OFFICE OF CLIMATE CHANGE, LICENSING & RESOURCE USE

INSPECTORS REPORT ON A LICENCE APPLICATION

To:	Directors
From:	Patrick Byrne **- LICENSING UNIT**
Date:	21ST NOVEMBER 2007
RE:	Application for an IPPC Licence from TopChem Pharmaceuticals Limited, Licence Register P0828-01

Application Details	
Class of activity:	5.16: The use of a chemical or biological process for the production of basic pharmaceutical products.
Licence application received:	14/06/07
Notices under Article 11(2)(b)(ii) issued:	09/08/07, 22/10/07
Information under Article 11(2)(b)(ii) received:	21/09/07, 30/10/07
Notice under Article 8(b):	09/08/07
Response under Article 8(b) received:	21/09/07
Submissions received:	None
Site notice inspected:	07/08/07
Site visits:	07/08/07

Company

Topchem Pharmaceuticals Limited (Topchem) have established a pharmaceutical production facility within two industrial units (c. 5000sq feet) in Ballymote Business Park, Ballymote Co Sligo. The premises were built by Ballymote Community Enterprise Limited on a green field site and have been leased to Topchem. Topchem is a subsidiary of Dublin based TopChem Laboratories Limited, a contract research organisation established in 2000. Topchem Laboratories Limited has an established customer base in Ireland, EU and the US.

Planning permission was granted for the construction of industrial units in 1999, further planning permission was granted in 2006 for alterations to two industrial units to form one unit. Topchem informed Sligo County Council of the proposed

use of the industrial units for the production of low volume pharmaceutical and medical products in accordance with condition 1 of the original planning permission granted. Sligo County Council, Planning Section, confirmed in writing to Topchem that the details submitted were acceptable. No EIS was required to support the planning applications.

Operating hours on-site will generally be 08:00 to 18:30, with overtime possible extending until 23:00. Currently six people are employed on-site with a projection of ten by the end of 2007.

To date the company have installed additional fixtures and fittings plus room modifications as part of Phase 2 fit out for the installation. The company have not yet commenced production of pharmaceutical ingredients. The company will be involved in the manufacture of low volume active pharmaceutical ingredients. The first active ingredient to be manufactured will be "Malathion" which will then be formulated by their customer for the treatment of head lice infestation.

The manufacture process proposed will be performed on a laboratory scale within fume hoods. Batch size will be c.2kg using batch reactors of a maximum size of 20 litres.

Process Description

The installation consists of the following areas, production laboratory area, QC/development laboratory area, stores area, administration area, and canteen and services. The production laboratory area consists of two walk in fume hoods each two meters wide and ducted to atmosphere, material handling booth and associated gowning area. The QC/development laboratory holds analytical equipment and there are two walk in fume hoods each two meters wide and ducted to atmosphere.

The production process proposed will use a maximum reaction vessel of 20 litres in capacity. Annual output of active ingredient is not predicted to exceed 40 kilograms per annum.

Malathion is the first product which will be manufacturer on-site. Further products will be developed and manufactured on-site in the future based on customer contracts. It is proposed that prior notice and approval for the manufacture of other products will be sough from the EPA under the RD.

The production of "malathion" shall take place in laboratory scale vessels and distillation columns. The main processes involved in the production process are mixing, heating and distillation. Emissions associated with these processes include emissions to atmosphere, and the generation of aqueous and solvent wastes.

Emissions

Due to the nature and scale of the proposed activity emissions to atmosphere are limited to minor emissions, and aqueous and solvent wastes are collected and sent for hazardous waste disposal/recovery off-site

Air

The production emissions to air are from the fume hood extractors. The emissions from the fume hoods are limited to the breathing losses from the production vessels, transfer of solvents. Emissions from the fume hoods are expected to occur irregularly. The scale of the emissions are predicted to be significantly below emission limit values specified in BREF, solvents directive, or TA Luft. Estimates submitted by the applicant based on annual usage of solvents and the predicted losses would indicate an emission of less than 0.01kg/hour.

In addition there are emissions from the fume hoods in the QC/development laboratory, these again are considered minor and emissions will be intermittent.

The emissions above are all considered minor. There are no boilers on-site, as all space heating is provided by electricity. Odour emissions are not considered likely to cause a nuisance due to the scale and nature of the activity.

