



## OFFICE OF LICENSING & GUIDANCE

### INSPECTORS REPORT ON A LICENCE APPLICATION

**To:** DIRECTORS

**From:** STUART HUSKISSON **- LICENSING UNIT**

**Date:** 25<sup>TH</sup> APRIL 2007

**RE:** IPPC LICENCE REVIEW APPLICATION FOR SWORDS LABORATORIES T/A BRISTOL-MYERS SQUIBB CRUISERATH, MULHUDDART, DUBLIN 15 (CURRENT LICENCE REGISTER NO. P0552-01).

LICENCE REGISTER NO. P0552-02

#### Application Details

Class of activity:	5.6 - The manufacture of pharmaceutical products and their intermediates, not included in paragraphs 5.12 to 5.17. 5.16 - The use of a chemical or biological process for the production of basic pharmaceutical products. 11.1 - The recovery or disposal 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 or in respect of which a licence under the said Part is or will be required.
Licence application received:	31 <sup>st</sup> October 2006
Notices under Article 17 issued:	15 <sup>th</sup> December 2006
Information under Article 17 received:	01 <sup>st</sup> February 2007, 08 <sup>th</sup> March 2007
Supplementary material submitted by applicant	None
Submissions received:	14 <sup>th</sup> February 2007 - Fingal County Council
Site Inspection:	12 <sup>th</sup> December 2006

### 1. Company

Bristol-Myers Squibb (BMS) Cruiserath operate a bulk pharmaceutical manufacturing installation at Cruiserath, Mulhuddart, Dublin 15. The installation is run in close co-ordination with another BMS plant - Swords Laboratories based at Swords, Co. Dublin (Reg. No. P0014-04). The installation at Cruiserath is a multipurpose manufacturing plant capable of producing a range of pharmaceutical intermediates and final active ingredient products. The only product currently manufactured at the Cruiserath site is *Irbesartan* – a member of a group of medicines known as Angiotensin II Receptor Antagonists (AIIRAs) used mostly in the treatment of hypertension (high blood pressure). The manufactured bulk active materials are shipped to BMS formulation plants worldwide where the finished formulation is made into a tablet, capsule or injectable form.

The plant was originally licensed in October 2000 (IPPC licence Reg. No.P0552-01) and commenced manufacturing operations in 2003. The installation runs 7 days per week, 24 hours per day, 365 days per year and currently has approximately 165 employees.

There is one Liquid Vapour Incinerator (LVI) on-site. The LVI handles the waste gases/vapours and residual aqueous/solvent waste generated from the on-site processes and specific solvent/aqueous wastes from Swords Laboratories (IPPC licence Reg. No. P0014-04). The amount of waste solvent generated is minimised as far as practicable through the operation of solvent recovery on-site. Solvent recovery is a Class 11.1 waste recovery activity.

Fingal County Council granted planning permission for the site development in September 1999 (PL F99A/0871) and an Environmental Impact Statement (EIS) was submitted and assessed as part of the original licence application (Reg. No. P0552-01). Subsequently, planning permissions have been granted for; minor modifications to the main planning application (F00A/1140), minor layout modifications (F04A/1527), erection of a Pressure Swing Adsorption (PSA) Nitrogen Building (F04A/1119), and erection of a two-storey production building extension to house a filter dryer (F05A/0550).

In July 2006 BMS were granted advanced planning (10 year permission) for a new manufacturing installation with associated utilities within the site boundary of the installation (F06A/0739). The additional development (F06A/0739) will include a three-storey production/warehouse building, a two-storey office and laboratory building, water treatment building and associated site development works. The proposed installation will be constructed on an undeveloped area of the c.160 acre site. An EIS accompanied this planning application. The additional activities/processes within the EIS have not been applied for as part of this review application and therefore do not form part of this licence review. It is noted that a licence review will be required prior to the commencement of the activities included within the planning application F06A/0739. The EIS will be assessed as part of such a licence review. The Agency has so notified the applicant.

### **Reason for Licence Review**

This licence review addresses the changes proposed by BMS concerning the operation of the on-site incinerator, compliance with EC Directive 2000/76/EC on the Incineration of Waste, minor operational modifications and amendment to the licensing provisions of the EPA Acts 1992 and 2003, as appropriate.

## **2. Process Description**

The installation operates standard pharmaceutical manufacturing operations including reaction, separation, crystallisation, purification, milling, drying and solvent recovery.

