hade LCC (5570)		∞83br
Wyeth Egypt Limited *	and Ana	Egypt
Wyelh Egypt Trading Ltd *	- 1 OCT\2010	Egypt
Pfizer Oy		Finland
Preve Oy		Finland
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# 31. Principal subsidiary companies (contd)

Legal Name		Country
Kiinteistö oy Espoon Pellavaniementie 14 *		Finland
Riveper S.A.S.		France
Cardel (99%)		France
Pfidev4 SAS		France
Pfizer PGRD SAS		France
Pfizer SAS		France
Pfizer PGM SAS	3:	France
Pfidev3		France
Pfizer Holding France SCA.		France
Capsugal France		France
Capsugel Ploemel (Formerly known as Medicaps)		France
Pfizer Services 1		France
Paris Montrouge II Sarl		France
Pfizer International Operations SAS		France
Wyeth Pharmaceuticals France * (79%)		France
Wyeth Sante Familiale (eka Wyeth Consumer Healthcare France) * (96%)		France
Fort Dodge Sante Animale SAS "		France
Pfizer Finance GmbH & Co. KG		Germany
Pfizer Finance Verwaltungs GmbH		Germany
Pfizer Helias, A.E.		Greece
Pfizer Caribe Limited		Guernsey
Pfizer HK Service Company Limited	Ø.* ·	Hong Kong
Pfizer Corporation Hong Kong Ltd	150	Hong Kong
Pharmacia Asia Limited	ex	Hong Kong
Pitzer Pharmaceutical Trading Limited Liability Company	Hillia	Hungary
Pfizer Hungery Asset Management LLC	8	Hungary
Pfizer Limited (61%)		India
Ouchem Laboratories Limited (61%)		India
PT. Pfizer Indonesia TBK (71%)		Indonesia
PT. Pfidex Pharma (51%)		Indonesia
Pfizer Caribe Limited Pfizer HK Service Company Limited Pfizer HK Service Company Limited Pfizer Corporation Hong Kong Ltd Pharmacle Asla Limited Pfizer Pharmaceutical Trading Limited Liebility Company Pfizer Huntgary Asset Management LLC Pfizer Limited (61%) Duchem Laboratories Limited (61%) PT. Pfizer Indonesia TBK (71%) PT. Pfizer Indonesia TBK (71%) PT. Pfizer Indonesia * Pfizer Healthcare Ireland (formerly Pfizer Sales Ireland) Pfizer Export Company Pfizer Distribution Company Pfizer Ireland Ventures Warner-Lambert Pottary Road Limited Pfizer Ireland Pfizer Science and Technology Ireland Limited Pfizer Holdings Europe Pfizer International Holdings Pfizer Cork Limited (Formerly known as Pharmacia & Upjohn Limited) Pharmacia Ireland Limited (Formerly known as Pharmacia & Upjohn Limited) Pfizer Scrvice Company Ireland		Indonesia
Pfizer Healthcare Ireland (formerly Pfizer Sales Ireland)		Ireland
Prizer Export Company		Ireland
Prizer Dismount Company		freland
Prizer Ireland Ventures		Ireland
Vyamer-Lemont remain		Ireland
Money i asked Policy Dead Limited		ireland Ireland
Direct Science and Technology Holord Limited		Ireland
Serar Haldings Europa		iraland
Diver International Haldings		Ireland
Pilzar Cork I Imited (Formerly Immunios Pharmacia & Holohn Cork I imited)		Ireland
Pharmacia tratand I imited (Formerly known as Pharmacia & Linichn I imited)		ireland
Plizer Global Trading		ireland
Pfizer Service Company Ireland		Ireland
Pfizer International Bank Europe		Ireland
Pfizer Investment Capital		Ireland
Pfizer Ireland Investments Limited		ireland
Pfizer PHF		Ireland
Pfizer Shared Services		Ireland
Pfizer Finance International		Ireland
Pfizer Biologics Ireland Holdings Limited		Ireland
Pfizer Holding Ventures		Ireland
Pfizer Ireland Pharmaceuticals (Formerly known as Pfizer Overseas Pharmaceuticals)	ruticals,	
Pfizer Ireland Pharmaceuticals (Formerly known as Pfizer Overseas Pharmaceuticals and Warner-Lambert Export Limited) Pfizer Manufacturing Services	·	Ireland
	A PARACE A COLLEGE	Ireland
Pfizer Biotechnology fretend	KPMG Audit	ireland
Thorney Company	<ul> <li>Decument to which our</li> </ul>	
Prosec (Ireland) Ltd.	()	Ireland
CovX Technologies Ireland Limited	a ach anan	ireland
Fort Dodge Laboratories Ireland Limited *	~ I ULI ZUM	ireland
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### 31. Principal subsidiary companies (cont'd)

