This report has been cleared for submission to the Director, by the Programme Manager
Frank Clinton
Signed: Noeleen Keavey **Date:** 20/10/2011

epa Environmental Protection Agency
An Ghníomhaireacht um Chaomhnú Comhshaoil

OFFICE OF CLIMATE, LICENSING & RESOURCE USE

LICENSING UNIT MEMORANDUM

TO:	Laura Burke, Director, OCLR
FROM:	Noeleen Keavey
DATE:	20 October 2011
RE:	Request for the transfer of IPPC licence, Reg. No.P0395-02, from Pfizer Ireland Pharmaceuticals to Pfizer Nutritionals Ireland Limited, CRO No.393631

Background

Licence Reg. No. P0395-02 was granted to AHP Manufacturing B.V. t/a Wyeth Nutritionals Ireland on the 23 January 2004 for Class 7.2.2 – *the manufacture of dairy products where the processing capacity exceeds 50 million gallons of milk equivalent per year* and Class 2.1 – *the operation of combustion installations with a rated thermal input equal to or greater than 50 MW.* This licence was subsequently transferred to Pfizer Ireland Pharmaceuticals on 25/01/11. Pfizer Ireland Pharmaceuticals and Pfizer Nutritionals Ireland Limited, applied to the Agency on 13 September 2011, to transfer the licence to Pfizer Nutritionals Ireland Limited. According to the applicants, the basis for the transfer application is a technical change in the ownership of the facility, as part of restructuring within the wider global Pfizer operations. The transfer of licence shall allow Pfizer Nutritionals Ireland Limited to operate the installation, currently operating at Askeaton, County Limerick, under licence Reg. No. P0395-02.

The Agency is informed that Pfizer Nutritionals Ireland Limited is a limited liability company incorporated under the laws of Ireland and registered in the Companies Registration Office (Registered Number 393631). Pfizer Inc., a Delaware corporation, is the ultimate parent company of Pfizer Nutritionals Ireland Limited.

Pfizer Inc. carries on business as a research-based global biopharmaceutical company and owns a large number of affiliates and subsidiaries in a number of different countries, the number of which may change from year to year. Certain affiliates of Pfizer Inc. also carry on the business of manufacturing pharmaceutical, animal health, consumer health and nutritional products. Pfizer Inc. has total consolidated assets of $195 billion (USD) as at 31 December 2010 and consolidated net income in excess of $8.2 billion (USD) for the financial year ended 31 December 2010.

Assessment

The application was assessed under Section 94 of the Environmental Protection Agency Acts 1992 to 2011. It is deemed to comply with the requirements of the above, as follows:

Requirements of Section 94(2) and 94(3)

- The application complies with Subsection (2) having been jointly made by the current licensee and the proposed transferee.
- The application was made in the form prescribed by the Agency.
- The application was accompanied by the appropriate fee, in accordance with Article 7(a) of the EPA (Licensing Fees) Regulations 1994 to 2008.

Such information as may be required by Section 94(3)

- Any costs associated with the closure (RMP, DMP, CRAMP, etc.) of the installation have been fully detailed by the applicants and have been approved by the Office of Environmental Enforcement (OEE).
- Any costs associated with environmental event (ELRA, etc.) at the installation have been fully detailed by the applicants and have been approved by OEE.
- The transferee or any relevant person has not had an application for a licence refused.

Requirements of Section 94(5)

- Information in relation to the status of the proposed transferee as a 'Fit and Proper Person' has been provided and, based on a review of the information; the proposed transferee has no relevant convictions and has sufficient technical experience and support.
- In relation to Financial Provision, a letter of Parental Guarantee is provided for Pfizer Nutritionals Ireland Limited. This Financial Provision has been agreed with the Office of Environmental Enforcement.

Approval memo from OEE in relation to ELR/RMP & Financial Provision is attached.

Requirements of Section 94(6)

- The proposed transferee has stated in writing that they accept all liabilities, requirements and obligations provided for in or arising under the licence regardless of how and in respect of what period, including a period prior to the transfer of a licence, that may arise.