Solvent recovery units (distillation) are used to recover and subsequently re-use solvent on-site, where possible. Solvent, which cannot be recycled, is incinerated on-site and the heat is recovered by generating steam.

There is one incinerator on-site. Wastewater from the cleaning of exhaust gases discharged from the incinerator is treated in a separate dedicated wastewater treatment plant (WWTP) prior to entering the Fingal County Council sewer. Water used in production is treated in the company's process effluent WWTP. This WWTP is fully enclosed and the air used in the treatment of wastewater is subsequently treated in the incinerator.

## **3. Recommended Determination**

### **3.1 Emissions to Atmosphere:**

BMS currently operate a Liquid Vapour Incinerator (LVI) under their existing licence (Reg. No. P0552-01) at a minimum operating temperature of 1,100°C with a minimum 2 seconds residence time.

The Recommended Determination (RD) allows BSM to operate the LVI under two modes of operation (i) to incinerate hazardous liquid/aqueous and gases/vapour waste streams at a minimum operating temperature of 1,100°C with a minimum 2 seconds residence time, and (ii) to incinerate solvent/aqueous wastes with <1% halogenated organic substances content and waste gases/vapours

with <1% halogenated organic substances content, at a minimum operating temperature of 850°C with a minimum 2 seconds residence time, subject to a test programme.

BMS requested this change to reduce the duration of running the LVI at 1,100°C and minimise the requirement for auxiliary fuel. This operational change will reduce auxiliary fuel use by approximately 10%.

The licensee provided a worst-case calculation of the halogenated organic substances concentration of the waste gas flow to the incinerator. The calculation predicts a maximum concentration of 0.43% halogenated organic substance as chlorine.

The waste feed to the incinerator is limited to waste liquid solvents, aqueous wastes and vapours/gases generated on site and waste liquid solvents and aqueous wastes imported from Swords Laboratories Installation (IPPC licence Reg. No. P0014-04).

BMS requested that the emission limit value (ELV) for nitrogen oxides as NO<sub>2</sub> from the incinerator be increased from 100mg/m<sup>3</sup> to 200mg/m<sup>3</sup>. The higher nitrogen oxides ELV is allowed for under the Incineration of Waste Directive (2000/76/EC). BSM state that the increased nitrogen oxides ELV will reduce the ammonia additions, by 18 tonnes per annum, for selective catalytic reduction (SCR) currently required to meet the 100mg/m<sup>3</sup> ELV. BMS completed air dispersion modelling of the proposed increased NO<sub>2</sub> emissions, using AERMOD with meteorological data from Birr, County Offaly and supplemented by cloud cover data from Casement meteorology station for the years 2001-2005 inclusive, to determine the maximum predicted ground level concentration. The model was run using the continuous maximum NO<sub>2</sub> emission rate from the incinerator with the boilers operating on gas oil. This is considered to be a worst-case scenario and the actual emission values are predicted to be significantly lower. A summary of the predicted worst-case ground level concentrations is presented in the table below.

Parameter	Modelled Impact	Predicted GLC mg/m <sup>3</sup> <sup>Note 2</sup>	National Air Quality Standard <sup>Note 1</sup> Limit Values mg/m <sup>3</sup>
Nitrogen Oxides (as NO <sub>2</sub> )	Highest predicted 1-hour Average GLC (mg/m <sup>3</sup> )	151	-
	99.8%ile of 1-hour Average GLC (mg/m <sup>3</sup> )	130	200
	Highest Predicted Annual Average GLC (mg/m <sup>3</sup> )	28.5	40

**Note 1:** Air Quality Standards Regulations (SI No. 271 of 2002) reducing standard to be fully achieved by 2010.

**Note 2:** Includes background concentration based on 3-week passive diffusion tube sampling results obtained during April and May 2006. The background concentration includes the contribution from the BMS site.

The maximum predicted ground level concentration for nitrogen oxides (as NO<sub>2</sub>) is 151mg/m<sup>3</sup> c. 0.8km northeast of the site. The predicted 99.8%ile of 1-hour Average GLC including the background concentration is 130mg/m<sup>3</sup>. This is 65% of the Air Quality Standard hourly average ground level concentration limit of 200mg/m<sup>3</sup>. The highest predicted annual average GLC including the background concentration is 28.5mg/m<sup>3</sup> this is 71% of the air quality standard limit. The RD accommodates the nitrogen oxides ELV increase as requested.