Legal Name		Country
AHP Finance Ireland Limited *		Ireland
Wyeth Medica Ireland Limited *		ireland
Wyeth Research Ireland Limited *		Ireland
Pharmacia Little Island Limited		Ireland
Pfizer Pension Trustees (Ireland) Limited		Ireland
Pfizer Strategic Investment Company Limited		isle of Jersey
Pfizer Searle Investment Ltd *		isle of Jersey
Pharmacia & Upjohn SpA (99%)		Italy
Bioindustria Farmaceutici S.r.i		Italy
Pfizer Italia S.r.l.		Italy
Balverda Sri		Italy
Pfizer Holding Italy SpA (Formerly known as Parke Davis S.p.A.) (80%)		Italy
Fondazione Pfizer Encysive Italy Srl.	• •	italy .
Sefarma Sri		Italy Italy
Wyeth Consumer Healthcare SpA *		Italy
Wyath -Lederle SpA * (51%)		Italy
Fort Dodge Animal Health SpA *		Italy
Capsugai Japan Inc. (K.K.)		Japan
Pfizer Consumer Inc.		Japan
Pfizer Japan Inc. (Formerly known as Pfizer Pharmaceuticals inc.)		Japan
Plizer Pharmaceuticals Jersey Limited		Jersey
Prizer Co-Promotions Limited		Jersey
Private Machine a Limited		Jersey Jersey
Offizer Jereau Company Ltd		Jersey
Pfizer Holdings Turkey Limited		Jersey
Pfizer Jersey Finance Limited		Jersey
Pfizer Jersey Capital Limited		Jersey
Pfizer Sterling Investments Limited		Jereey
Pitzer Japan Inc. (Formerly known as Pfizer Pharmaceuticels Inc.) Pfizer Pharmaceuticels Jersey Limited Pfizer Co-Promotions Limited Parke Davis & Co. Limited Pfizer Venturas Limited. Pfizer Jersey Company Ltd. Pfizer Holdings Turkey Limited Pfizer Jersey Finance Limited Pfizer Jersey Capital Limited Pfizer Starling Investments Limited Pfizer Starling Investments Limited Pfizer Starling Investments Limited Pfizer Starling Investments Limited Pfizer Enternational Limited Wamer-Lambert (East Africe) Limited Pfizer Luxembourg Sarl Pfizer International Luxembourg SA Pfizer Warner Lambert Luxembourg SARI Pfizer Enterprises Sarl (Formerly known as Pharmacis Enterprises S.A.) Pfizer Pholdings International Luxembourg (PHIL) Sarl Pfizer Shareholdings International Luxembourg (PHIL) Sarl Pfizer Proclaion Holdings Sarl Pfizer Proclaion Holdings Sarl Pfizer Proclaion Holdings Sarl Pfizer Proclaion Holdings Sarl Wyeth Ayersi Sarl * Wyeth Ayersi Sarl * Wyeth Ayersi Sarl *		Jarsey
Pfizer Laboratories Limited		Kenya
Wamer-Lambert (East Africa) Limited		Kenya
Office Limited Columns Corl	, i	Korea Luxembourg
Officer International Levemboure SA		Luxembourg
Pfizer Warner Lambert Luxambourn SARLO		Luxembourg
Pfizer Enterprises Serl (Formerly known as Pharmacia Enterprises S.A.)		Luxembourg
Pfizer Holdings International Luxembourg (PHIL) Sarl		Luxembourg
Pfizer Shareholdings intermediate Sark		Luxembourg
Pfizer Luxco Holdings Sarl		Luxembourg
Prizer Precision Holdings Sen		Luxembourg
PUNCO I manhoura Sori *		Luxembourg Luxembourg
Wyeth Ayerst Sarl *		Luxembourg
Wyeth Whitehall Sarl *		Luxembourg
Pfizer (Malaysia) Snd. Bhd.		Malaysia
Wyeth (Malaysia) SDN SHD *		Malaysia
Pharmacia & Upjohn, SA de CV (90%)		Mexico
Pfizer, S.A. de C.V.		Mexico
Pfizer Holding Mexico, S. de R.L. de C.V.		Maxico
Capsugel de Mexico, S. de R.L. de C.V.		Mexico
A S Ruffel (Mozambique) Limitada Pfizer (Namibla) (Proprietary) Limited		Mozambique Namibia
SmithKline Animal Health (SWA) (Pty) Ltd.		Namibia
	ha am a	Netherlands
Pharmacla RV	MG Audit	Nemerlands
Pfizer Holdings Netherlands B.V.	cument to which our	niptronende
Jouveinal Holland B.V.	11	Netherlands
Pfizer Asia Holdings BV	1 OCT KOM	Netherlands
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#### 31. Principal subsidiary companies (cont'd)