Recommendation

It is recommended that the transfer of IPPC licence Reg. No. P0395-02 from Pfizer Ireland Pharmaceuticals to Pfizer Nutritionals Ireland Limited, CRO No. **393631**, is approved under Section 94 of the Environmental Protection Agency Acts, 1992 to 2011.

Noeleen Keavey
Programme Officer
Environmental Licensing Programme

Office of
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Mr Brian Shiel
Engineering Services Manager
Pfizer Ireland Pharmaceuticals
Askeaton
County Limerick

19/10/11 Our Ref: P0395-02/AP06SMcD.docx

Dear Mr Shiel

Further to the Agency's letter of 26 August 2011, the Agency approves the proposed parent company guarantee financial provision submitted on 26 January 2011 as an initial measure. The Agency is currently reviewing the financial mechanisms used to provide for known and unknown liabilities and the suitability of parental guarantee.

The Agency also recommends that Environmental Impairment Liability Insurance is also put in place within **2 months** of the date of this letter to cover unknown liabilities in the future. Please refer, in particular to pages 47 and 48 of the *Guidance on Environmental Liability Risk Assessment, Residuals Management Plans and Financial Provision* [EPA, 2006] i.e. factors to be considered when evaluating insurance provision. The Agency should be provided with details of the insurance policy when available.

If you have any queries in relation to this, please contact the undersigned.

Yours sincerely

Kieran O'Brien

Kieran O'Brien
Programmer Manager
Office of Environmental Enforcement

Mr Brian Shiel
Engineering Services Manager
Pfizer Ireland Pharmaceuticals
Askeaton
County Limerick

26/08/11 Our Ref: P0395-02/AP05SMcD.docx

Dear Mr Shiel

I refer to your report dated 23/03/11 received by the Agency on 07/04/11 in relation to the Environmental Liabilities Risk Assessment (ELRA) and the Closure Restoration and Aftercare Management Plan (CRAMP) dated 23/03/11 received by email on 29/06/11, for Pfizer Ireland Pharmaceuticals, IPPC licence number P0395-02.

I am to advise you that the reports as submitted (regarding the technical aspects of the reports and the proposed adequacy of the costings of the financial provision) is to the satisfaction of the Agency.

The licensee should note that the proposed form of the financial provision associated with both documents will be dealt with under separate correspondence by the Agency.

Agreement by the Agency of the ELRA/CRAMP costings does not constitute an acceptance on the part of the Agency that the ELRA/CRAMP costings constitute a description of all potential risks or liabilities or costs that may arise or materialise in relation to the facility but, rather, constitute in the view of the Agency as of 26/08/11 a general assessment of risk and general estimate of costs to inform the overall environmental management and understanding of the licensed site and the putting in place of FP etc.

Where additional costs arise relating to prevention or remediation of environmental pollution, these remain the responsibility of the Licensee. Notwithstanding the ELRA and proposed financial provision, the EPA will only accept a surrender of a Licence once satisfied that all steps, including all necessary expenditures, have been taken to ensure that the site no longer poses a threat of environmental pollution etc.

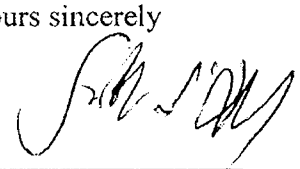
Note on the next review of the CRAMP:

- Clarify whether the costs in Table 5.1.5.1 and 5.1.5.2 cover both disposal and transport costs; Table 5.1.5.2 references 'transport costs only' despite the text stating the costs being for disposal and/or transport and disposal.

- Sections of the plan relating to the liquid wastes being sent to the onsite wastewater treatment plant including page 27 relating to the compliance monitoring of the effluent, should stipulate that only wastes suitable for the wastewater treatment plant will be sent to same and the controlled drip-feed will be conducted in such a manner which will ensure the full compliance of the final treated effluent against the ELVs for the duration of the decommissioning period.

- Clarify whether provision for site security has been provided for in the decommissioning stage.

Yours sincerely



Siobhán McDonnell, Inspector
Office of Environmental Enforcement