Due to the introduction of hydrogen bromide (HBr) on-site since the original licence application (Reg. No. P0552-01), ELVs and quarterly monitoring for hydrogen bromide have been included in *Schedule B.1 – Emissions to Atmosphere* and *Schedule C.1.2 - Monitoring of Emissions to Atmosphere* for the emissions from the incinerator (A2-1).

The monitoring of NO<sub>x</sub>, SO<sub>x</sub> and CO emissions from the on-site boilers is amended from continuous monitoring to a quarterly frequency. This is in accordance with an adjustment previously agreed with the Office of Environmental Enforcement - 27<sup>th</sup> April 2005 - Ref. No.M552/AP06MG.

### Requested Incinerator monitoring requirement changes

The licensee requested that in the event of the failure of the continuous monitor for dust that incineration be allowed to continue. The monitoring requirements of the Incineration of Waste Directive (2000/76/EC) specify continuous measurement of total dust. In the event of a dust monitor failure the incinerator shall be shut down as soon as practicable in a manner consistent with safety and the protection of the environment in accordance with **Condition 3.14** of the RD.

The licensee requested that the treatment of the gaseous/vapour stream only in the incinerator be allowed to continue in the event of specific continuous monitor failures:

- Failure of FTIR analysis of NO<sub>x</sub>, SO<sub>x</sub>, CO, NH<sub>3</sub> and HCl.  
Proposed contingency monitoring of grab sampling and analysis for NO<sub>x</sub>, SO<sub>x</sub>, CO and HCl.
- Failure of FID analysis of TOC.  
Proposed contingency monitoring of absorbent tube monitoring for 1 hour in every 12.
- Failure of oxygen analysis used for normalisation of pollutants.  
Proposed use un-normalised data.

The monitoring requirements of the Incineration of Waste Directive (2000/76/EC) specify continuous monitoring of the above parameters. In the event of failure of any of the above listed continuous monitors, the licensee shall cease the incineration of liquid waste in line with **Condition 3.14**.

Conditions within the RD provide monitoring flexibility inline with the Incineration of Waste Directive (2000/76/EC). **Condition 3.14** provides for the possibility of a contingency system, which must have been previously agreed by the Agency. **Condition 6.3** of the RD requires all automatic monitors and samplers to be functioning at all times (except during maintenance and calibration) when the activities are 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 is required to contact the Agency as soon as practicable, and put in place alternative sampling and monitoring facilities. **Condition 6.6** allows that, subject to the requirements of Article 11 of the Council Directive 2000/76/EC on the incineration of waste, the frequency, the locations, the methods and scope of monitoring may be amended with the agreement of the Agency following evaluation of test results.

### Back-up abatement system

The licensee operates a cryogenic condensing system as a back up to the incinerator, for the treatment of gaseous emissions. The emissions from the cryogenic condensing system (and from any incinerator/cryogenic bypass) are emitted via emission point A2-2, which is continuously monitored. During regular operation of the incinerator there are no emissions from this emission point.

Under the original licence (Reg. No.P0552-01) the cryogenic condensing system was maintained ready for instantaneous treatment of waste gases from production when the incinerator would go off-line. BMS made the case to the Office of Environmental Enforcement (OEE) that the negative environmental impacts of maintaining the cryogenic condenser at the operational temperature of minus 95°C, in terms of liquid nitrogen and electricity usage, outweigh any operational or environmental benefits that arise from having the unit instantaneously available. The information provided to the OEE included atmospheric dispersion modelling of the predicted worst-case emissions from a bypass of the incinerator. In April 2006 the OEE agreed that BMS could cool the cryogenic condenser system to operational temperature (-95°C) when an incinerator trip occurs (known as 'quick start stand-by mode'). The 'quick start stand-by mode' was allowed for provided: (i) the cryogenic condenser takes no longer than 30 minutes to come on line when required, (ii) there is a continuous emission monitor (CEM) of gaseous and vapour organic substances, expressed as total organic carbon (A2-2 is now continuously monitored), (iii) all unplanned bypass events for which the cryogenic condenser is in use be notified to the Agency as an incident, (iv) the licensee continues the preventative programme to minimise site operations which lead to bypass periods, including analysis and reporting of the bypass events in the annual environmental report (AER).