Legal Name Country Pfizer Global Holdings B.V. Netherlands Paris Montrouge II (Nederland) BV Pfizer OTC B.V. Netherlands Netherlands Pharmacia International BV (81%) Searle Nederland Holdings BV Pfizer Netherlands B.V. \* Netherlands Netherlands Netherlands Pfizer Neurenanos B.V. \*
Pfizer Investments Netherlands BV \*
Pfizer Pharma Holdings Cooperatief U.A. \*
Wyeth Consumer Healthcare BV \*
AHP Holdings BV \*
AHP Manufacturing BV \* Netherlands Metherlands Netherlands Netherlands Wyeth Pharmaceuticals 8V \*
Fort Dodge Animal Health Benefux BV \*
Pfizer New Zealand Limited (Formerly known as Pfizer Laboratories Limited) Netherlands Netherlands New Zealand Catapult Global Limited
Catapult Genetics (New Zealand) Limited New Zealand New Zealand Pfizer A/S (87%)
Parke, Davis & Company Limited (89%)
Pharmacia de Centroamerica S.A. Norway Pakistan Section buffores outh, and other use. Panama Prizer Corporation - New York Account
Prizer Corporation - Panama Supply Point
Prizer International Corporation - New York
Prizer International Corporation - Panama
Prizer International Corporation Reporting Branch Panama Panama Panama Panama Panama Peru Philippines Philippines Philippines Pfizer S.A. (62%) Pfizer, Inc. Roorlg Inc. Pfizer Philippines Foundation, Inc. (90%)
Fort Dodge Anima! Health Philippines, Inc. \*
Pfizer Polska S.p.z.o.o
Warner Lambert Poland Sp.z.o.o. Philippines Poland Poland Pfizer Trading Polska sp.z.o.o. Poland Laboratorios Pfizer, Ldz. (68%) Pfizer S.G.P.S. Lda. (68%) Portugal Portugal Frizer S.G.P.S. Lda. (68%)

Roerig, Produtos Farmaceuticos, Lda. (68%)

Farminova Produtos Farmaceuticos de Inovação, Lda. (68%)

Sinergis Farma-Produtos Farmaceuticos, Lda. (68%)

Carlistas - Produtos Químicos e Farmaceuticos, Lda. (68%)

Carlistas - Produtos Químicos e Farmaceuticos Lda (68%)

Farmagene Productos Farmaceuticos Lda (68%) **Portugal** Portugal Portugal Portugal Portugal Portugal Parke Davis Productos ramaceuticos tas (68%)
Uplohn Laboratorios, Lda. (68%)
Searis Laboratorios, Lda. (68%)
Parke Davis Products Farmaceuticos Lda \* (65%)
Pfizer Pharmaceuticals LLC (68%)
Wyeth-Ayerst Lederle LLC (formerly Wyeth-Ayerst Lederle, Inc.) \*
Wyeth-Whitehall Pharmaceuticals LLC \*
Wyeth-Whitehall Pharmaceuticals LLC \* Portugal Portugal Puerto Rico Puerto Rico Puerto Rico Wyeth-Whitehall Pharmaceuticals LLC \* Puerto Rico Pfizer Romania SRL Romania Pfizer LLC Russia Pfizer Afrique de l'Ouest Senegal Pfizer Asia Pacific Pte Ltd.
Pfizer Singapore Trading Pte. Ltd.
Pfizer Asia Manufacturing PTE. LTD Singapore Singapore Singapore Prizer Asia Wanufacturing PTE. LTD
Pfizer Asia Contract Operations Pte. Ltd.
Wyeth (Singapore) Pte. Ltd.
Wyeth Pharmaceuticals (Singapore) Pte. Ltd.
Wyeth Nutritionals (Singapore) Pte. Ltd.
Wyeth Regional Manufacturing (Singapore) Pte. Ltd. Singapore Singapore Singapore
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### 31. Principal subsidiary companies (contd)

