



# Integrated Pollution Prevention and Control Licensing

## IPPC Licence Review Application Form

**EPA Reg. N<sup>o</sup>:**

*(Office use only)*

*This document does not purport to be and should not be considered a legal interpretation of the provisions and requirements of the EPA Acts 1992 and 2003.*

**Environmental Protection Agency**  
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*IPPC Licence Review Application Form*

# Environmental Protection Agency

Application for a Review of an Integrated Pollution Prevention and Control Licence

Environmental Protection Agency Acts, 1992 and 2003.

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## INTRODUCTION

The Protection of the Environment Act 2003 (POE Act) has transposed the Integrated Pollution Prevention and Control (IPPC) Directive (96/61/EC) into national legislation. This IPPC licence review application form enables the applicant to show compliance with the statutory requirements as set out in the IPPC Directive and the POE Act and any regulations made thereunder.

Article 3 of the IPPC Directive (96/61/EC) specifies that the Agency shall ensure that installations are operated in accordance with basic obligations. This application form requires applicants to describe measures in place to ensure compliance with these basic obligations including use of *best available techniques* (BAT), energy efficiency and waste minimisation as set out in Article 6 of the IPPC Directive. Furthermore the applicant is required to submit information to show compliance with the requirement of the *Fit and Proper Person* provisions in accordance with Section 84(4) of the EPA Act as amended.

Each page of the application form must be numbered, e.g. *page 5 of 45*, etc. The basic information should for the most part be supplied in the spaces given in application form and any supporting documentation should be supplied as attachments, as specified.

While all sections in the application form may not be relevant to the activity concerned, the applicant should look carefully through all aspects of the form and provide the required information, in the greatest possible detail.

All maps/drawings/plans must be no larger than A3 size and scaled appropriately such that they are clearly legible. In exceptional circumstances, where A3 is considered inadequate, a larger size may be requested by the Agency.

Information supplied in this application, including supporting documentation will be put on public display and open to inspection and copying by any person at Agency headquarters and on its website. Should the applicant consider certain information to be confidential, this information should be submitted in a separate enclosure bearing the legend, "***In the event that this information is deemed not to be held as confidential, it must be returned to .....***" When submitting such information you should outline clearly the nature of information. The reasons why the information is considered confidential (with reference to the "Access to Information on the Environment" Regulations of 1993) should be stated in the Application Form, where relevant.

## SECTION A NON-TECHNICAL SUMMARY

### Non-Technical Summary of IPPC Licence Application

A non-technical summary of the application is to be included here. The summary should identify all environmental impacts of significance associated with the carrying on of the activity/activities, and describe mitigation measures proposed or existing to address these impacts. This description should also indicate the normal operating hours and days per week of the activity.

The following information should be included in the non-technical summary:

A description of:

- the installation and its activities,
- the raw and auxiliary materials, other substances and the energy used in or generated by the installation,
- the sources of emissions from the installation,
- the conditions of the site of the installation,
- the nature and quantities of foreseeable emissions from the installation into each medium as well as identification of significant effects of the emissions on the environment,
- the proposed technology and other techniques for preventing or, where this not possible, reducing emissions from the installation,
- where necessary, measures for the prevention and recovery of waste generated by the installation,
- further measures planned to comply with the general principles of the basic obligations of the operator, i.e.
  - (a) all the appropriate preventive measures are taken against pollution, in particular through the application of best available techniques (BAT);
  - (b) no significant pollution is caused;
  - (c) waste production is avoided in accordance with Council Directive 75/442/EEC of 15 July 1975 on waste; where waste is produced, it is recovered or, where that is technically and economically impracticable, it is disposed of while avoiding or reducing any impact on the environment;
  - (d) energy is used efficiently;
  - (e) the necessary measures are taken to prevent accidents and limit their consequences;
  - (f) the necessary measures are taken upon definitive cessation of activities to avoid any pollution risk and return the site of operation to a satisfactory state.
- measures planned to monitor emissions into the environment.

Supporting information should form **Attachment N<sup>o</sup> A.1**

\*\*\*\*\*

An updated Non Technical Summary is included in **Attachment N<sup>o</sup> A.1** of this Licence Review Application.



Confirm whether the information submitted in relation to the legal entity of the company has changed from that detailed in the original application or in the most recent review application.

<b>Has information in relation to legal entity of the company changed?</b>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
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If yes, supply the following information:

- (a) Certified Copy of Certificate of Incorporation
- (b) Company's Number in Company's Registration Office and
- (c) Particulars of Registered Office of the Company.

Supporting information should form **Attachment N° B.1.**

Name and address of the proprietor(s) of the Land on which the Activity is situated (if different from review applicant named above).

*Proprietor's Name:* \_\_\_\_\_

*Address:* \_\_\_\_\_

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Name and address of the owner(s) of the building and ancillary plant in which the activity is situated (if different from review applicant named above).

*Name:* \_\_\_\_\_

*Address:* \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## B.2. Location of Activity

*Company Name:* Bristol-Myers Squibb, Cruiserath, Dublin

*Full Address:* Cruiserath Road

Mulhuddart

Dublin 15

*Telephone N<sup>o</sup>:* 01-8854000 *Fax N<sup>o</sup>:* 01-8854151

*Contact Name(s):* Ian Boyle

*Position(s):* Director, Environmental Health & Safety

*Contact e-mail:* ian.boyle@bms.com

*Irish National Grid Reference (12 digit-6E,6N) \** 307840, 241440

\* The Grid Reference should be supplied using GPS in Irish National Grid.

Location maps (no larger than A3) with site boundary outlined in colour, a specified drawing number and grid references should be enclosed in **Attachment N<sup>o</sup> B.2.**

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### B.3. Class of Activity

1. Identify the relevant activity / activities in the First Schedule of the EPA Acts, 1992 and 2003 to which the activity relates:

Schedule No	Class No.	Description <sup>Note 1</sup>
1	5.6	The manufacture of pharmaceutical products and their intermediates
1	5.16	The use of a chemical process for the production of basic pharmaceutical products
1	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

**Note 1:** In order to give a precise identification select only those words from the description of the class or classes that best describes the nature of the activity for which the licence is being applied for.

### B.4. Employees

Give the number of employees and other persons working or engaged in connection with the activity on the date of submission of this application for a review and the number required during normal levels of operation.

Number of Employees (at the present): 165 (October 2006)

Number of Employees (normally) : 175

### B.5. Relevant Planning Authority

Give the name of the planning authority in whose functional area the activity is carried out.

Name: Fingal County Council

Address: County Hall

Main Street

Swords

Co. Dublin

Telephone N<sup>o</sup>: 01-8905000

Planning Permission for this project :-

Obtained  Applied for  Not applied for

Local Authority Planning File Reference N<sup>o</sup>: F99A/0871

**Attachment N<sup>o</sup> B.5** should contain a schedule of all planning permissions in force at the time of this submission. Evidence should also be included in the attachment of a notification having been given to the relevant Planning Authority in accordance with the requirements of Section 87(1)(a) of the EPA Acts 1992 and 2003, as well as a copy of notice published in a newspaper (circulating in the district) of intention to apply for a review of licence.

A list of Planning Permissions received since the original Licence Application in 2000 is provided in **Attachment N<sup>o</sup> B.5**.

A copy of the letter of notification to the Planning Authority and newspaper notice publication is also contained in **Attachment N<sup>o</sup> B.5**.

**B.6. Relevant Sanitary Authority.**

In the case of a discharge of any trade effluent or other matter to a piped sewer of a sanitary authority, give the name of the sanitary authority in which the sewer is vested or by which it is controlled.

Name: Fingal County Council

Address: County Hall  
Main Street  
Swords  
Co. Dublin

Telephone N<sup>o</sup>: 01-8905000

In the case of a discharge of any trade effluent or other matter to a sewer not owned by or vested in a sanitary authority, the applicant must supply as **Attachment N<sup>o</sup> B.6** the names, addresses and telephone contact information for the owners or those responsible for:

- a. The sewer or drain into which the trade effluent is discharged;
- b. The waste water treatment facility into which the sewer discharges; and
- c. The quality of the resultant treated effluent prior to discharge to waters.

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## SECTION C APPROVED ADJUSTMENTS

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In the case where the Office of Environmental Enforcement (OEE) of the Agency has agreed any variations or adjustments to the conditions of the existing licence, the applicant must supply a schedule detailing these agreed variations and adjustments to the existing licence conditions. An updated, scaled drawing of the site layout (no larger than A3) providing visual information on such adjustments or variations where appropriate should be included.