BMS requested in the licence review application that no conditions be imposed in relation to the maximum start-up time of the cryogenic condenser, stating that there is no correlation between total

mass emission and bypass duration. The licensee has provided information on the bypass events over a four-month period (September 06 – December 06), including the duration and total mass emission of each bypass event. The bypass events ranged from 2 minutes to 137 minutes duration with the total mass emissions ranging from 0.01kg to 14.38kg. The average bypass event was 31 minutes in duration.

The explanation for the length of each bypass event was not provided. On 11 of the 18 bypass events recorded during the four-month period, the bypass duration was less than 30-minutes. While, from the bypass information provided there is no obvious correlation between the length of bypass event and the total mass emission, reducing the duration of a particular bypass event will reduce the total mass emission. **Condition 3, 6, and 11** and the glossary included in the RD maintain the requirements specified by the OEE in relation to the operation of the cryogenic condenser under 'quick start stand-by mode'.

All other emissions to atmosphere from the installation remain as agreed under the original licence (Reg. No. P0552-01). The original licence application included atmospheric dispersion modelling of the maximum emissions from the installation and these emissions do not exceed any relevant or derived ground level concentration limits.

### 3.2 Emissions to Sewer:

Waste water from the WWTP and from the dedicated incinerator WWTP combine prior to passing through a monitoring station (SE-1) and then being discharged to the Fingal County Council Sewer system. The final receiving destination is the Dublin Corporation municipal treatment plant at Ringsend.

The licensee has requested that the maximum hourly flow rate from the incinerator WWTP (emission point SE-2) be increased from 12m<sup>3</sup>/hour to 16.5m<sup>3</sup>/hour. The licensee states that the higher flow rate is the design capacity of the incinerator WWTP. The RD includes this increased maximum hourly flow rate. The maximum total daily volume remains as set within the original licence (Reg. No.P0552-01), 240m<sup>3</sup>/day.

The original licence (Reg. No.P0552-01) set ELVs on metal concentrations within the discharge from the incinerator WWTP (SE-2) in accordance with the requirements of Council Directive 94/67/EC of 16<sup>th</sup> December 1994 on the *Incineration of Hazardous Waste*. Since the original licence was issued (October 2000), Directive 2000/76/EC of 4<sup>th</sup> December 2000 on the *Incineration of Waste* has repealed Council Directive 94/67/EC. The ELVs within the RD have been revised in accordance with Directive 2000/76/EC.

Fingal County Council has proposed, within the Section 99E consent, minor amendments to the discharge and monitoring requirements of the emission to sewer.

- The maximum discharge volume to sewer is reduced from 2,000m<sup>3</sup> to 1,500m<sup>3</sup> per day.
- The BOD daily mean concentration ELV is reduced from 500mg/l to 400mg/l.
- The COD daily mean concentration ELV is reduced from 1,250mg/l to 1,000mg/l.
- The suspended solids daily mean concentration ELV is reduced from 500mg/l to 400mg/l.
- The chloride ELV is increased to 20,000mg/l to cover peak concentrations and the maximum daily loading remains set at 20,000kg/day.
- An orthophosphate ELV of 100mg/l is included.
- Fortnightly fluoride monitoring is introduced.
- Individual ELVs are set for zinc, chromium, copper, lead, nickel and arsenic.

Due to the low concentrations of oils, fats & greases and detergents within the discharge from the WWTP the monitoring frequency for these parameters is reduced to biannual.

These amendments have been incorporated into RD.

The Section 99E consent from Fingal County Council requested the inclusion of the following consent condition "*Best available technology (BAT) for the relevant activities (Manufacture of Pharmaceutical products and their intermediates and the Incineration of Hazardous Waste) 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)”. However, **Condition 2.2.2.2** requires the licensee to maintain a Schedule of Environmental Objectives and Targets under the Environmental Management Programme that shall provide for an evaluation of practicable options for resource efficiency, the use of cleaner technology and cleaner production.

Fingal County Council requested the inclusion of a consent condition requiring the licensee to maintain, or have maintained the on-site effluent treatment system. **Condition 6.5** of the RD requires all treatment/abatement and emission control equipment to be calibrated and maintained.

The licensee has requested contingency monitoring of emissions to sewer in the event of failure of the continuous online monitoring for pH, conductivity and TOC. There is provision within the RD for alternative monitoring to be considered by the Agency in the event of a continuous monitor failure. **Condition 6.3** of the RD requires all automatic monitors and samplers to be functioning at all times (except during maintenance and calibration). In the event of the malfunction of any continuous monitor, the licensee is required to contact the Agency as soon as practicable, and put in place alternative sampling and monitoring facilities.

