Environmental Protection Agency An Ghníomhaireacht um Chaomhnú Comhshaoil	**OFFICE OF LICENSING & GUIDANCE**

INSPECTOR'S REPORT ON A LICENCE APPLICATION

To:	Directors	
From:	Emer Cooney	**- Licensing Unit**
Date:		
RE:	Application for an IPPC Licence Review from Swords Laboratories, Licence Register P0014-04	

Application Details	
Class of activity:	Class 5.6 The manufacture of pharmaceutical products and their intermediates. Class 5.16 The use of a chemical process for the production of basic pharmaceutical products. Class 11.1 The recovery of waste in a facility, within the meaning of the Act of 1996, which facility is connected or associated with another activity specified in this Schedule in respect of which a licence or revised licence under Part IV is in force.
Licence application received:	29 September 2006
Further information requests issued:	27 October 2006, 26 January 2007
Further information requested received:	6 December 2006, 27 February 2007
Submissions received:	One
Site visits:	15 August 2006

Company

Swords Laboratories, a subsidiary of Bristol Myers Squibb (BMS), is based in Swords, Co. Dublin. It specialises in the manufacture of bulk pharmaceutical intermediates and products, including drugs for the treatment of cancer, hypertension and HIV. Bulk products are shipped to other BMS finishing plants.

The manufacturing installation includes four large-scale manufacturing plants, two small-scale manufacturing plants and a high containment plant. Support services include a wastewater treatment plant, solvent recovery unit and thermal oxidiser (TO).

The site operates 24 hours a day, seven days a week and employs approximately 400 staff.

Reason for Review

- To incorporate the amendments to the licensing provisions of the Environmental Protection Agency Acts 1992 and 2003, as appropriate.
- To incorporate Class 11.1 for the solvent recovery unit.

Emissions

Air:

There are no new main emissions to atmosphere since the issue of the current licence Reg. No. P0014-03 in April 2000. Dispersion modelling was last carried out for the site in 2004 and the results of this modelling remain valid for the current activities. This modelling demonstrated that the impacts of the air emissions from the installation are in compliance with Air Quality Standards. Three previously licensed vents (1, 5 & 47) are now no longer in existence and have been removed from the Schedules of the RD.

All emission limit values (ELVs) for emissions to atmosphere, as licensed in licence Reg. No. P0014-03, are in compliance with BAT, with the exception of HCl emissions from the thermal oxidiser. The licensee is proposing to meet the TA Luft 2002 ELV of 30 mg/m^3. Air dispersion modelling has demonstrated that the impact of the current ELV of 60 mg/m^3 does not cause a breach of air quality standards. The licensee has reviewed HCl emissions for the past three years and states that the installation of condensers has reduced HCl emissions and that further actions can be taken if required to meet the ELV.

All main emissions to atmosphere are normally ducted to the TO. Condition 2.2.2.2 requires the licensee to address the minimisation of TO bypass events. In the event of a TO bypass, the following requirements of the RD apply:

- Condition 6.13 requires that the solvent recovery unit ceases operation after one hour;
- Condition 12.1 requires the licensee to notify the Agency of the bypass;
- Schedule C.1.2 requires the licensee to monitor emissions from all other main emissions if the duration of the bypass exceeds 24 hours. Schedule B.1 contains ELVs for each of the main emission points.

The use of a thermal oxidiser for the treatment of waste gases is considered BAT.
Due to excess capacity, the licensee is to replace the TO combustor with a smaller model. This proposal was approved by the OEE inspector (Ref: P0014-03/ap22PK), subject to a test programme. Condition 6.1 requires that a test programme on the new TO combustor be carried out within three months of the date of commencement of operation of the new unit.
The licensee has also proposed to operate the TO at a reduced temperature of 980°C. Condition 6.12 requires the licensee to submit a Standard Operating Procedure and a report to the Agency on the methodology to be used in the determination and control of the halogenated content of the waste gases being ducted to the thermal oxidiser. Schedule B.1 of the RD requires the licensee to operate the thermal oxidiser at a minimum temperature of 1100°C until such time as the Agency agrees in writing with the SOP proposed.

Odour:

The Agency received 27 complaints in 2006 in relation to Swords Laboratories, 24 of which related to odour. Residential dwellings are located adjacent to the site. The two main sources of odour have been the wastewater treatment plant and leaks and spills of chemicals. A biofilter was installed at the wastewater treatment plant in order to abate odours from the wastewater treatment plant. Air from the wastewater treatment plant can also be diverted to the TO if odour is detected or if the biofilter malfunctions. The following measures have been included in the RD:

- Condition 5.2 states that odour from the site shall not interfere with amenities or impair the local environment.