**Attachment N<sup>o</sup> C1** shall include the schedule of variations and/or adjustments together with the updated drawing.

\*\*\*\*\*

See **Attachment N<sup>o</sup> C.1** for a list of approved adjustments since the issuing of Licence Register No. P0552-01.

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## SECTION D EMISSIONS AND ENVIRONMENTAL IMPACT

### D.1. Emissions to Atmosphere

Specify whether there has been a change in the quantity or nature of emissions to atmosphere from that detailed in the original application or earlier review application(s) and/or specified in your existing licence:

Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>
---	-----------------------------

If yes, provide further information as detailed below.

#### D.1.A Point-source emissions to atmosphere

Outline significant adjustments to the operations on site, if any, which has led to a change in the quantity or nature of emissions to atmosphere.

A summary list of any revised emission points, together with maps/drawings (no larger than A3) and supporting documentation should be included as **Attachment N<sup>o</sup> D.1.A**

The applicant should address in particular any emission point where those substances listed in the Schedule to the Environmental Protection Agency (Licensing) (Amendment) Regulations, 2004 (S.I. No. 394 of 2004) are emitted.

For emissions outside the BAT guidance level, a full evaluation of the existing abatement/treatment system must be provided. A planned programme of improvement towards meeting upgraded standards in advance of 30<sup>th</sup> September 2007 is required. This should highlight specific goals and a time scale, together with options for modification, upgrading or replacement as required to bring the emissions within the emission levels as set out in the BAT guidance note(s).

#### D.1.B Fugitive and Potential Emissions

State whether the Council Directive 1999/13/EC on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations apply to the operation:

<b>Council Directive applies</b>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
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If yes, **Attachment N<sup>o</sup> D.1.B** should include details of relevant category of activity in the Schedule and how the requirements in relation to fugitive emissions will be met.

#### D.1. C Assessment of atmospheric emissions

If relevant, give summary details and an assessment of the impacts of any emissions (as detailed above) on the environment, including environmental media other than those into which the emissions are being made. The assessment should include details of relevant ambient air quality standards.

Details of the assessment and any other supporting information should form **Attachment N<sup>o</sup> D.1.C**.

\*\*\*\*\*

A site location map displaying the location of all on site minor emission points is included in **Attachment N<sup>o</sup> D.1.A**. There is no new main or boiler emission points on site.

All emissions to atmosphere are within specified limits as per the existing IPC licence. See **Attachment N<sup>o</sup> D.1.C** for a summary of 2004 & 2005 atmospheric emission data from the facility.

Details of all minor and potential emission points were presented in Tables 12A(v) & 12A(vi) of the original IPC Licence Application (Register No. P0552-01), submitted prior to the detailed design process. During the design process it was possible to reduce the overall number of emission points by utilising the existing header system, and others points have since become superfluous to requirements.

Updated tables detailing all on site minor and potential atmospheric emissions using an updated reference numbering system are included as part of **Attachment N<sup>o</sup> D.1.A**.

The impact of all on site main emissions at current emission limit values was assessed as part of the original IPC Licence Application, Register No. P0552-01.

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## D.2. Emissions to Surface Waters

Specify whether there has been a change in the quantity or nature of emissions to surface waters from that detailed in the original application or earlier review application(s) and/or specified in your existing licence:

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
------------------------------	--

If yes, provide further information as detailed below.

### D.2.A Emissions to Surface Water

Outline significant adjustments to the operations on site, if any, which has led to a change in the quantity or nature of emissions to surface waters.

A summary list of any revised emission points, together with maps/drawings (no larger than A3) and supporting documentation should be included as **Attachment N<sup>o</sup> D.2.A.**

The applicant should address in particular any emission point where those substances listed in the Schedule to the Environmental Protection Agency (Licensing) (Amendment) Regulations, 2004 (S.I. No. 394 of 2004) are emitted.

State whether Water Quality (Dangerous Substances) Regulations, 2001 (S.I. No. 12 of 2001) apply to the operations on site:

<b>Water Quality (Dangerous Substances) Regulations apply</b>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
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If yes, include in **Attachment N<sup>o</sup> D.2.A** whether the operations on site comply with the prescribed standards set out in the S.I. No. 12 of 2001.

For emissions outside the BAT guidance level, a full evaluation of the existing abatement/treatment system must be provided. A planned programme of improvement towards meeting upgraded standards in advance of 30<sup>th</sup> September 2007 is required. This should highlight specific goals and a time scale, together with options for modification, upgrading or replacement as required to bring the emissions within the emission levels as set out in the BAT guidance note(s).

### D.2.B Assessment of Impact on Receiving Surface Water

If relevant, give summary details and an assessment of the impacts of any emissions (as detailed above) on the environment, including environmental media other than those into which the emissions are to be made. The assessment should include details of relevant environmental quality standards or other legislative standards.

Details of the assessment and any other supporting information should form **Attachment N<sup>o</sup> D.2.B.**

\*\*\*\*\*

There are no emission discharges from the BMS Cruiserath site to surface waters. Uncontaminated surface water from hard standing areas is discharged to the local municipal stormwater drainage system as per the IPC Licence No. P0552-01.

### D.3 Emissions to Sewer

Specify whether there has been a change in the quantity or nature of emissions to sewer from that detailed in the original application or earlier review application(s) and/or specified in your existing licence:

Yes	<input type="checkbox"/>	No	<input checked="" type="checkbox"/>
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If yes, provide further information as detailed below.

#### D.3.A Emissions to Sewer

Outline significant adjustments to the operations on site, if any, which has led to a change in the quantity or nature of emissions to sewer.

A summary list of any revised emission points, together with maps/drawings (no larger than A3) and supporting documentation should be included as **Attachment N° D.3.A**.

For emissions outside the BAT guidance level, a full evaluation of the existing abatement/treatment system must be provided. A planned programme of improvement towards meeting upgraded standards in advance of 30<sup>th</sup> September 2007 is required. This should highlight specific goals and a time scale, together with options for modification, upgrading or replacement as required to bring the emissions within the emission levels as set out in the BAT guidance note(s).

#### D.3.B Assessment of Impact of Sewage Discharge

If relevant, give summary details and an assessment of the impacts of any emissions (as detailed above) on the environment, including environmental media other than those into which the emissions are to be made. The assessment should include details of relevant environmental quality standards or other legislative standards.

Details of the assessment and any other supporting information should form **Attachment N° D.3.B**.

\*\*\*\*\*

All on site emissions to sewer are discharged via the onsite biological wastewater treatment plant (WWTP) to the local authority municipal WWTP at Ringsend and are as detailed in the IPC licence application, Register No. P0552-01. Wastewater emissions from the incinerator are treated separately in the on site Incinerator WWTP before discharge to the local authority WWTP.

All emissions to sewer are within specified limits as per the existing IPC licence. See **Attachment N° D.3.A** for a summary of 2005 sewer emission data from the facility.

All emissions to sewer are considered to be within BAT guidance levels. See Section D.6 Environmental Consideration and BAT for further detail.

## D.4 Emissions to Ground

Specify whether there has been a change in the quantity or nature of emissions to ground from that detailed in the original application or earlier review application(s) and/or specified in your existing licence:

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
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If yes, provide further information as detailed below.

### D.4.A Emissions to Ground

Outline significant adjustments to the operations on site, if any, which has led to a change in the quantity or nature of emissions to ground.

For emissions outside the BAT guidance level, a full evaluation of the existing abatement/treatment system must be provided. A planned programme of improvement towards meeting upgraded standards in advance of 30<sup>th</sup> September 2007 is required. This should highlight specific goals and a time scale, together with options for modification, upgrading or replacement as required to bring the emissions within the emission levels as set out in the BAT guidance note(s).

Any supporting information should form **Attachment N<sup>o</sup> D.4.A.**

### D.4.B Assessment of impact of ground/groundwater emissions

If relevant, give summary details and an assessment of the impacts of any emissions (as detailed above) on the ground (aquifers, soils, sub-soils and rock environment), including any impact on environmental media other than those into which the emissions are to be made. This includes landspreading, land injection etc.

Details of the assessment and any other supporting information should be included in **Attachment N<sup>o</sup> D.4.B.**

\*\*\*\*\*

There are no discharges to ground at the BMS Cruiserath site.

## D.5. Noise Emissions

Specify whether there has been a change in the quantity or nature of noise emissions from that detailed in the original application or earlier review application(s) and/or specified in your existing licence:

Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
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If yes, provide further information as detailed below.