### **3.3 Surface Water:**

The existing surface water infrastructure and monitoring regime are to be maintained. **Condition 6.12** requires the licensee to maintain a response programme for occurrences when the storm water pH, conductivity or total organic carbon (TOC) warning and/or action level is reached.

### **3.4 Emissions to ground:**

There are no emissions to ground/groundwater from the installation. The RD maintains the groundwater monitoring requirements.

### **3.5 Waste:**

Hazardous wastes generated on-site include solvent waste, aqueous waste, laboratory samples, spent filters and contaminated packaging and protective clothing.

On-site processing includes solvent recovery via distillation columns: a Class 11.1 recovery activity. The existing solvent recovery plant is maintained. Distillation processes are used where it is technically feasible and economical to separate clean solvents from the various mixtures leaving the plant. The plant consists of four processing units, a liquid/liquid extraction tank, main distillation column, deodorising/purification distillation column and a wastewater stripper. Recovered solvents are stored in bulk storage tanks and returned to the manufacturing process. Vent gases are sent directly to the incinerator as part of the process vent system.

The RD specifies control and monitoring requirements for on-site hazardous liquid and vapour waste incineration. The monitoring frequency of the waste gas streams to the on-site incinerator is increased from annually to quarterly due to the lower temperature operation when disposing of off-gas vapours with <1% halogenated organic substances content.

The RD specifies the requirements for the control, analysis and recording of liquid solvent waste and aqueous wastes imported from Swords Laboratories installation (Reg. No.P0014-04) and the waste incinerated on-site. Waste consignments imported from Swords Laboratories (Reg. No.P0014-04) are required to be accompanied by waste analysis results. The RD requires the licensee to carry out periodic sampling and analysis of the solvent/aqueous waste consignments from Swords Laboratories. This shall consist of a minimum of two consignments per month for the full suite of parameters in order to confirm the analysis results accompanying the waste load.

All the hazardous waste generated by the installation that is unsuitable for recovery or treatment on-site is sent off site for specialist recovery and/or incineration.

Non-hazardous waste includes office waste, canteen waste, glass, plastics and metals.

### 3.6 Noise:

Noise monitoring has determined that the noise levels at the nearest noise sensitive locations (NSLs) are greater than the licence limits. The monitoring revealed that off-site traffic noise was the most significant contributor to the  $LA_{eq}$ . 'The  $LA_{90}$  (an indicator of general background noise)' levels recorded at the NSL were below the day-time (55dBA) and night-time (45 dBA) licence limits for 2005 & 2006. The licensee states that the BMS Cruiserath installation is fully compliant with the existing noise limits. The provision of an additional 2dB(A) included within the noise interpretation of the original licence (Reg. No. P0552-01) has been removed and the RD sets the standard limits (in accordance with the Agency Guidance Note on Noise) at noise NSLs of the site. This is considered BAT for the installation.

## 4. Use of Resources

The licensee estimates an annual fuel usage of c. 12,300 litres heating oil, electricity usage c. 33,250 MWh/annum, natural gas usage of c. 68,900 MWh/annum and water usage of c. 279,540 m<sup>3</sup>/annum.

### 4.1 Materials

There are five TA Luft Class I substances used in production on-site; dichloromethane (c. 2,067 tonnes/annum used), benzoyl chloride (c. 30 tonnes/annum used), acetic anhydride (c. 10 tonnes/annum used), triethylamine (TEA) (c. 5.8 tonnes/annum used) and methylamine solution 40% (c. 4.4 tonnes/annum used). There are a further three TA Luft Class I substances which are used in the laboratory in smaller quantities. In addition there are twelve TA Luft Class II substances and fifteen TA Luft Class III substances used on-site.

Dichloromethane is a List I substance under the Dangerous Substances Directive and the Groundwater Directive. Other List I substances used in production on-site include acetonitrile, acetoxyacetyl chloride, benzene, benzoyl chloride, chlorine dioxide, ethyl acetate and laboratory chemicals. There are 13 substances used in production and 18 laboratory chemicals that are classified as List II under the Dangerous Substances Directive and the Groundwater Directive.

The licensee has identified fifteen chemicals, used in production processes, which contain substances with risk phrases, R50, R51, R52 and R53, classified as dangerous to the aquatic environment. Four chemicals on site carry the risk phrase R45 (may cause cancer), nine chemicals carry the risk phrase R48 (danger of serious damage to health by prolonged exposure) and one chemical carries the risk phrase R58 (may cause long-term adverse effects in the environment).