- Conditions 6.14.1 and 6.14.2 require the licensee to carry out three odour patrols per day and to maintain records of these patrols.
- Condition 6.14.3 requires the licensee to treat the detection of odour off-site by an odour patrol or the receipt of an odour complaint as an incident. An incident must be dealt with in accordance with Condition 9.3, which contains requirements on investigation, reporting, remedial measures and preventive action.
- Condition 6.1 requires the licensee to carry out a test programme on the biofilter to ensure its efficient operation;
- Condition 8.9 requires the licensee to ensure that all containers used for storage of wastes/materials are sound and that they are regularly inspected for leaks and weathering. Condition 12.13 requires the licensee to maintain a record of such inspections.
- Schedule C.1.1 contains requirements for the operation and control of the biofilter.

Emissions to Sewer:
The licensee is seeking to increase the discharge volume limits for the emission to sewer from 500m^3/day to 600m^3/day. This is due to:

- The treatment of groundwater in the WWTP; and
- Anticipated increases in manufacturing capacity.

This increase has been agreed by the Sanitary Authority. In addition, Fingal County Council has specified a number of additional emission limit values and monitoring requirements. This includes limit values for certain substances to ensure compliance with the Water Quality (Dangerous Substances) Regulations, 2001. The RD contains all the requirements of the Fingal County Council Section 99E consent, with the exception of the following additional consent condition:

- "Best available technology (BAT) for the relevant activity (Manufacture of Pharmaceutical products and their intermediates) shall be used to prevent, minimise, manage and treat pollutants in the wastewater stream discharging to foul sewer under this consent".

The Agency considers that the installation satisfies BAT, as confirmed under the section of this report entitled "Best Available Techniques (BAT)". Therefore the RD does not recommend the inclusion of this specific condition. However, Condition 2.2.2.2 requires the licensee to maintain a Schedule of Environmental Objectives and Targets under the Environmental Management Programme which shall provide for an evaluation of practicable options for resource efficiency, the use of cleaner technology and cleaner production.

Surface Water:
Surface water from low-risk manufacturing areas of the site drains to a collection tank. This tank discharges to the River Ward on a batch basis. The licensee has proposed a system of sampling and analysis of the water in the tank prior to release. These requirements are contained in Schedule C.2.3 of the RD. Condition 6.16.5 of the RD requires a procedure to be put in place to manage this discharge. Other surface water run-off from roofs, car-parks and clean yards leaves the site at six different points which are monitored as per Schedule C.2.3.

Ground and Groundwater:
There are no emissions to ground. However, groundwater contamination has been a long-standing issue on this site. Licence Reg. No. P0014-01 issued on 18/12/95 required the licensee to identify and isolate sources of contamination and carry out a programme of remediation. Works carried out on the site to date include investigations, drilling and sampling of boreholes, installation of a groundwater barrier to prevent contaminated groundwater entering the Ward River, pumping of groundwater to the wastewater treatment plant and relocation of chemical storage tanks from an underground vault to an overground

location. In addition, both the current licence and the RD require the licensee to carry out the following:

- Monitoring of the remaining underground solvent storage tank vaults for any leakage of stored materials or contamination by stored materials of rainwater/water condensate accumulations within the vaults.
- Monitoring of the water quality of the Ward River.

The contamination was thought to be confined to the perched aquifer under the site until 2006 when three wells were drilled into the bedrock aquifer where further contamination was discovered. Condition 10 requires the preparation and execution of a Contaminated Land Investigation, Assessment and Remediation Plan (CLIARP) in order to identify the sources of the contamination and to set and achieve clean-up targets; the aim being that the contamination in the soils and subsoils shall no longer represent a pollution risk to groundwater and surface waters in the area. The licensee is also required to have regard to the requirements of the CLIARP when preparing the Residuals Management Plan for the site.

Waste:

There are no changes to wastes generated on the site as a result of this review. Swords Labs has requested that the frequency of analysis of drummed waste solvent be changed from analysis per disposal batch to analysis per process batch as processes are consistent which results in consistent waste composition. The waste monitoring table in the RD (Schedule C.4) has been amended to reflect this. The solvent recovery unit has been in operation since 2001 and requires licensing under Class 11.1.

Noise:

Licence Reg. No. P0014-03 required a 6 dB(A) reduction in noise levels over a six-year period. The applicant is now complying with a day-time limit of 55 dB(A) L_{Aeq}. The most recent noise survey recorded night-time noise levels of 47 dB(A) L_{Aeq} and 45 dB(A) L_{A90}. The applicant states that traffic noise levels contribute significantly to noise levels.