### D.5.A Noise Emissions

Outline significant adjustments to the operations on site, if any, which has led to a change in source, location, nature, level and the time period or periods during which the noise emissions are made or are to be made.

For emissions which lead to an impact in excess of the limits set out in the EPA Guidance Note for Noise for Scheduled Activities, a full evaluation of the existing abatement/treatment systems must be provided. A planned programme of improvement towards meeting upgraded standards in advance of 30<sup>th</sup> September 2007 is required. This should highlight specific goals and a time scale, together with options for modification, upgrading or replacement as required to bring the emissions within the required limits as set out in the Guidance Note for Noise for Scheduled Activities (1995).<sup>1</sup>

Any supporting information should form **Attachment N<sup>o</sup> D.5.A.**

### D.5.B Noise Impact.

If relevant, give summary details and an assessment of the impacts of any emissions (as detailed above) on the environment, including environmental media other than those into which the emissions are to be made.

Details of the assessment and any other supporting information should be included in **Attachment N<sup>o</sup> D.5.B.**

\*\*\*\*\*

The noise emission limits for BMS Cruiserath, as per IPC Licence No. P0552-01, are 55dB and 45dB for daytime and night-time noise levels respectively at the nearest noise sensitive location (NSL) (600m west of the site). Although annual noise monitoring in 2005 and 2006 recorded the average noise emission levels ( $LA_{eq}$ ) to be greater than the IPC licence limits, the surveys also revealed that off-site traffic noise levels were the most significant contributors to the  $LA_{eq}$ .

As detailed in the BMS Cruiserath Annual Environmental Reports for 2005 & 2006, an examination of  $LA_{10}$  (an indicator of traffic noise) noise monitoring results demonstrates that traffic levels contribute most to the  $LA_{eq}$  noise levels monitored. In addition, the  $LA_{90}$  (an indicator of general background noise) results recorded at the NSL for 2005 &

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<sup>1</sup> Where noise evaluation / assessment reports have been prepared for the purposes of compliance with an existing licence, such reports may be submitted in fulfilment of the requirements of this part of the application.

2006 ranged from 48dBA (Daytime) 39.5dBA (Night-time) respectively, less than the relevant Licence limit of 55dBA and 45dBA. These levels are a good indicator of background noise levels at the BSL in the absence of passing road traffic.

Therefore, a closer examination of the 2005 & 2006 daytime and night-time noise levels monitoring results recorded at the NSL demonstrate that the BMS Cruiserath facility is fully compliant with the IPC Licence limits.

A summary of noise monitoring results for 2005 & 2006 are contained in **Attachment N<sup>o</sup> D.5.A.**

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## D.6 Environmental Consideration and BAT

Describe any environmental considerations which have been made with respect to the use of cleaner technologies, waste minimisation and raw material substitution since the grant of the existing licence.

Describe the measures proposed or in place to ensure that the Best Available Technique (BAT) will be used to prevent or eliminate or, where that is not practicable, generally reduce an emission from the activity.

Supporting information should form **Attachment N° D.6**.

\*\*\*\*\*

A detailed assessment of all BAT considerations was detailed in Section 19 of the original IPC licence application (P0552-01) submitted to the Agency in 2001. A summary of the main considerations is provided below.

### Incinerator:

The following streams are fed to the incinerator for thermal oxidation:

- Nitrogen/organic vapour VOC streams from the process vessels
- Air rich/organic vapour VOC streams from the point extraction system (micropolluted air)
- Air exhaust containing trace organic components from the biological wastewater treatment plant
- Organic vapour from the wastewater stripper
- High calorific value (HCV) liquids that are unsuitable for solvent recovery
- High calorific value (HCV) chlorinated solvents that are unsuitable for solvent recovery
- Low calorific value (LCV) aqueous streams that are unsuitable for bio-treatment

The incinerator is currently controlled to maintain an outlet temperature of >1100°C and an oxygen content of >6% v/v. The combustion stream is cooled in a waste heat boiler that raises steam for use around the site. The stream then passes through neutral and acid scrubbers to remove acid gases. Particulate material is removed in a wet electrostatic precipitator. The final treatment is in a catalytic deNO<sub>x</sub> reactor that reduces nitrogen oxide and dioxin to minimum levels before emission. The flue gas is discharged to atmosphere via a vent stack 35m high. This is considered BAT.

All daily averages were well within IPC licence limits for the incinerator emission point during the periods covered by the 2005 & 2006 Annual Environmental Reports (AERs).

### Incinerator backup:

In the event of incinerator failure the following systems are provided to prevent harmful emissions to atmosphere.

- Liquids for incineration are stored in storage tanks until the incinerator is restarted, or are disposed of off site by approved waste disposal contractors.
- VOC rich gas streams are diverted to a cryogenic condenser unit in which the gases are chilled to  $-95^{\circ}\text{C}$  with liquid nitrogen.
- VOC lean gas streams are diverted to a carbon adsorption unit where contaminants are adsorbed onto the carbon prior to discharge.
- Wastewater treatment plant exhaust gases are vented directly to atmosphere as they are not hazardous.

### Biological wastewater treatment plant (WWTP):

Aqueous waste streams are treated in the biological wastewater treatment plant. Streams with high organic content can be pre-treated in the wastewater stripper to reduce the organic load to levels suitable for treatment in the WWTP.

Incoming streams are screened for solids and then mixed in the equalisation tank. There is pH adjustment before addition to the first stage of treatment for removal, primarily, of carbonaceous content. The system uses aerated activated sludge technology. Existing streams are settled in a clarifier for sludge recycling, before they are pumped to the second stage of treatment. Denitrification and further biological oxidation may be carried out in the secondary aeration tanks. The existing stream is allowed to settle in an upward-flow clarifier and some of the resulting sludge is recycled.

Excess sludge is thickened in a picket fence thickener and subsequently dewatered in a filter press. The resulting solids are sent off site as non-hazardous waste for disposal.

All emissions of effluent from the facility are within BAT guidance values. Table D.6.1 compares the percentage removal of emissions from BMS Cruiserath WWTP and Ringsend Municipal WWTP (MWWTP) with BAT Guidance values. The percentage removal of average influent load in 2005 to the on site WWTP was calculated against Ringsend MWWTP. All values were within recommended BAT Guidance values.

**TABLE D.6.1 – BAT ASSESSMENT OF WASTEWATER TREATMENT PLANT**

	<b>BOD</b>	<b>COD</b>	<b>TP</b>	<b>SS</b>
Influent to WWTP, mg/l	5,750	11,500	515	900
Ringsend MWWTP discharge limit <sup>1</sup> , mg/l	25	125	2	35
% Removal	99.6	98.9	99.6	96.1
BAT Guidance	>99% removal	>95% removal	82 – 98% removal	10 – 20 mg/l

Note 1: Limits taken from the Urban Waste Water Treatment Directive (91/271/EEC).

An efficient wastewater collection system plays an essential role in effective wastewater reduction and/or treatment. It directs the wastewater streams to their appropriate

treatment systems and prevents mixing of contaminated and uncontaminated waste water. Thus, BAT is to:

- Segregate process water from uncontaminated rainwater and other uncontaminated water releases;
- Install retention capacity for failure events and fire-fighting water.

The treatment of collected wastewater (to remove biodegradable substances by using an appropriate biological treatment system), by a central final treatment in a biological WWTP on the site is considered BAT.

### **Odour**

It is considered BAT to control odour by enclosing the wastewater treatment plant and ducting the exhaust air to an odour treatment system.

The BMS Cruiserath WWTP is a covered system. Odour control within the WWTP is effected by means of a central odour control system. Air arising from the WWTP is contained, collected under vacuum conditions, and conveyed to the incinerator via the WWTP micro polluted header. This is considered BAT.

### **Water Minimisation**

Water usage and waste water discharges are reviewed daily by the Technical Services Department and monthly by BMS senior management. Detailed analysis of flows is routinely carried out with a view to minimising flows to W1 effluent discharge point.

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## SECTION E CONTROL AND MONITORING

**Describe any adjustment (not detailed in Section C) made to technology and other techniques for preventing or, where this is not practicable, reducing emissions from the installation.**

### **E.1: Treatment, Abatement and Control Systems**

Details of revised treatment/abatement systems (air and effluent emissions) should be included, together with schematics as appropriate.

**Attachment N<sup>o</sup> E.1** should contain any supporting information.

\*\*\*\*\*

The control and abatement of on site air and effluent emissions is described in detail in Section 19 of the original IPC licence application, Register No. P0552-01.