Legal Name	Country
Laberatorios Parke Davis, S.L.	Spain
Davis Medica, Sociedad Limitada, Sociedad Unipersonal	Spain
Nefox Farma, S.A.	Spain
Vinci Farmá, S.A.	Spain
Fundacion Pfizer	Spain
Invicta Farma, S.A.	Spain
Nostrum Farma, S.A.	Spain
Pfizer, S.A. (60%)	Spain
BINESA 2002, S.L.	Spain
Pharmada Grupo Pfizer, SL	Spain
Kenfarma, SA	Spain
Continental Farmaceutica, St.	Spain
Pfizer Health AB (Formerly known as Pharmacle AB)	Sweden
Pfizer Expert AB (Formerly known as Pharmacia Expert AB)	Sweden
Pfizer A.Ś.	Sweden
Kommanditbolaget Hus Gron	Sweden
Prosec Forsakrings AB	Sweden
Pharmacia Holding AB	Sweden
Wyeth AB *	Sweden
Pfizer A.G (Formerly known as Warner-Lambert (Schweiz) A.G.)	Switzerland
Pfizer A.G (Formerly known as Warner-Lambert (Schweiz) A.G.) Warner-Lambert Company AG Encysive Switzerland GmbH Wyeth Pharmaceuticals AG * Pfizer Limited Capsugel (Thailand) Co., Ltd. C.C.T. (Thailand) Ltd. Pfizer Limited Pfizer Pharmaceuticals Tunisie Sarl Pfizer Tunisie SA (70%) Pfizer Rectart Limited Sirkett Warner Lambert Rac Sanayl ve Ticaret Limited Sirkett (Formerly known as Hayet Farma Rac Sanayl ve Ticaret Limited Sirkett) Pharmacla Rac Sanayl ve Ticaret Limited Sirkett	Switzerland
Encysive Switzerland GmbH	Switzerland
Wyeth Pharmaceuticals AG *	Switzerland
Pftzer Limited	Tanzania
Capsugel (Thailand) Co., Ltd.	Theiland
O.C.T. (Thelland) Ltd.	Thailand
Pfizer Limited Silver S	Thelland
Pfizer Pharmaceuticals Tunisie Sarl	Tunisla
Pfizer Tunisis SA (70%)	Tunisla
Pfizer Haclari Limited Sirketi	Turkey
Wamer Lambert Ilec Sanayl ve Ticaret Limited Sirketi	T
(Formerly known as Hayet Farma liac Sanayi ve Ticerat Limited Sirketi)	Turkey
Pharmeds liec Senayl ve Ticaret Limited Sirketi (Formenly known as Umut Farma liec Senayl ve Ticaret Limited Sirketi) Pitzer Limited Pitzer Gulf FZ-LLC *  W-L (Portugal) (38%) Encysive (UK) Limited Pharmacia Europa EEIG (50%) Cycloflutilic Limited (50%) Pharmacia-Pitzer EEIG Pitzer Europa MA EEIG Pitzer Europa MA EEIG	Wasabaas a
(Formerly known as Umut Farma Ilac Sanayl ve Tograft Limited Sirketi)	Turkey Uganda
Pfizer Gulf FZ-LLC *	United Arab
FIRST CHILD FARE CONTROL OF THE CONT	Emirates
W-L (Portugal) (88%)	United Kingdom
Encysive (UK) Limited	United Kingdom
Pharmacia Europa EEIO (50%)	United Kingdom
Cyclofluidic Limited (50%)	United Kingdom
Pharmacia-Pilzer EEIG	United Kingdom
Pfizer Europe MA EEIG	United Kingdom
Pfizor Animal Health MA EEIG	United Kingdom
MTG Divestitures Ltd. (Formerly known as Viagra Ltd. And MTG Divestitures Limited)	United Kingdom
Pfizer U.K. Group Limited	United Kingdom
Pfizer Group Limited	United Kingdom
Pfizer Limited	United Kingdom
Pfizer Technologies Limited	United Kingdom
W-L (Spain)	United Kingdom
Warner Lambert (UK) Limited	United Kingdom
W-L (Europe) (54%)	United Kingdom
Catapult Systems Limited	United Kingdom
Vlagra Ltd (Formerly known as Confectionery Limited)  Manddica Limited  KPMG Audit	United Kingdom
And the same and t	United Kingdom
Pfizer Pension Trustees Ltd. Document to which or	
Warner Lambert del Uruguay S.A.	Uruguay
Pfizer Services LLC Pfizer Venezuela, S.A. (Formerly known as Warner Lambert de Venezuela, S.A.) 7 00 2010	USA
Pfizer Venezuela, S.A. (Formerly known as Warner Lambert de Venezuela, S.A.) 1 11 2010	Venezuela
Roerig, S.A.	Venezuela
A S Ruffel (Private) Limited also refers.	Zimbabwe
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#### 31. Principal subsidiary companies (contd)

Between 1 December 2008 and 30 November 2009, the following companies were sold, dissolved, merged, or restructured:

Legal Name

Pharmacia Australia Pty Limited
Warner Lambert Pty Limited
Warner Lambert Pty Limited
Warner Lambert Pty Limited
Searle Belgium BVBA (99%)
Pfizer Distribution Services (Formerly known as Pharmacia Distribution Center NV / SA)
Klintelsto oy Heisingin Tietokuja
Substantia SAS
Encysive France SAS
Encysive France SAS
Encysive GmbH
Pfizer Laboratories Limited (99%)
Fundacion para el Desarrollo Sanitario
Maderio AG (99%)
Leema Chemicals & Cosmetics Pvt. Ltd.