The RD requires the licensee to monitor solvent usage by annual mass balance reports, an example of the methodology which may be used is described in Schedule 6 of the Solvents Regulations S.I. 543 of 2002, this can also be used to establish the fugitive emissions from the activity.

The RD requires the licensee to provide notification and an assessment of emissions associated with any change in active pharmaceutical ingredient production. New active pharmaceutical ingredients shall not be produced until the licensee has received Agency agreement.

Emissions to Sewer

No process emissions are discharged to sewer. All liquid wastes are collected, stored on site and sent for appropriate disposal/recovery off-site. Sanitary effluent is discharged to sewer.

Emissions to Waters

There are no process emissions discharged to surface water.

Surface Water

The only emission to surface water is the rainwater falling on the surrounding yard/car park and building roof. The surface water is not likely to be contaminated as all activities are undertaken within the building and the quantities of materials and waste delivered to and taken from the installation are small. All chemicals and liquid wastes stored on-site shall be bunded.

Emissions to ground

There are no emissions to ground associated with the activity.

Waste

Production wastes (including aqueous and solvent wastes, packaging etc.) generated on-site shall be classified and sent off site for disposal/recovery at appropriate facilities. There shall be no waste recovery/disposal proposed on-site.

Noise

Ballymote Business Park is a purpose built development of industrial units. The park is located on the outskirts of Ballymote and adjacent to the railway station. Topchem are the first tenants to move into the business park. The nature of the activity is not likely to generate noises which would be audible outside the building.

Use of Resources

The main resource used on-site shall be electricity for heating, operation of fans etc. Water shall be supplied from the local mains supply. The applicant identified that dichloromethane would be used in the production of Malathion however they have since clarified in further information that it will not be used on-site. The applicant has identified that a catalyst and the final product are "very toxic to aquatic organisms" however the quantities handled by the activity are very small and they should not come in contact with the aquatic environment.

Compliance with EU Directives

IPPC Directive (91/61/EC)

This installation falls within the scope of category 4.5 (Installations using a chemical or biological process for the production of basic pharmaceutical products) of Annex I of Council Directive 96/61/EC concerning integrated pollution prevention and control.

As a new activity the IPPC Directive requires that the competent authority take account of the general principles set out in Article 3 when determining the conditions of a permit. The Proposed Determination (PD) as drafted takes account of the requirements of the Directive. BAT is taken to be represented by the guidance given in the draft BAT Guidance Note on Best Available Techniques for Pharmaceutical and other Speciality Organic Chemicals (Final Draft August 2007)

Best Available Techniques (BAT)

I have examined and assessed the application documentation and I am satisfied that the site, technologies and techniques specified in the application and as confirmed, modified or specified in the attached Recommended Determination comply with the requirements and principles of BAT. I consider the technologies and techniques as described in the application, in this report, and in the RD, to be the most effective in achieving a high general level of protection of the environment having regard - as may be relevant - to the way the installation is located, designed, built, managed, maintained, operated and decommissioned.

Fit & Proper Person Assessment

The Fit & Proper Person test requires three elements of examination, technical ability; legal standing; and financial standing.

It is my view, and having regard to the provisions of Section 84(5) of the EPA Acts and the Conditions of the RD, that the applicant can be deemed a Fit & Proper Person for the purpose of this licence.

Submissions

No submissions were received in relation to the licence application.

Recommended Determination (RD)

Prior to the commencement of production of another active ingredient the applicant shall request Agency approval, establish that the new production process does not result in a minor emission point becoming a major emission point. The RD gives effect to the requirements of the POE Act 2003.

Charges

The annual charge proposed in the RD is €4,680, this annual charge is considered appropriate to cover the cost of enforcing the proposed activity.

Recommendation

In preparing this report and the Recommended Determination I have consulted with Agency technical and sectoral advisor Ms Marie O Connor. I recommend that a Proposed Determination be issued subject to the conditions and for the reasons as drafted in the RD.

Signed

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Patrick Byrne

Procedural Note

In the event that no objections are received to the Proposed Determination of the application, a licence will be granted in accordance with Section 87(4) of the Environmental Protection Agency Acts 1992 and 2003 as soon as may be after the expiration of the appropriate period.