### **Upgrade of Cryogenic Unit with Pre-Condensers**

There has been an approved change (refer to **Attachment N<sup>o</sup> C.1**, Note 6 of this Review Application) to the cryogenic system entailing the installation of pre-condensers. A schematic of new process layout and a summary of the process are provided in **Attachment N<sup>o</sup> E.1**.

There has been no further alteration to Treatment, Abatement and Control Systems since the original IPC licence application (P0552-01) was submitted to the Agency in 2000.

However, BMS Cruiserath request a change in the operating conditions of the on site incinerator. The basis for this request is detailed below:

### **Proposed Change to Operating Conditions of Incinerator**

#### **Historical Legislative Basis for Operating Conditions**

The first incineration control Directives were issued in 1989 by the European Commission:

- Directive 89/369/EEC for new municipal incineration plants; and
- Directive 89/429/EEC for existing municipal incineration plants.

These established the combustion conditions for the incineration of waste of at least 850°C for at least two seconds in the presence of at least 6% oxygen. These conditions were set so as to avoid the formation of dioxins and ensure organic residues were fully combusted. Strict emission control conditions were set for carbon monoxide (CO) as this can be relatively easily measured and high levels can indicate that oxidation is incomplete.

However, public concern remained over the control of hazardous waste incinerators and Directive 94/67/EC (Incineration of Hazardous Waste) was introduced specifically to regulate this sector. This Directive again specified for the combustion chamber at least 850°C for at least two seconds in the presence of at least 6% oxygen; if hazardous wastes with a content of more than 1% of halogenated organic substances are incinerated, then the temperature has to be raised to at least 1,100°C. For furnaces burning liquid waste only or with a mixture of gaseous substances and powdered solids from a thermal pre-treatment of hazardous waste under oxygen deficiency, and when the gaseous part accounts for more than 50% of the entire heat released, the oxygen content after the last injection of combustion air shall amount to at least 3%.

This Directive was introduced into Irish Law under S.I. No. 64 of 1998: European Communities (Licensing of Incinerators of Hazardous Waste) Regulations, 1998 and has formed the basis for the IPC licensing conditions of a number of hazardous waste incinerators operating in the Pharmachem sector in Ireland.

### **Current Standards**

The Technical Regulations for incineration 17 BImSchV were introduced in 1989 in Germany. These Regulations formed the basis of the 1994 EU Directive and were considered technology forcing, in that the technology was not readily available at that time but it was believed it could be developed to meet the standards set.

Since then the technology has developed such that the equipment suppliers can comfortably meet and exceed the emission levels set. In setting the EU standards detailed earlier, three combustion variables were defined; namely

- Temperature;
- Residence time; and
- Oxygen content.

With the improvements in technology the equipment vendors found that they could meet the prescribed emission standards with reduced temperature, residence time and oxygen content, with significant savings in energy use.

The EU also recognised in the late nineties that incineration legislation needed to be updated. Given that the furnace conditions ensure near total destruction it was recognised that there was little difference technically between hazardous waste incineration and standard waste incineration. There was also a need to regulate co-incineration plants, in particular the cement industry, who were increasing their utilisation of waste derived fuels. Furthermore, as mentioned above, technical progress had been achieved in the performance of incineration units.

Therefore Directive 2000/76/EC on the incineration of waste entered into force in December 2000 and the Member States were required to implement this Directive by December 2002. In Ireland S.I. No. 275 of 2003, European Communities (Incineration of Waste) Regulations, 2003 gives effect to the Directive with the practical implementation being through the EPA licensing system.

From a technical perspective the Directive 2000/76/EC made the following changes with regard to previous EU legislation, namely:

- While a reference oxygen level is specified for the purpose of emission control measurements there is no minimum oxygen concentration specified as a combustion condition.
- The same conditions as previous are specified for residence time, namely 2 seconds and temperatures of 850°C or 1,100°C depending on whether 1% halogenated organic substances are present or not. However, conditions different to the above may be authorised by the competent authority, provided the requirements of the Directive are met, i.e. the emission limit values are maintained.

### **Amendments to BMS Cruiserath Incinerator Operating Conditions**

BMS Cruiserath request a change in the operating conditions of the incinerator as specified in their IPC Licence, No. P0552-01. The request for change is a consequence of the incinerator being oversized for the present waste load. Currently, the incinerator is used for the disposal of waste gases from on site operations and for the disposal of liquid waste.

Liquid waste solvents and waste gases generated on site are incinerated under the following conditions:

- Temperature – 1,100°C
- Oxygen – 6%
- Residence time – minimum 2 seconds

It should be noted that BMS only request a change in temperature operating conditions to the incinerator for the burning of waste gas streams generated on site. It is requested that the present IPC licence operating conditions with respect to oxygen be removed for the burning of liquid wastes and waste gas streams.

BMS propose to operate the incinerator as a Thermal Oxidiser at lower oxygen and temperature operating conditions for the destruction of waste gas streams. When sufficient volumes are available, liquid waste solvents will be incinerated on a batch basis. It is proposed to implement control safeguards to ensure that the incinerator continues to operate at specified operating conditions (i.e. 1100°C) during the disposal of liquid waste solvents.

The European Integrated Pollution Prevention and Control Bureau in Seville publish a series of BAT Reference Documents (BREFs). Although not legally binding, the BREFs provide information on techniques associated with BAT and which should be considered in the determination of BAT for on site operations.

An example of co-incineration of halogenated waste solvents is published in the BREF for the Organic Fine Chemicals (Section 4.3.5.8), December 2005. This example relates to the co-incineration of waste solvents, namely methylene chloride, isopropanol and methanol, with exhaust gases from the production buildings in which successful trials were carried out to demonstrate that emission levels could be met with lower temperatures and residence times. It was acknowledged in the BREF that energy savings could be obtained from lower support fuel consumption, lower maintenance and lower rate of wear.

Solvents used on site at the Cruiserath facility are relatively clean as opposed to complex and difficult molecules such as PCBs. Therefore it is expected that the same performance level can be obtained as in example 4.3.5.8 of the BREF for a similar facility in the fine chemicals sector.

BMS Cruiserath therefore propose to operate the incinerator at lower temperatures and unrestricted oxygen levels, in agreement with the Agency, in two modes as follows:

1. Disposal of Waste Gas Streams at  $\geq 850^{\circ}\text{C}$  & excess oxygen concentrations
2. Disposal of Waste Liquid Solvents at  $\geq 1100^{\circ}\text{C}$  & excess oxygen concentrations

Considerable environmental benefits including improved energy efficiency and a significant reduction in greenhouse gas emissions will be achieved through a reduction in operating temperature and oxygen conditions of the incinerator. It is anticipated that the fuel consumption of the incinerator could be reduced by approximately 75 kg/hr and 100 kg/hr for a decrease in oxygen and temperature operating conditions respectively. This would be a 10% reduction in overall consumption.

Furthermore, as a result of a decrease in oxygen and temperature operating conditions during the disposal of VOCs only,  $\text{NO}_x$  emissions and ammonia consumption will also be reduced. It is anticipated ammonia consumption for the control of  $\text{NO}_x$  will be reduced by approximately 100-150m<sup>3</sup>/year.

Prior to the permanent implementation of the proposed operation modes, BMS propose to conduct appropriate monitoring to ensure that all emissions remain within current emission limit values.

**TABLE E1.1 PROPOSED OPERATING CONDITIONS FOR AIR EMISSION ABATEMENT SYSTEM**

Operating Conditions	Abatement System Mode	
	Incinerator	Thermal Oxidiser
Temperature, °C	1100°C	$\geq 850^{\circ}\text{C}$ <sup>1</sup>
Oxygen, %	Not Applicable	Not Applicable
Residence Time	Minimum 2 seconds	Minimum 2 seconds

Note 1: For the abatement of the gaseous VOC stream only.

### Incinerator Wastewater Treatment Plant

The operation of the Incinerator WWTP has been reviewed against the requirements of the Waste Incinerator Directive (2000/76/EC) and conforms to the requirements outlined in Article 8 of the Directive concerning Water Discharges from the cleaning of exhaust gases.

The incinerator WWTP unit is designed to treat the polluted blow-down from the incinerator. It is requested that the wastewater flow rate on this system be increased from the existing IPC licence limit value of 12m<sup>3</sup>/hr to 16.5m<sup>3</sup>/hr. The requested increase is in line with the design capacity flow rate of the incinerator WWTP which is 16.5m<sup>3</sup>/hr.