Country

Australia Australia Australia Belgium Belgium Finland France France Germany Pakistan Spain Switzerland India

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### PARTNERSHIP BALANCE SHEET AS AT 30 NOVEMBER 2009

(after appropriation of results for the year)

(USD'000) Fixed assets	Note	-	
Fixed assets	Note		
Financial fixed assets	33	129,349,898	65,082,470
Current assets		•	
Receivables	34	2,436,519	8,134,024
Cash and banks		2,437,215	723 8,134,747
			0,10-1,1-17
TOTAL ASSETS		131,787,113	73,217,217
Legal reserve on participations		<u>ي</u> . 91,447	60,785
Legal reserve on R&D	•	19,813,150	6,747,742
Revaluation reserve Legal reserve on currency adjustments	, a di	251,943 6,521,309	3.876.830
Other reserves	Sould, suy	34,184,026	40,606,951
Partners Capital Accounts	red 35	60,861,875	51,292,308
Provision for subsidiaries citon let	36	3,313,552	1,661,460
TOTAL ASSETS  Legal reserve on participations Legal reserve on R&D Revaluation reserve Legal reserve on currency adjustments Other reserves  Partners Capital Accounts  Provision for subsidiaries  Current liabilities  TOTAL LIABILITIES  Consent of Consen	37	67,611,686	20,263,449
to of		**************************************	
TOTAL LIABILITIES		131,787,113	73,217,217
Cate			

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Page 62

# PARTNERSHIP STATEMENT OF INCOME FOR THE PERIOD 1 DECEMBER 2008 UNTIL 30 NOVEMBER 2009

(USD'000)	2008/ 2009	2007/ 2008
Result of C.P. Pharmaceuticals International C.V. after tax Result of subsidiaries after tax	665,000 12,429,722	283,073 10,163,612
Net profit for the period	13,094,722	10,446,685

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### NOTES TO THE PARTNERSHIP ANNUAL ACCOUNTS

#### 32. Summary of significant accounting policies

#### General

The consolidated financial statements are part of the 2009 financial statements of the Partnership. If there is no further explanation provided for the items in the balance sheet and the profit and loss account, please refer to the notes in the consolidated balance sheet and profit and loss account.

Principles for the valuation of assets and liabilities and the determination of the result

The principles for the valuation of assets and liabilities and the determination of the result are the same as those applied to the consolidated balance sheet and profit and loss account, with the exception of the following:

#### Partners Capital Account

Financial instruments are presented in the consolidated annual accounts on economic reality. In the Partnership-only financial statements, financial instruments are presented on legal form.

#### Result of subsidiaries after tax

The share in the result of subsidiaries consists of the share of the Partnership in the result of these subsidiaries. Results on transactions, with transfer of assets and liabilities between the Partnership and its subsidiaries and between subsidiaries, are not recorded insofar as these are unrealized.

The assets and liabilities are stated using the same accounting principles as disclosed in the notes to the consolidated annual accounts for the year ended 30 November 2009.

### 33. Financial fixed assets

CHECK TO THE	30 November 2009	30 November 2008
(USD'000)		2000
Participations stated at net equity	ь	654
Participations stated at cost	599,830	599,000
Subsidiaries	106,683,905	41,609,827
Long term loans to subsidiaries	22,066,163	22,872,989
	129,349,898	65.082.470

429 349,898 65,082,470

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also refers. Initials for identification purposes KPMG Accountants N.V.

