



**OFFICE OF CLIMATE,
LICENSING & RESOURCE
USE**

**REPORT OF THE TECHNICAL COMMITTEE ON
OBJECTIONS TO LICENCE CONDITIONS**

TO:	Directors	
FROM:	Technical Committee	- LICENSING UNIT
DATE:	18 th January 2008	
RE:	Objection to Proposed Determination for TopChem Pharmaceuticals Limited, IPPC Reg: P0828-01	

Application Details	
Class of activity:	5.16: The use of a chemical or biological process for the production of basic pharmaceutical products.
Location of activity:	Ballymote Business Park, Carrownanty, Ballymote, County Sligo
Licence application received:	14/06/07
PD issued:	29/11/07
First party objection received:	04/01/08
Third Party Objection received	None

Company

TopChem Pharmaceuticals Limited, proposes to develop a pharmaceutical production facility in Ballymote Business Park, Carrownanty, Ballymote, County Sligo. 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, at another site, for the treatment of head lice infestation.

The manufacturing process proposed will be performed on a laboratory scale within fume hoods.

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 projective staff number of ten.

Consideration of the Objection

The Technical Committee, comprising of Ann Marie Donlon (Chair) and Maeve Mc Hugh, has considered all of the issues raised in the Objections and this report details the Committee’s comments and recommendations following the examination of the objections together with discussions with the inspector, Patrick Byrne, who also provided comments on the points raised.

This report considers the first party objection.

First Party Objection

The applicant state they cannot comply with six conditions and object to one other condition.

A.1. Condition 2.2.2.2

The applicant objects to the condition as it sets out very clear targets for waste reduction and minimization which will be difficult to achieve until routine production on Malathion and other products (as they come on stream) is achieved. The applicant seeks advice on Agency expectations.

Technical Committee's Evaluation:

Condition 2.2.2.2 requires the preparation and maintenance of a Schedule of Environmental Objectives and Targets to be addressed over a five-year period as a minimum. The condition indicates the aspects of the activity to be considered in the preparation of the Schedule such as waste minimisation. This long-term strategy to ensure that there are clear environmental goals within the organisation. It provides for continual improvement at the installation and is considered BAT. Further guidance is given in the EPA Guidance Note for Annual Environmental Report.

Recommendation: No change.

A.2. Condition 3.3

The applicant objects to this condition as it requires installation of sampling points or equipment including data-logging equipment on all emission points. However, as per Schedule C, no such monitoring is required. Therefore the applicant cannot comply with this Condition.

Technical Committee's Evaluation:

The TC is satisfied that there are no sampling points or monitoring requirement required at this installation. The TC considers that the requirements should be removed from the licence.

Recommendation:

Delete Condition 3.3 and renumber Condition 3 accordingly.

A.3. Condition 3.4

The applicant objects to this condition, as it requires labelling and provision of safe and permanent access to all on-site sampling and monitoring points. However, as per Schedule C, no such monitoring is required. Therefore the applicant cannot comply with this Condition.

Technical Committee's Evaluation:

The TC is satisfied that in these circumstances of laboratory scale operations with no monitoring requirements for emissions to air, water or sewer and a limited noise monitoring requirement, the condition requiring the provision of safe and permanent access to monitoring points is not relevant.

Recommendation:

Delete Condition 3.4 and renumber Condition 3 accordingly.

A.4. Condition 3.8

The applicant objects to this condition as it requires the provision of a catchment system for leaks from flanges, valves and overground pipes used to transport materials other than water. No such pipes, valves or flanges exist on-site. Therefore the applicant cannot comply with this Condition.

Technical Committee's Evaluation:

The TC note that production equipment includes vessels and distillation columns. At an installation of this nature, with no emission limit values and no monitoring requirements, that main consideration is containment of materials. Flanges, valves and pipes are used at all scales of operations and appropriate measures should be taken. The condition requires the applicant to examine the provision of catchment systems. The TC consider that this condition is a significant control in the protection of the environment from the carrying on of the activity at all scales. As a laboratory scale operation, the building itself will act as a catchment system.

Recommendation: No change.

A.5. Condition 6.3

The applicant objects to this condition as it requires all automatic monitors and samplers shall be functioning. There are no automatic monitors and samplers required. Therefore the applicant cannot comply with this Condition.

Technical Committee's Evaluation:

The TC is satisfied that there are no automatic monitors and samplers required at this installation. The TC considers that the requirements should be removed from a licence.

Recommendation:

Delete Condition 6.3 and renumber Condition 6 accordingly.

A.6. Condition 6.10

The applicant objects to this condition as it requires weekly inspection of all flanges and valves on over-ground pipes. As no such pipes or flanges exist on-site, the applicant cannot comply with this Condition.

Technical Committee's Evaluation:

In line with the considerations of A.4 above, the TC is satisfied that inspection of equipment integrity on a weekly basis provides for the protection of the environment.

Recommendation: No change.

A.7. Condition 6.14

The applicant objects to this condition that requires the establishment of a Data Management System as there are no monitoring requirements specified in Schedule C.

Technical Committee's Evaluation:

The TC notes requirements for a Solvent Management Plan, Pollutant Release and Transfer Register and waste monitoring. The data generated under these requirements and others must be managed in a coherent manner. A data management system can be tailored to the specific circumstances of the installation.

Recommendation: No change.

Overall Recommendation

It is recommended that the Board of the Agency grant a licence to the applicant

- (i) for the reasons outlined in the proposed determination and
- (ii) subject to the conditions and reasons for same in the Proposed Determination,
and
- (iii) subject to the amendments proposed in this report.

Signed

Ann Marie Donlon

for and on behalf of the Technical Committee