### Biological Wastewater Treatment Plant

Process wastewaters are currently discharged to municipal sewer via the onsite biological wastewater treatment plant. It is requested to amend the discharge limit and monitoring requirements to a number of parameters in the existing IPC Licence, Register P0552-01.

The requested discharges limits which were discussed in October 2006 with Fingal County Council are tabulated below (Table E1.2) together with existing licence limits and average wastewater discharge values.

**TABLE E.1.2. COMBINED WASTEWATER DISCHARGE TO SEWER & REQUESTED IPPC LICENCE LIMITS**

Discharge Parameter*	As per Original IPC Application		Current IPC Licence		Average Current Discharge (i.e. Start-up)		Discharge When Full Production Achieved		Requested IPPC Licence Limits	
	mg/l	kg/d	mg/l	kg/d	mg/l	kg/d	mg/l	kg/d	mg/l	kg/d
BOD	500	825	500	1,000	<500	<1,000	15	8.3	500	1,000
COD	615	1,015	1,250	2,500	<1,250	<2,500	342	190.5	1,250	2,500
Suspended solids	107	176	500	1,000	<500	<1,000	83	46.2	500	1,000
Sulphates (as SO <sub>4</sub> )	500	825	500	1,000	<500	<1,000	122	67.9	500	1,000
Detergents	-	-	100	200	<100	<200	0.1	0.1	100 <sup>1</sup>	200 <sup>1</sup>
Fats, oils, grease	-	-	100	200			4	2.2	100 <sup>1</sup>	200 <sup>1</sup>
Total heavy Metals	5	8.25	5	10	<5	<10	<0.19	<0.1	5	10
Chloride	10,000	16,500	10,000	20,000	18,507	11,104	7,603	6,569	20,000	20,000
Phosphate (as P)	205	338	No limit applied	No limit applied	99	35	14.9	13	100	35
Max Flow/day (m <sup>3</sup> )	1,650		2,000		557		<2,000		1,800	
Max Flow/hr (m <sup>3</sup> )	-		84		24		<84		84	
pH	6-9		6-10		7.8		6-10		6-10	

\*All values are based on maximum average values expressed as mg/l and kg/day (except pH and flow). The source for current values is the company Annual Environmental Report 2005 or other internal monitoring and/or calculations.

Note <sup>1</sup> – Reduced monitoring frequency to bi-annually requested.

### Hydraulic Load

Following discussion with Fingal County Council, BMS Cruiserath proposes to reduce the maximum daily hydraulic load by 10%.

### Phosphorus

BMS are seeking a phosphate limit of 100mg/l, 35 kg/d (as P) as discussed with Fingal County Council. The projected phosphate emission values (as mg/l and kg/d) are approximately 300kg/day below the values submitted as part of the original IPC licence application. It is noted that the design load at the Ringsend WWTP for phosphorus (as P) is 3,700 kg/d and that in this context the input by BMS is not significant (<1% of design load).

### Chloride

While the current and projected chloride loads (kg/d as Cl) are comfortably within the IPC limits, the projected chloride concentrations are not. While it is recognised that the rationale for the chloride concentration standard is that values above 10,000 mg/l Cl can potentially impair biological treatment performance BMS contend that in the context of the discharge to such a large WWTP (Ringsend - Dry Weather Flow 4.55m<sup>3</sup>/sec, 393,120 m<sup>3</sup>/day) the peak concentration will be rapidly diluted to below the 10,000mg/l value in the sewer, even before arriving at Ringsend. It is estimated that this discharge would on average add approximately 11.5 mg/l of Chloride to the existing Ringsend load. Therefore BMS are seeking an increase (to 20,000 mg/l) in the concentration limit, but no increase in the current mass emission limit would be necessary.

### Fats Oils and Grease

The monitoring results clearly indicate that the operations at Cruiserath are not a notable source of fats, oils and grease. The FOG maximum average concentration is 4mg/l compared to the 100mg/l limit, consequently it is apparent that the current necessity for monitoring of this parameter is of little environmental value, and we will be seeking to have the frequency of monitoring for this parameter reduced to bi-annually.

### Detergents

The monitoring results indicate that the operations at Cruiserath are an insignificant source of detergents. The maximum average concentration is 0.1mg/l compared to the 100mg/l limit, and 0.1kg/Day against a 200kg/day limit. Consequently it is apparent that the current necessity for frequent monitoring of this parameter is of little environmental value and we will be seeking to have the frequency of monitoring for this parameter reduced to bi-annually.

### Waste Disposal

The disposal of sludge from BMS Cruiserath is via AVR Safeway's plant from where it is shipped to Shanks, Roeselare Belgium and then on to Holcim Ltd Belgium to be used as a waste derived fuel in a cement Kiln. BMS Cruiserath also intends to retain the alternative of liquid sludge disposal to Ringsend MWWTP should this disposal route be unavailable.

BMS Cruiserath propose to consign certain aqueous waste streams to Swords Laboratories WWTP for treatment. It is also proposed to accept certain aqueous waste streams into the Cruiserath WWTP from the Swords Laboratories site for treatment.

BMS Cruiserath also wish to have the licence amended to provide for the disposal of aqueous washing liquids and mother liquors (EWC 07 05 01) in the incinerator, which is not currently provided under schedule 3(ii) of the current licence.

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## **E.2: Emissions Monitoring and Sampling Points**

Identify any revised monitoring and sampling points and outline any revised or updated proposals for the monitoring of emissions.

**Attachment N<sup>o</sup> E.2** should contain an updated drawing (no larger than A3) detailing all proposed monitoring points including National Grid References (12 digit 6E, 6N).

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### **Proposed Increase in NO<sub>x</sub> Emission Limit Value**

At present, an emission limit value of 100mg NO<sub>x</sub>/m<sup>3</sup> is currently assigned for NO<sub>x</sub> emissions at the BMS Cruiserath facility. It is requested that this value be increase to 200 mg NO<sub>x</sub>/m<sup>3</sup> in accordance with the recommended ELVs as set out in *Annex V* of Directive 2000/76/EC on the incineration of waste (Waste Incineration Directive).

Air Dispersion Modelling has confirmed that an increase in the ELV to 200mg/m<sup>3</sup> does not have an adverse impact on Air Quality Standards (See **Attachment N<sup>o</sup> E.2**).

### **Proposed Change to Monitoring of Incoming Hazardous Waste Shipments**

#### **Current Practice:**

Wastes are imported from Swords Laboratories for disposal and recycling in BMS Cruiserath. At Swords Laboratories the waste storage tank is sampled and analysed for organic solvent composition, water content and residue on evaporation. This is to provide sufficient information for classification of the waste for transportation purposes.

Two road tankers transport the waste to BMS Cruiserath where each tanker is sampled and unloaded to the HCV or LCV storage tank for incineration.

Each tanker samples is re-analysed as per IPC licence P0552-01 for organic solvent composition, water content, residue on evaporation, calorific value, halogens and metals. This leads to unnecessary duplication of analysis.

#### **Proposed Practice:**

At Swords Laboratories the waste storage tank is sampled and analysed for organic solvent composition, water content and residue on evaporation. This is to provide sufficient information for classification of the waste for transportation purposes.

The tankers are unloaded to the HCV or LCV storage tank for incineration.

The sample from Swords Laboratories is analysed for calorific value, Halogens and metals. It is proposed that the organic solvent composition, water content and residue on evaporation parameters from Swords will meet the requirements of the P0552-02 licence for BMS Cruiserath therefore removing the requirement for duplicate analysis at the BMS Cruiserath facility.

### Advantages of the Proposal:

The reduction of sampling from each batch of waste (i.e. from three samples to one) will reduce time and the costs per load, and will reduce duplication of analysis. In effect this proposal will eliminate sampling and reduce analysis by half.

### Proposed Change to Contingency Monitoring for the Incinerator

Condition 7.7.1 of the existing IPC Licence, Register No. P0552-01, in agreement with the Agency, makes allowance for contingency monitoring in the event of failure of a continuous monitoring system, thus allowing the continued operation of the incinerator. It is therefore requested that a contingency monitoring regime for the Incinerator system for specified parameters, as outlined below in the following table, be implemented.