### 33. Financial fixed assets (cont'd)

The movement is as follows:

	Participations	Participations	Subsidiaries	Long term	Total
	stated at net	stated at cost		loans to	
	equity	Administrative A		subsidiaries	
(USD'000)					
Beginning balance	654	599,000	41,609,827	22,872,989	65,082,470
Additions	(113)	-	51,369,321	6,931	51,376,139
Share in result	(1,564)	-	12,429,722		12,428,158
Dividends received	-	•	(1,910,104)	-	(1,910,104)
Accrued Interest	-	•	**	1,585,355	1,585,355
Repayment of loan	•	-	•	(2,399,112)	(2,399,112)
Repayment of capital		-	(518,178)	-	(518,178)
Pension effect	-	•	(794,582)	•	(794,582)
Tax effect	•	~	274,220	-	274,220
Movement of provision	-	•	1,652,092	-	1,652,092
Movement in financial					
instruments	-	-	251,943	-	251,943
Purchase Goodwill	-	-	(234,931).	-	(234,931)
Currency translation			, USE		
difference	-	_	2,644,479	-	2,644,479
Transfer to loans			·4· ~4°		
receivable	1,023	- 8	illy att.	-	1,023
Other movement		830 55 S	160 (89,904)		(89,074)
Ending balance	epideliki KISP yanga yanga nababa	589,830	106,683,905	22,068,163	129,349,898
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### 33. Financial fixed assets (cont'd)

Long term loans to subsidiaries

In 1998 a loan with a principal amount of USD 17 billion was provided to a subsidiary. The interest rate applied amounts to 4%. The loan maturity was extended to 14 January 2012, There may be repayments without premium or penalty, for all or part of the principal at any time. In October 2009, the loan increase by USD 7 million. The repayment in 2008/2009 was USD 564 million.

In July 2004 another loan with a principal amount of USD 19 billion was provided to a subsidiary. This loan matures on 13 July 2014 and the interest rate is fixed at 4.93%. The repayment in 2008/2009 was USD 971 million.

In March 2006 another loan with a principal amount of USD 11 billion was provided to a subsidiary. This loan matures on February 28 2016 and the interest rate is fixed at 8,04%. The repayment in 2008/2009 was USD 864 million.

in March 2006 another loan with a principal amount of USD 1.6 billion was provided to a subsidiary. This loan matures on 13 July 2014. No interest shall accrue on this loan. There were no repayments made during 2008/2009.

In June 2009 another loan with a principal amount of USD 60 million was provided to a subsidiary. This loan matures on 22 December 2015. No interest shall accrue on this loan. There were no repayments made during 2008/2009.

#### 34. Receivables

US DE LUBE CONTRACTOR	30 November 2009	30 November 2008
(USD'000)		
Loans receivable from subsidiaries and affiliated companies	1,488,824	6,799,166
Short term loans and investments	223,695	221,387
Other receivables and prepaid expenses	724,000	1,113,471
Cont	2,436,510	8,134,024

The majority of the receivables are due within one year.

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#### 35. Partners Capital Accounts

#### Partners and their percentage of interest

	30 November 2009	30 November 2008
	%	%
General Partners:		
Pfizer Manufacturing LLC	11.53172%	11.53172%
Pfizer Production LLC	0.36485%	0.36485%
	11.89657%	11.89657%
Limited Partners:		
Pfizer International LLC	31.07258%	31.07258%
International Affiliated Corporation LLC	22.11427%	22.11427%
Parke, Davis & Company LLC	8.56151%	8.56151%
Renrall LLC	0.00041%	0.00041%
Solinor LLC	0.37539%	0.37539%
Pfizer Inc	0.00487%	0.00487%
Warner-Lambert Company LLCPharmacia	16.63075%	16.63075%
Hepar Inc	9.34365%	9.34365%
	88.10343%	88.10343%

88.10343%	88.10343%
tot stra	
2008/ 2009	2007/2008
eurobaba Antonio in autorio galanti, la ciga regulari School antonio in anton	
51.292.308	49,361,000
	2,276,652
2,644,479	(2,529,566)
(3,743,303)	(7,363,781)
13,094,722	10,446,685
(794,582)	(373,913)
274,220	144,351
251,943	-
(1,959,104)	(669, 120)
(198,808)	-
60,861,875	51,292,308
string.	
	(3,743,303) 13,094,722 (794,582) 274,220 251,943 (1,959,104) (198,808)

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### 35. Partners Capital Accounts (contd)

The detailed movement in Partners capital accounts is as follows:

	Legal reserve on participations 2008/2009	Legal reserves on R&D 2008/2009	Revaluation reserve 2008/2009	Legal reserve on currency adjustments 2008/2009	Other reserves 2008/2009	Total partner capital accounts 2008/2009
(USD'000)						
Beginning balance	60,785	6,747,742	-	3,876,830	40,608,951	51,292,308
Additions	741	15,240,081		<b>≠</b> .	(15,240,822)	
Disposal	-	•	-	· · ·	-	
Current year						
charge	•	(2,174,673)	251,943	•	1,922,730	
Currency						
translation						
adjustments	-			2,644,479	-	2,844,479
Net result	18,970	•	_	-	13,076,762	13,094,72
Pension						
movement	-	-		<b>ي.</b>	(794,582)	(794,582
Tax movement		-	•.X	100	274,220	274,22
Goodwill recorded			dille		•	
directly to capital	-	•	14. A -	•	(1,959,104)	(1,959,104
Dividends paid	*	-	Official at	-	(3,743,303)	(3,743,303
Financial		_ جون	3 9 40		, , ,	• • •
nstrument		170° i	Ties .			
valuation		2 Direct				
adiustmants		ation set			251.943	251,94
Nrite-off of		Decomit		•		
nvestment in		inspire				
oerent stock		of Wills	-	-	(198,808)	(198,808
Other movements	10.951	·05,	_		(10,951)	(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
	6,0019	TIBARIAN TURBURE TO STATE TO S			(,,	
Ending balance	91,437	19,613,150	251,943	6.521.309	34.184.026	60,881,87
. 🕶	ANAMAN ANAMANAN ANAMAN ANAMANAN ANAMAN ANAMA	carried and a second	NACONAL CAMPAGA CO	<i>พ.พ.ศ.</i>	CHESCHOOL CHECK TO CHESCHOOL CO.	such melanatementament

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### 35. Partners Capital Accounts (cont'd)

NECTOR OF PROPERTY AND	Legal reserve	Legal reserves	Revaluation	Legal reserve on	Other reserves	Total partner
	on	on R&D	reserve	currency	2007/2008	capital accounts
	participations	2007/2008	2007/2008	adjustments		2007/2008
•	2007/2008			2007/2008		
(USD'000)						
Beginning						
balance	55,910	8,812,737	40,402	6,406,396	34,045,555	49,361,000
Additions	4,995	•	-	-	(4,995)	•
Disposals	-	(1,286,858)	-	-	1,286,858	-
Current year						
charge	-	(778,137)	(40,402)	_	818,539	-
Currency		, ,	•			
translation						
adjustments	-	-	-	(2,529,566)	-	(2,529,566)
Net result	10,048	-	-	· et v	10,436,837	10,446,685
Dividend in kind	-	-	-	Office	2,276,852	2,276,652
Pension effect	-	-	22, 92	. 8	(373,913)	(373,913)
Tax effect			201601.	-	144,351	144,351
Goodwill			Ser di			
recorded directly			HP WILL			
to capital	-	-07	5, 400	•	(669,120)	(669, 120)
Dividends paid		CLOS COLOR	jer		(7,363,781)	(7,363,781)
Other		20° 034				
movements	(10,168)	Cor itight	-	-	10,168	-
Ending balance	60,785	For Hagedion	-	3,876,830	40,606,951	51,292,308

### Lagal reserve on participating interests

This legal reserve relates to profits retained from participating interests. The legal reserve was calculated in accordance with the collective method.

#### Legal reserves on R&D

A legal reserve has been formed for the book value of capitalized research and development expenses.

#### Revaluation reserve

Revaluation reserve relates to value increase of securities available for sale that are valued at fair value. A revaluation reserve is recorded for each individual asset and is not higher than the difference between book value according to historical cost price and sold at fair value. If an asset is disposed of, the related revaluation reserve is released to profit and historical against the effective tax rate.

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Legal reserve on currency adjustments

Foreign exchange rate differences resulting from the translation of foreign operations (including group loans to foreign units) are recognised in the reserve for exchange rate differences. When an associate is disposed of, the related accumulated foreign exchange rate difference is transferred to other reserves.

#### 36. Provision for subsidiaries

CONTROL OF CHARACTER CONTROL OF C	2008/ 2009	2007/ 2008
(USD'000)		
Balance beginning of year Movement provisions for subsidiaries	1,661,460 1,652,092	3,923,130 (2,261,670)
Balance end of year	3,313,652	1,661,460

#### 37. Current liabilities

OILY, FILM	30 November 2009	30 November 2008
(USD'000)		
Accounts payable to subsidiaries and affiliated companies	67,611,348	20,263,387
Other accounts payable and accrued expenses	338	62
cot itight of	67,811,886	20,263,449

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#### 38. Tax

According to the obtained tax ruling of August 30, 2007, CPPi CV is considered transparent for Dutch tax purposes and as such not subject to Dutch corporate income tax or dividend withholding tax.

The tax ruling is valid up to and including December 31, 2011.

#### 39. Audit Fees

In 2009 KPMO Accountants N.V. received EUR 212,000 for the audit and subsequent review of CPPI CV financial statements.

In 2009 the General Partners clid not receive any remuneration.