While the L_{Aeq} records all noise at the monitoring location (including any offsite noise) the operator carrying out the monitoring should be able to clearly comment on the extent of the offsite noise. If there is only a small amount of intermittent offsite noise, e.g. occasional offsite traffic, then the effects of this can be removed during monitoring by pausing the monitoring equipment whenever an offsite noise event occurs, so the L_{Aeq} should accurately reflect the noise from the installation. If there is a significant difference between the L_{Aeq} and the L_{A90} the licensee should be able to clearly set out the reason why in their monitoring report. The limit value only refers to emissions from the installation, so if the L_{Aeq} is exceeded and the licensee can clearly demonstrate that this is attributable to noise from outside the installation, then this would not constitute a non-compliance. Therefore, L_{Aeq} remains the parameter against which compliance is assessed and the RD specifies noise limits of 55 dB(A) L_{Aeq} for daytime and 45 dB(A) L_{Aeq} for night-time.

Annual Use of Resources

Natural Gas: 3,999,868 m^3.
Electricity: 35.05 MWhr
Water: 264,460 m^3.

An energy audit was carried out at the site in 2003 and a number of energy saving measures have been implemented. Condition 7.3 of the RD requires the licensee to implement the opportunities for energy use reduction and efficiency identified in that energy audit and to incorporate the recommendations of the audit into the Schedule of Environmental Objectives and Targets.

Compliance with EU Directives

IPPC Directive

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.

This Directive has been transposed into Irish law by the enactment of the Protection of the Environment Act, 2003 (POE Act). The Recommended Determination (RD), as drafted, takes account of the requirements of the POE Act. In particular, Condition 7 provides conditions dealing with water, energy and raw materials use, reduction and efficiency on site. Conditions 9 and 11 deal with accidents, emergency response, decommissioning and residuals management at the installation. BAT is taken to be represented by the technologies described in the *IPPC Reference Document on Best Available Techniques in the Common Waste Water and Waste Gas Treatment/Management Systems in the Chemical Sector* and the technologies and emission limit values in the *BATNEEC Guidance Note for the Chemical Sector* and Technical Instruction on Air Quality Control (T.A. Luft) 2002.

Council Directive 1999/13/EC-Solvents Directive

The processes carried out do not fall within the scope of EU Council Directive 1999/13/EC on the limitation of emission of volatile organic compounds due to the use of organic solvents in certain activities and installations.

European Communities (Control of Major Accident Hazards involving Dangerous Substances) Regulations, 2006 (S.I. No. 74 of 2006)

This site has been classified as a lower tier site under S.I. No. 74 of 2006. The National Authority for Occupational Safety and Health (NAOSH) is the competent authority responsible for administration and enforcement of these regulations.

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 Decision 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 applicant's experience, technical abilities, financial and legal standing would qualify them as Fit & Proper Persons.

Compliance Record:

The Agency issued five non-compliances to Swords Laboratories in 2006, which related to non-notification of incidents, odours and emission limit value exceedances.

The main issues identified in the enforcement of the existing licence are as follows:

- Exceedances of volume flow limit for discharge to sewer – the licensee has sought a higher limit (600 m^3/day vs. previous limit of 500 m^3/day) in order to rectify this issue. The higher daily volumetric limit has been included in the RD subject to the conditions specified in the Section 99E response received from Fingal County Council. This issue is dealt with in the Section of this report entitled "Emissions to Sewer".

- Odour – this issue is dealt with in the section of this report entitled “Odour”.
- Groundwater contamination - this issue is dealt with in the section of this report entitled “Ground and Groundwater”.

Complaints:
The Agency received 27 complaints in 2006 in relation to this installation. 24 of these related to odour. This issue is dealt with in the section of this report entitled “Odour”.

Submissions:
One submission was received from the Health Service Executive (HSE) on 13 December 2006. The submission relates to a particular waste stream (acid chloride residue) which was being treated in the on-site wastewater treatment plant. This waste stream was identified by the licensee as the source of odour which was the subject of complaints received by the HSE. The waste stream is now tankered off-site for treatment. The HSE request that the licence contain a condition requiring the waste stream to be treated off-site.

Response: Condition 5.3.8 of the RD specifies that the acid chloride residue waste stream shall not be treated in the on-site wastewater treatment plant.

Charges:
The invoiced charge for 2006 was €27,952.80. The proposed charge in the RD is €30,545. The proposed charge reflects the significant enforcement effort required for this installation.

Recommendation:
I recommend that the Proposed Determination be issued subject to the conditions and for the reasons as drafted.

Signed

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Emer Cooney

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.