**TABLE E.2.1 – CONTINGENCY MONITORING FOR INCINERATOR (A2-1) EMISSIONS**

Analyser on incinerator stack A2-1	Parameter(s) Measured	Contingency		Justification
		Monitoring Response	Operational Response	
Durag	Dust	No additional monitoring in the event of online Durag failure	Incinerator operation to be continued	Historically, there are no dust emissions (<2mg/m <sup>3</sup> ). Provided dust abatement is operational Incinerator operation to be continued. See also Attachment N <sup>o</sup> D.1.C.
FTIR	NO <sub>x</sub> SO <sub>x</sub> CO NH <sub>3</sub> HCl	Daily Grab sampling and analysis for NO <sub>x</sub> , SO <sub>x</sub> , HCl and CO.	Stop burning liquid waste & burn VOC gas stream only.	The most efficient and BAT compliant mode for the abatement of VOC waste gases is Thermal Oxidisation. Provided Incinerator remains within its normal operational range it is proposed that VOC waste gases will continue online to the incinerator.
FID	TOC	Monitoring using absorbent tubes every for 1 hour in every 12 hours	Stop burning liquid waste & burn VOC gas stream only.	The most efficient and BAT compliant mode for the abatement of VOC waste gases is Thermal Oxidisation. Provided Incinerator remains within its normal operational range it is proposed that VOC waste gases will continue online to the incinerator.
Normalisation of Pollutants	Oxygen	Use unnormalised data	Stop burning liquid waste & burn VOC gas stream only.	The DCS has alarms for non-normalised emission data.

**Proposed Change to Contingency Monitoring for Emissions to Sewer**

In the event of failure of continuous online monitoring of specified parameters for emissions to sewer, it is requested that the following contingency monitoring measures be approved by the Agency:

**TABLE E.2.3 – CONTINGENCY MONITORING FOR W1 (SE-1) EMISSIONS TO SEWER**

<b>Analyser on W1 (SE-1)</b>	<b>Parameters Measured</b>	<b>Contingency Monitoring Proposed</b>
pH meter	pH	Daily composite sample taken
Conductivity	Conductivity	Daily composite sample taken
Total Organic Carbon Units	TOC	Daily composite sample taken

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## SECTION F ACCIDENT PREVENTION & EMERGENCY RESPONSE

Describe the existing or proposed accident prevention measures and procedures. Provide details of emergency procedures to minimise the impact on the environment of an accidental emission or spillage.

Also outline what provisions have been made for response to emergency situations outside of normal working hours, i.e., during night-time, weekends and holiday periods.

Describe the arrangements for abnormal operating conditions including start-up, leaks, malfunctions or short-term stoppages.

Supporting information should form **Attachment N<sup>o</sup> F**.

### Accident Prevention

BMS Cruiserath is a lower tier SEVESO II Site and as such is required under Directive 96/82/EC on the Control of Major Accident Hazards involving dangerous substances (SEVESO II) and European Communities (Control of Major Accident Hazards involving Dangerous Substances) Regulations, (S.I. No. 476 of 2000, S.I. No. 402 of 2003 & S.I. 74 of 2006) to prepare a major accident prevention policy (MAPP).

The Major Accident Hazards Regulations provide members of the EC with uniform rules for:

- The prevention of serious industrial accidents or limitation of damage in the event of an accident, and
- The avoidance of environmental damage.

It shall be the duty of every operator to prepare a document which specifies the manner in which major accidents are to be prevented (the major accident prevention policy (MAPP)). The MAPP outlines the company's policy to identify and prevent all major accidents, both on and off-site. See **Attachment N<sup>o</sup> F** for an overview of the accident prevention measures and personnel responsible at the facility.

### Emergency Operations Plan

BMS Cruiserath has in place an Emergency Operations Plan which describes in detail the responsibility of personnel and the information required during an emergency at the facility (See **Attachment N<sup>o</sup> F**).

The site has a policy on the safe shut-down of plant in emergency situations which outlines the response to be taken to safely shut-down plant in the event of an evacuation from that plant or in any emergency situation, and where applicable, the safe start-up of plant. This policy is implemented through Standard Operating Procedures.

## **HSA Auditing**

The Health and Safety Authority carries out an on-site inspection at least annually. Topics covered include a Seveso review, reported accidents and incidents and a general site tour. In addition, periodically a specific safety system is audited in detail using a safety proforma e.g. the permit-to-work system.

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## SECTION G RESOURCE USE & ENERGY EFFICIENCY

*Provide a description of resources used, energy used or energy generated by the activity.*

\*\*\*\*\*

BMS Cruiserath production processes require controlled environmental conditions, which are energy intensive. These requirements have resulted in a large standing use of energy within the plant. This high standing energy usage of energy is a common feature of pharmaceutical plants. The plant operates 24hrs/7days per week throughout the year.

The principal energy sources used on site are Natural Gas, Heating Oil and Electricity. Water is also used in large volumes.

**TABLE G.1 – RESOURCE USE IN 2005**

Resource Use (Units)	2005	Usage 2005 (Unit/kg Product)
Electricity (MWhr)	33,234	23.531
Natural Gas (m <sup>3</sup> )	6,198,195	0.126
Heating Oil (L)	12,300	0.047
Municipal water supply (m <sup>3</sup> )	279,540	1.061

*Provide summary information on the details and results of any previously conducted audit of the energy efficiency of the site. (See note 1 below in relation any proposal to carry out an audit.)*

\*\*\*\*\*

Condition 10 of Integrated Pollution Control Licence Register No. P0552-01, requires an audit of the energy efficiency of the site. The audit programme was performed in accordance with the “Guidance Note on Energy Efficiency Auditing of July 2003”. This requires the submission of a summary of the audit finding as part of the Annual Environmental Report. This audit was carried out and submitted to the EPA in the Annual Environmental Report of 2005.

The site energy consumption for 2005 was 102,275,400 kWh. This represents a 2% reduction on the usage in 2004 (104 million kWh), even though the site manufacturing output increased by greater than 700%. Metering to date indicates that 82% of the natural gas was burned in the incinerator.

**TABLE G.2 – SUMMARY OF PURCHASED ENERGY FOR 2005**

<b>Energy Stream</b>	<b>Annual Quantity 2004</b>	<b>Annual Quantity 2005</b>	<b>Units</b>	<b>Comments 2005</b>
Electricity	28,916,645	33,250,000	kWh	32.5% of site energy usage
Natural Gas	75,491,645	68,900,000	kWh	67.4% of site energy usage
Fuel Oil	105,613	125,400	kWh	0.1% of site energy usage
<b>Total</b>	<b>104,513,903</b>	<b>102,275,400</b>	<b>kWh</b>	

***Outline the measures taken to ensure that resources and energy are used efficiently in the operation.***

Efficient resource and energy management has been reviewed in detail in Section 19 of the original IPC Licence Application, Register No. P0552-01. As part of the BMS Cruiserath Site Environmental Management System, resource and energy consumption is continuously monitored for opportunities to reduce any potential environmental impacts where possible.

**Note 1:** Any proposed audit which is to be conducted after the submission of this application shall be carried out in accordance with the guidance published by the Agency "Guidance Note on Energy Efficiency Auditing". The audit shall identify all opportunities for energy use reduction and efficiency.

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## SECTION H REMEDIATION, DECOMMISSIONING, RESTORATION & AFTERCARE

Describe the existing or proposed measures to minimise the impact on the environment after the activity or any part of the activity ceases operation, including provision for post-closure care of any potentially polluting residuals.

Supporting information should be included as **Attachment No. H**.

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It is proposed, under condition of the revised Licence, to prepare a Residuals Management Plan (RMP), Environmental Liabilities Risk Assessment (ELRA) and Financial Provisions (FP) in order to minimise the impact on the environment after the activity or any part of the activity ceases operation, including provision for post-closure care of any potentially polluting residuals. The RMP, ELRA and FP will be carried out having reference to the *Guidance on Environmental Liability Risk Assessment, Residuals Management Plans and Financial Provision* issued by the EPA in August of 2006.

The guidance note sets out a number of steps that will be adhered to in the preparation of the RMP, ELRA and FP. The first step in the process is an initial screening step which will classify the site as low, medium or high risk and thereby determine the specific RMP, ELRA, and FP requirements that apply to the facility. The second step is the preparation of the Residual Management Plan which will include costing. The RMP will deal with the site closure process and the known liabilities for the facility at closure. Step three is the preparation of the Environmental Liability Risk Assessment.

In accordance with the Guidance, a site specific ELRA is recommended for high risk sites with potential environmental liabilities. This ELRA will cover environmental risks leading to a potential or anticipated liability. Once the known liabilities (RMP) and unknown liabilities (ELRA) have been identified the fourth step of financial provisioning can commence. The main objectives of this process will be to ensure that sufficient financial resources are available to cover environmental liabilities at closure and that are associated with the aftercare and maintenance of the BMS Cruiserath facility and any unknown environmental liabilities that may occur during the operating life of the facility.