1 October 2010

General Partners

KPMG Audit

All Partners have confirmed their approval and discharge of the GeneRat Partners which Pillstoff (), dated

- 1 OCT 2010

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#### OTHER INFORMATION

#### Provisions in the Partnership's Association Agreement for the appropriation of results

Article 14.1 of the Partnership's Association Agreement states that the profit shall be allocated to and can (subject to section 14.2) be withdrawn by the Partners pro rata to their respective Percentage Interests. Section 14 shall not apply in the event of a withdrawal of a Partner from the Partnership.

Article 14.2 Withdrawals of profits by the Partners shall be made by all (but not less than all) of the Partners and only if authorized by (i) Limited Partner(s) holding at least fifty percent (50%) of the votes allocable to the Limited Partner(s), (ii) the General Partner holding at least fifty percent (50%) of the votes allocable to the General Partner, and (iii) if there is more than one General Partner, the Central Management Board, all acting in an exercise of their good faith discretion with regard to the financial advisability of such withdrawals at the time.

Article 14.3 Losses, if any, shall first be borne by each Limited Partner separately in proportion to such Limited Partner's Percentage Interest and be deducted from the Capital Account of such Limited Partner until the amount of the Limited Partner's Capital Account is zero. Losses that remain after the application of the provision in the previous sentence shall lead to negative Capital Accounts of the General Partners who will equally divide the remaining losses.

Article 14.4 Any negative Capital Accounts of a General Pariner must have been fully restored by allocations of profits before any Partners, Limited Partners and other General Partners, are entitled to any altocations to their Capital Accounts pursuant to Section 14.1 of profits that have been gained in later financial years.

## Appropriation of results for the year

The Partnership paid dividends of USD 3.7 billion from the profits earned in 2009. Management proposes to allocate the net profit to the Partners Capital Accounts.

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#### Post-balance sheet events

There was no dividend distributed subsequent to the year end.

On May 18th 2010 Pfizer announced plans to reconfigure its worldwide plant network to create a fully aligned manufacturing and supply organization from the combined networks of Pfizer and Wyeth. The planned reductions will increase manufacturing efficiency and lower costs by more effectively using resources and technology, improving plant processes, eliminating excess capacity, and better aligning production with market demand. Pfizer plans to discontinue or reduce manufacturing operations at particular locations over the next 18 months to 5 years. These changes will result in a reduction of approximately 6,000 jobs globally. The timing of specific exits will depend upon the complexity of operations, the amount of time required for product transfers and other business requirements. In an effort to preserve jobs and minimize the impact to communities, Pfizer will explore opportunities to divest plants in the event operations are discontinued. Success will depend more upon a number of market factors including present demand for pharmaceutical manufacturing facilities. In the case of plants within the network which are owned by the CV the financial impact is currently estimated at approximately \$ 2 billion during the period 2010 to 2015.

In addition, we are expecting to initiate a consolidation project to reduce the number of existing and new US owners of the Partnership by combining ownership interests where possible, using various approaches.

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To: the partners of C.P. Pharmaceuticals International C.V.

#### Auditor's report

#### Report on the annual accounts

We have audited the accompanying annual accounts for the year ended 30 November 2009 of C.P. Pharmaceuticals International C.V., Rotterdam, which comprise the consolidated and company balance sheet as at 30 November 2009, the consolidated and company profit and loss account, the consolidated statement of recognized income and expense and the notes for the year then ended.

#### Management's responsibility

Management is responsible for the preparation and fair presentation of the annual accounts and for the preparation of the General Partners' Report, both in accordance with Part 9 of Book 2 of the Netherlands Civil Code. This responsibility includes designing, implementing and maintaining internal control relevant to the preparation and fair presentation of the annual accounts that are free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

#### Auditor's responsibility

Our responsibility is to express an opinion on the annual report based on our audit. We conducted our audit in accordance with Dutch law. This law requires that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance whether the annual accounts are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the annual accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the annual accounts, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the annual accounts in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the annual accounts.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

KPMG Accountants N.V., registered with the trade register in the Nethorlands under number 33263663, is a subsidiary of KPMG Europe LLP and a member firm of the KPMG network of independent member firms affiliated with KPMG laterational Concepting (EXPMG International). a Subsequently

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#### Opinion

In our opinion, the annual accounts give a true and fair view of the financial position of C.P. Pharmaceuticals International C.V. as at 30 November 2009, and of its result for the year then ended in accordance with Part 9 of Book 2 of the Netherlands Civil Code.

Report on other legal and regulatory requirements

Pursuant to the legal requirement under 2:393 sub 5 part f of the Netherlands Civil Code, we report, to the extent of our competence, that the General Partners' Report is consistent with the annual accounts as required by 2:391 sub 4 of the Netherlands Civil Code.

Rotterdam, 1 October 2010

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