BMS is required to evaluate the possibility of replacing List I substances and substances with the risk phrases R45, R48, R50, R51, R52 R53 and R58 with less harmful alternatives, where possible, under the Schedule of Objectives and Targets (**Condition 2.2**).

## 5 Compliance with EU Directives

### 5.1 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*) and category 5.1 (*Installations for the disposal or recovery of hazardous waste as defined in the list referred to in Article 1 (4) of Directive 91/689/EEC as defined in Annexes II A and II B to Directive 75/442/EEC and in Council Directive 75/439/EEC of 16 June 1975 on the disposal of waste oils, with a capacity exceeding 10 tonnes per day*) of Annex I of Council Directive 96/61/EC concerning integrated pollution prevention and control.

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 RD as drafted takes account of the requirements of the Directive. In particular **Condition 7**, Resource Use and Energy Efficiency, provides conditions dealing with water, energy and raw material use, reduction and efficiency on site and **Condition 10**, Decommissioning, provides for decommissioning of the site following cessation of the activity.

BAT for the installation was assessed against the guidance given within the BREF Reference Documents on *Best Available Techniques in Common Wastewater and Waste Gas Treatment/Management Systems in the Chemical Sector* (February 2003), *Best Available Techniques*

for the *Manufacture of Organic Fine Chemicals* (December 2005), and *Best Available Techniques for Waste Incineration* (August 2006).

#### **5.2 Solvents Directive (1999/13/EC)**

The activities carried out at the BMS site do not fall under the scope of the Solvents Directive.

#### **5.3 Seveso Directive (96/82/EC)**

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

Swords Laboratories trading as Bristol-Myers Squibb Cruiserath fall within the scope of the Seveso II regulations. The site has been classified as *a lower-tier establishment and is subject to the requirements of Regulations 8-11 of SI No. 74 of 2006. The company's material inventory includes materials within Categories 2 (Toxic) and 8 (Extremely Flammable)*. The company has prepared a major accident prevention policy document. The National Authority for Occupational Safety and Health (NAOSH) is the competent authority responsible for administration and enforcement of these regulations.

#### **5.4 Emissions Trading Directive (2003/87/EC)**

BMS hold a Greenhouse Gas Emission Permit, Reg. No. IE-GHG059-02.

#### **5.5 Incineration of Waste Directive (2000/76/EC)**

The RD sets conditions to ensure compliance with EC Directive 2000/76/EC Council Directive on the Incineration of Waste.

#### **5.6 Habitats Directive (1996/43/EC) & Birds Directive (1979/409/EEC)**

The activities will not have a significant impact on any designated sites when carried out in accordance with the requirements of the RD.

### **6. 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.

### **7. Fit & Proper Person Assessment**

The applicants experience, technical abilities, financial and legal standing would qualify them as Fit & Proper Persons.

### **8. Compliance Record:**

Swords Laboratories trading as Bristol-Myers Squibb Cruiserath are generally compliant with their existing licence.

### **9. Complaints:**

Three complaints were received in the period June 2006 to July 2006, all in relation to odour. The odour nuisance was considered to have originated from the WWTP. BMS have subsequently revised the air extraction control and the sludge tank sealing mechanism of the WWTP to address the odour complaints.

### **10. Submissions:**

One submission from Fingal County Council was received in relation to this application and I have taken its content into account when making my recommendation to the Board.

**Submission received 14/02/07 - Fingal County Council (Mr David Devine A/Senior Executive Engineer)**



The submission states that Fingal County Council received a request from Bristol-Myers Squibb for approval for additional sources of Trade Effluent Discharge to sewer. The additional sources of effluent arise in the processing of Irbesartan, an active ingredient for hypertension medication. A three-month pilot study confirmed that the on-site WWTP could handle these additional waste streams, within the limits of the existing IPC licence and those requested within the IPPC licence review application.

Fingal County Council advise that they have no objection to the inclusion of the additional aqueous process wastewaters in the on-site WWTP subject to compliance with the existing IPC licence and proposed IPPC consent conditions.

**11. Charges:**

The charge for 2007 as calculated by the enforcement inspector is €32,885. The RD has retained this charge as no significant increase in enforcement is expected as a result of this review.

**12. Recommendation:**

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

Signed

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Stuart Huskisson

Inspector

**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.