## SECTION I STATUTORY REQUIREMENTS

### 1. The applicant should provide the following information:

- (i) Indicate how the requirements of Section 83(5)(a)(i) to (iv) of the EPA Acts 1992 and 2003 shall be met, having regard, where appropriate, to any relevant specification issued by the Agency under section 5 (3) of the Act and the reasons for the selection of the arrangements proposed.

#### *Section 83(5) (a) (i)*

*“Any emissions from the activity will not result in the contravention of any relevant air quality standard specified under section 50 of the Air Pollution Act 1987, and will comply with any relevant emission limit value specified under section 51 of the Air Pollution Act 1987”.*

Cumulative Air dispersion modelling for on site air emissions (main & boiler emissions) was carried out as part of this Review Application (see **Attachment N<sup>o</sup> E.2**). The ground level concentrations of sulphur dioxide (SO<sub>2</sub>), nitrogen dioxide (NO<sub>2</sub>), particulates, ammonia and carbon monoxide (CO) were predicted. All parameters were found to be well below the 1987 & 2002 Air Quality Standard (AQS) limit values.

Historical monitoring data for emissions of dioxins, hydrogen chloride, hydrogen fluoride and metals also demonstrate compliance with the existing IPC licence conditions, Register No. P0552-01.

For details of present day emissions to atmosphere from the facility and their treatment, abatement, control and monitoring, refer to Sections D.1 and E of this Application.

#### *Section 83(5) (a) (ii)*

*“Any emissions from the activity will comply with, or will not result in the contravention of, any relevant quality standard for waters, trade effluents and sewage effluents and standards in relation to treatment of such effluents prescribed under Section 26 of the Local Government (Water Pollution) Act 1977 and 1990”.*

Section 26 enables the Minister for the Environment to set quality standards for water, trade effluent and sewage. This is generally implemented by a licensing system operated by the Local Authorities under Section 16 of the Act.

BMS Cruiserath are in possession of an IPC Licence (No. P0552-01) issued by the EPA which specifies limits for discharges to sewer. BMS Cruiserath are currently operating within those licence limits.

The site does not discharge emissions directly to surface water bodies. Uncontaminated Surface water from hard-standing areas is discharged to the local authority stormwater drainage network.

Trade and domestic effluent emissions from the facility are discharged to the municipal WWTP via the on-site WWTP. The site is equipped with a state-of-the-art wastewater treatment system to meet and exceed all relevant IPC licence limits.

An environmental management system is in place which focuses on the safe and efficient operation and maintenance of the onsite WWTP facilities to ensure compliance with all relevant regulatory requirements. Therefore the above discharges to waters do not result in any contravention of quality standards made under the Local Government (Water Pollution) Acts, 1977 and 1990.

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**Section 83(5) (a) (iii)**

***“Any emissions from the activity of any premises, plant, methods, processes, operating procedures or other factors which affect such emissions will comply with, or will not result in the contravention of, any relevant standard including any standard for an environmental medium prescribed under regulations made under the European Communities Act 1972, or under any other enactment”.***

The relevant standards for emissions to air and water have been discussed in Sections 83(5) (a) (i) and 83(5) (a) (ii) respectively. The Waste Management Act, 1996 to 2003 and regulations made thereunder, provide a comprehensive legal framework for the management and control of waste in Ireland. Regulations which have been made pursuant to the Act which would be relevant to the operation of the facility include regulations on hazardous waste, the transport of hazardous waste and packaging waste. A Waste Management Programme is implemented at the facility and BMS Cruiserath comply with all applicable statutory provisions relating to waste management.

The facility was designed to operate utilising the best available techniques (BAT) in compliance with application regulations, so no such contraventions have occurred or are anticipated in the future.

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**Section 83(5) (a) (iv)**

***“Any noise from the activity will comply with, or will not result in the contravention of any regulations under Section 106”.***

Section 106 of the EPA Act 1992 enables the Minister for the Environment and Local Government to make regulations for the purpose of the prevention or limitation of any noise which may cause a nuisance. The existing IPC Licence (Register No. P0552-01) states noise emission limits at the nearest noise sensitive locations (NSL) of 55dB(A) & 45dB(A) for night-time and daytime noise emission levels respectively in accordance with the EPA *Guidance Note for Noise in Relation to Scheduled Activities (2<sup>nd</sup> Edition) 2006*.

Annual noise monitoring for the years 2005 & 2006 entailed monitoring at 5 No. site boundary locations and 1 No. Noise sensitive receptor located approximately 600m west of the site boundary for daytime & night-time noise emission levels. Although noise monitoring survey results for 2005 & 2006 recorded the average noise emission levels (LA<sub>eq</sub>) to be greater than the IPC licence limits, the surveys also revealed that off site traffic noise levels were the most significant contributor to the LA<sub>eq</sub> emissions from the BMS site.

As detailed in the BMS Cruiserath Annual Environmental Reports for 2005 & 2006, an examination of the LA<sub>10</sub> (indicator of traffic noise) noise monitoring results demonstrates that the background noise levels (i.e. traffic noise) contribute to the LA<sub>eq</sub> noise emission levels monitored. In addition, the LA<sub>90</sub> (indicator of background noise) results recorded at the NSL for 2005 & 2006 ranged from 48dBA (Daytime) 39.5dBA (Night-time) respectively, less than the relevant Licence limit of 55dBA and 45dBA. These levels are a good indicator of background noise levels at the BSL in the absence of passing road traffic. Therefore, the daytime and night-time noise levels (LA<sub>eq</sub>) recorded at the NSL greater than the relevant Licence limits are not associated with on site activities at the BMS site.

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- (ii) **Indicate whether or not the activity is carried out on, or may be carried out on, or is located such that it is liable to have an adverse effect on:-**
- (a) **a site placed on a list in accordance with Chapter 1 of S.I. No. 94 of 1997, or**
  - (b) **a site where consultation has been initiated in accordance with Article 5 of the EU Habitats Directive (92/43/EEC).**

The BMS Cruiserath facility is not located on an existing or candidate/proposed Special Area of Conservation (SAC), Natural Heritage Area (NHA) or Special Protection Area (SPA). However, there are a number of designated areas located within a 10km radius of the facility. These comprise proposed Natural Heritage Areas and are isolated from the pharmaceutical plant.

**TABLE I.1 – NATURAL HERITAGE AREAS**

NPWS Code	Site Name	Designation	Distance from BMS Site
002103	Royal Canal	pNHA	3km S
001208	Liffey Valley	pNHA	4.5km S
002104	Grand Canal	pNHA	8.5km S
000178	Santry Demesne	pNHA	9km E

Uncontaminated surface water run-off drains from the site into the stormwater drainage network. As the surface water runoff is uncontaminated the emission of surface water to the stormwater system does not have any adverse impact on

these designated areas. Emissions to atmosphere from the facility do not give rise to ground level concentrations of parameters which could have an adverse impact on designated areas. There are no other significant environmental emissions from the facility which could adversely impact the designated areas. The operation of the facility does not have any adverse effect on the integrity of existing or proposed/candidate Special Areas of Conservation (SAC), Natural Heritage Areas (NHA) or Special Protection Areas (SPA).

Therefore the BMS facility does not have an adverse effect on the integrity of:

- (a) a site placed on a list in accordance with Chapter 1 of S.I. 94 of 1997, or
- (b) a site where consultation has been initiated in accordance with Article 5 of the EU Habitats Directive (9/43/EEC).

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- (iii) ***Indicate whether or not the activity is liable to have an adverse effect on water quality in light of S.I. No. 258 of 1998 (Local Government (Water Pollution) Act, 1977 (Water Quality Standards for Phosphorus) Regulations, 1998).***

BMS Cruiserath does not have any discharges to surface waters. Uncontaminated stormwater from the site is discharged to the local stormwater drainage system. Effluent emissions are discharged via on site WWTP to the local authority municipal WWTP. Therefore the facility does not have any effect on surface water quality with regards to SI 258 of 1998 Local Government (Water Pollution) Act, 1977 (Water Quality Standards for Phosphorus) Regulations, 1998.

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- (iv) ***Indicate whether any of the substances specified in the Schedule of the EPA (Licensing)(Amendment) Regulations, 2004 (S.I. No. 394 of 2004) are discharged by the activity to the relevant medium and whether the emission of these substances are likely to have an adverse effect on the environment.***

**AIR**

(1) Sulphur dioxide and other sulphur compounds	Combustion sources: not significant. Within Air Quality Limits
(2) Oxides of nitrogen and other nitrogen compounds	Combustion sources: NOx within Air Quality Limits
(3) Carbon monoxide	Combustion sources: not significant. Within Air Quality Limits
(4) Volatile organic compounds	Within Air Quality Limits
(5) Metals and their compounds	Within Air Quality Limits
(6) Dust	Particulates only from the combustion of diesel oil in the emergency generators and

	firewater pumps
(7) Asbestos (suspended particles, fibres)	No
(8) Chlorine and its compounds	HCl: Within Air Quality Limits
(9) Fluorine and its compounds	HF: Within Air Quality Limits
(10) Arsenic and its compounds	Within Air Quality Limits
(11) Cyanides	No
(12) Substances and preparations which have been proved to possess carcinogenic or mutagenic properties or properties which may affect reproduction via the air	No
(13) Polychlorinated dibenzodioxins and polychlorinated dibenzofurans	Within Air Quality Limits

#### WATER – EMISSION TO SEWER

(1) Organohalogen compounds and substances which may form such compounds in the aquatic environment	No
(2) Organophosphorus compounds	No
(3) Organotin compounds	No
(4) Substances and preparations which have been proved to possess carcinogenic or mutagenic properties or properties which may affect reproduction in or via the aquatic environment	No
(5) Persistent hydrocarbons and persistent and bioaccumulable organic toxic substances	No
(6) Cyanides	No
(7) Metals and their compounds	Within IPC licence limits
(8) Arsenic and their compounds	No
(9) Biocides and plant health products	Controlled as per IPC licence Condition
(10) Materials in suspension	Within IPC licence limits
(11) Substances which contribute to eutrophication (in particular, nitrates and phosphates)	Yes – Phosphate present. Treated at Ringsend WWTP. No IPC licence limit assigned.
(12) Substances which have an unfavourable influence on the oxygen balance (and can be measured using parameters such as BOD, COD, etc.)	Within IPC licence limits

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- (v) *State whether the activity is an establishment to which the EC (Control of Major Accident Hazards involving Dangerous Substances) Regulations, 2000 (S.I. No. 476 of 2000) apply.*

Note that regulations S.I. 476 of 2000 have been superseded by S.I. No. 74 of 2006. BMS Cruiserath is classified as a lower tier site.

## 2. **Fit and Proper Person:**

The EPA Acts, 1992 and 2003 (Section 83(5)(xi)) specifies that the Agency shall not grant a licence unless it is satisfied that the applicant or licensee or transferee as the case may be is a fit and proper person. Section 84(4) of the Act specifies the information required to enable a determination to be made by the Agency. In order for the Agency to make a determination the following is to be provided:

- ***Indicate whether the applicant or other relevant person has been convicted under the PoE Act, the Waste Management Act 1996, the Local Government (Water Pollution) Acts 1977 and 1990 or the Air Pollution Act 1987.***

It is confirmed that neither the applicant nor any other relevant person has been convicted of an offence under the EPA Acts 1992 to 2003, the Waste Management Acts, 1996 to 2003, the Local Government (Water Pollution) Acts 1977 and 1990 or the Air Pollution Act 1987.

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- ***Provide details of the applicant's technical knowledge and/or qualifications, along with that of other relevant employees.***

The BMS recruitment policy ensures that necessary personnel have the requisite technical knowledge and qualifications to carry all site activities, including the ability to carry out those activities in accordance with the licence.

The site has an Environmental department and team that is dedicated to environmental management of site operations. This ensures the day to day operation of the wastewater treatment plant, Incinerator and waste acceptance are done in accordance with the companies internal procedures as well as all legal requirements including the IPC Licence.

The Environmental Laboratory operates a management system (ISO:17025). The environmental management team also drives continuous improvement measures and is committed to implementing environmental excellence measures. The site is supported by a Corporate Environmental division that provides technical assistance and resources where required.

The applicant is the Director of Environmental Health and Safety and under the terms of Section 84(4) of the PoE Act qualifies as a "*Fit and Proper Person*", being qualified in Environmental Management with 19 years relevant experience in this field, 10 years of this in an Environmental, Health and Safety role within major international pharmaceutical facilities. Duties are as detailed in the attached Job Specification (**Attachment N<sup>o</sup>. I**).

The Environmental Manager manages the Environmental function and reports to the Director of Director of Environmental Health and Safety as per the

attached Job Specification (**Attachment N<sup>o</sup>. I**). He holds various third level qualifications in the areas of Environment, Health and Safety. The Environmental Manager has 8 years experience in the pharmaceutical industry, and in an environmental, health and safety role with a major international pharmaceutical facility.

The Director of Environmental Health and Safety represents the EHS function at management board level and reports directly to the General Manager.

The facilities Technical Services Department manages site maintenance, Utilities and Technical Services. The Technical Services function manages the operation of the Incinerator, back up abatement Cryogenic system, the waste water treatment Plant, and drive continuous improvement in the areas of Pollution Prevention, Waste Management and emissions control. The Technical Services Director is a qualified Chemical Engineer with 11 years Engineering and Manufacturing experience within the Chemical & Pharmaceutical industry. Responsibilities are as detailed in the attached Position Profile (**Attachment N<sup>o</sup>. I**). The Technical Services Director is represented at management board level and reports directly to the General Manager.

The Technical Services Manager is responsible for the operation and day-to-day management of the Incinerator, Cryogenic system, the waste water treatment Plant, Solvent Recovery and all Hazardous waste management, and reports to the Director of Technical Services. The post holder is a qualified Chemical Engineer with over 14 years experience within the Pharmaceutical industry. Responsibilities are as detailed in the attached Position Profile (**Attachment N<sup>o</sup>. I**).

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- ***Provide information to show that the person is likely to be in a position to meet any financial commitments or liabilities that may have been or will be entered into or incurred in carrying on the activity to which the application relates or in consequence of ceasing to carry out that activity.***

BMS is in a position to meet all reasonable financial commitments & liabilities that have been or will be entered into or incurred by carrying on the activity to which the license relates.

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### **3. Obligations as set out in the IPPC Directive (96/61/EC)**

The Agency shall ensure that installations are operated in accordance with basic obligations as set out in Article 3 of the IPPC Directive (96/61/EC). Article 6 of the IPPC Directive (96/61/EC) specifies that a description of the measures in place to ensure compliance with the general principles of the basic obligations of the operator shall be part of the application.

Describe the measures proposed or in place to ensure that:

- (a) ***The best available techniques are or will be used to prevent or eliminate or, where that is not practicable, generally reduce an emission from the activity;***

Refer to Section D.6 of this application.

- (b) ***no significant pollution is caused;***

Refer to Section D.1, D.2, D.3, D.4 and D.5 of this application

- (c) ***waste production is avoided in accordance with Council Directive 75/442/EEC of 15 July 1975 on waste; where waste is produced, it is recovered or, where that is technically and economically impossible, it is disposed of while avoiding or reducing any impact on the environment;***

The Waste Management Act, 1996 to 2003 and regulations made thereunder, provide a comprehensive legal framework for the management and control of waste in Ireland. Regulations which have been made pursuant to the Act which would be relevant to the operation of the facility include regulations on hazardous waste, the transport of hazardous waste and packaging waste. A Waste Management Programme is implemented at the facility and BMS Cruiserath comply with all applicable statutory provisions relating to waste management.

- (d) ***energy is used efficiently;***

Refer to Section G of this application

- (e) ***the necessary measures are taken to prevent accidents and limit their consequences;***

Refer to Section F of this application

- (f) ***the necessary measures are taken upon definitive cessation of activities to avoid any pollution risk and return the site of operation to a satisfactory state.***

Refer to Section H of this application

Supporting information should be included as **Attachment N<sup>o</sup> I** with cross-references to where the relevant information can be found in other parts of this review application.

**SECTION J DECLARATION**

**Declaration**

I hereby make application for a revised licence, pursuant to the provisions of the Environmental Protection Agency Acts, 1992 and 2003 and Regulations made thereunder.

I certify that the information given in this application is truthful, accurate and complete.

I give consent to the EPA to copy this application for its own use and to make it available for inspection and copying by the public, both in the form of paper files available for inspection at EPA headquarters and via the EPA's website. This consent relates to this application itself and to any further information, submission, objection, or submission to an objection whether provided by me as Applicant, any person acting on the Applicant's behalf, or any other person.

Signed by : Ian Boyle  
(on behalf of the organisation)

Date : 31<sup>st</sup> OCTOBER 2006

Print signature name: Ian Boyle

Position in organisation : Director of Environmental Health and Safety

Company stamp or seal:

