Permitting decisions

Bespoke permit.

We have decided to grant the permit for **Cambridge Science Park** operated by **Johnson Matthey Plc**

The permit number is **EPR/JP3739JH**

We consider in reaching that decision we have taken into account all relevant considerations and legal requirements and that the permit will ensure that the appropriate level of environmental protection is provided.

Purpose of this document

This decision document provides a record of the decision making process. It summarises the decision making process in the decision checklist to show how all relevant factors have been taken in to account.

This decision document provides a record of the decision making process. It:

- highlights key issues in the determination
- summarises the decision making process in the decision checklist to show how all relevant factors have been taken into account
- shows how we have considered the consultation responses.

Unless the decision document specifies otherwise we have accepted the applicant's proposals.

Read the permitting decisions in conjunction with the environmental permit. The introductory note summarises what the permit covers.

Key issues of the decision

1. Introduction

This is a new installation. In practice this is an existing facility which operated as a Research and Development facility alone and is moving to a combination of Research and Development and Commercial Production. This change is leading to the requirement for an installation EPR permit for the chemical activities on site.

The installation is a chemical manufacturing site with three specific scheduled 4.1 A (1) (ii) activities:

All operations are contained within a single building comprising Unit 28 of the Cambridge Science Park. The principal operations are

- Bio-catalysis - commercial production using biological fermentation and separation processes and R&D work.
- Chemo Catalysis - small scale production of chemicals and R&D work.
- Pharma Services - small scale R&D alone not commercial production work for external companies. This can include sending out samples.

Overall the Applicant has presented operating techniques which has shown the site is in compliance with relevant BAT measures as outlined in our TGN EPR 4.02 Speciality Organic Chemicals Sector, without the requirement for improvement conditions

The installation is to be operated under the envelope of a Multi-Product Protocol (MPP) in line with our MPP guidance (report reference GEHO0511BTUN-E-E). The MPP is discussed in more detail below.

2. Activities

The pharma services process has been confirmed by the applicant as not being defined as production of Active Pharmaceutical Ingredients (API's) based on our guidance RGN No.2 Understanding the meaning of the regulated facility- Appendix 2.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/435475/LIT_6529.pdf

Specifically Note 4.2 of this guidance under the chemical section defines a threshold of exceeding 20 kg per product per year which would lead to process being classed as manufacture of API's. This installation does not operate at this level and hence we have not ascribed a "*4.5 (a) Producing pharmaceutical products"* scheduled activity for this process. Instead we have allocated the chemical activity which is the most apt description which is 4.1 A (1) (a) (ii), which is the same as other scheduled activities within the installation.

(a) Producing organic chemicals such as

(ii) organic compounds containing oxygen, (for example alcohols, aldehydes, ketones, carboxylic acids, esters, ethers, peroxides, phenols, epoxy resins);

3. H1

Air

The Applicant provided a H1 assessment with their final H1 assessment submitted 14/05/18. The air emission parameters linked to this installation are as follows:

- Acetic Anhydride
- Acetonitrile
- Ammonia
- Chloroform
- Di-isopropyl Ether
- Formaldehyde
- Methanol
- Ortho phosphoric Acid
- Sulphuric Acid
- Tetrahydrofuran
- Toluene

The Applicant has utilised estimates for inputs to the H1 assessment and a worst case production for each of the three processes (Bio-catalysis, Chemo Catalysis and Pharma services) of operating a maximum of 5 % of annual hours.

H1 screening.

The above data was used to perform a H1 screening. The H1 assessment utilized our H1 screening tool to create the output long and short term process contributions and then these were compared against the relevant long and short term Air Quality Standards.

Step 1

The emissions which warrant further investigations are

- PC (Long term) >1% of the LT Environmental benchmark.
- PC (Short term) >10% of the ST environmental benchmark.

Assessment

A summary of the results of the Application H1 assessment of emissions to air are as follows utilising assumptions as described above:

- For all the parameters the long term process contributions are < 0.03 % of the relevant long term Air Quality Standard
- For all the parameters the short term process contributions are < 0.2 % of the relevant short term Air Quality Standard

H1 Step 1 Screening Conclusion

- All parameters are an order of magnitude below the screening criteria for insignificance. Hence for all the parameters the installation atmospheric emissions impact are classed as insignificant and no further assessment is required.

NO_2/Oxides of Nitrogen assessment

The A11 and A12 boilers combined thermal input is less than 1 MW based on standard gas boiler design, with usage for both process and general site facilities steam usage with operation no more than 3000 hours per annum.

We have concluded from our experience of similar facilities that on the above basis the impacts from these two boilers are assessed as insignificant.

Therefore no further assessment is required.

Particulates

In the kilo lab for pharma services the particulate emissions are abated by HEPA filters with 99.95 % abatement

The operator is not able to fully estimate the particulate emission from the kilo lab but has provided re-assurance via a worst case scenario
The maximum emission potential of approximately 0.00009 g/s would be equivalent to a short term process contribution of 0.3 µg/m3 which is 0.6 % of Short Term Air Quality Standard for PM10 and clearly insignificant from H1 criteria above.
Based on the size of the facility and order of magnitude of mass emissions of PM10 without any specific figures we have made a conclusion that the long term PM10 emission impact would also be insignificant.

H1 Effluent assessment

The operator completed a H1 assessment as part of their duly making response (submitted 20/03/18).

The process effluent discharges via a single sewage discharge point S1 via Cambridge Sewage Treatment Plant to the River Cam Estuary, as such this is an inland river discharge.

The Applicant has utilized the following worst case data

- Maximum installation effluent flow if 0.4 litres per second
- Long term average daily flow of 500 litres/day maximum
- 0.80 m3/second 95^{TH} percentile flow at Jesus Lock immediately upstream of the discharge of effluent treatment plant into the River Cam.

The assessment was carried out in line with our guidance *Permitting of hazardous pollutants in discharges to surface waters.*

Test 1: Does the concentration of the substance in the discharge exceed 10 percent of the EQS?

The results of the initial phase are as follows.

These assessments have been carried out on a conservative basis without the application of sewage treatment reduction factors and using actual date from process mass balances.

Parameter	Annual Average Long term EQS µg/l	ELV Long Term discharge emission µg/l	Maximum Allowable Concentration (MAC) Short Term EQS µg/l	ELV Short term discharge emission µg/l
Chlorides	2500000 *	11900	-	

Conclusion

The installation emissions screen out at test 1 for all relevant Environmental Quality Standards. Therefore no further assessment is required

3. Multi Product Protocol (MPP)

We required the operator to supply a MPP for the installation having regard to our MPP guidance (report reference GEHO0511BTUN-E-E). The final MPP submitted was dated 14/05/18 and document reference P162-R08-D5

The MPP covers

- The range of chemical processes.
- Chemical process equipment.
- Chemical process capacities per annum for each of three processes (Pharma Services, Bio-catalysis, chemo-catalysis).
- H1 assessment for worst case operating scenario providing worst case environmental impacts
- Operations detail criteria within section 7 of our guidance GEHO0511BTUN-E-E)
- Change control protocols – including a commitment to a commissioning report submission to the Environment Agency for the first batch of any new product

Conclusion

We concluded that the installation MPP is acceptable. This MPP has been integrated into operating techniques table S1.2 and also the MPP condition has been added to the permit (condition 1.51)

4. Containment

Raw materials/wastes are stored within contained buildings/facilities. The installation included 200 Litre maximum drums which are stored only for short timescales externally in contained metallic containers.

Potential contaminants are stored in locked flame vaults which are fire retardant and bunded with corrosion resistant steel. Smaller drip trays are added to capture any potential leaks to provide double form of bund protection.

These containers ensure containment of all raw materials and waste materials comply with the criteria of volume > 110 % of individual storage tanks and > 25 % of aggregated total storage volumes within each bund.

Decision checklist

Aspect considered	Decision
Receipt of application	
Confidential information	A claim for commercial or industrial confidentiality has not been made.
Identifying confidential information	We have not identified information provided as part of the application that we consider to be confidential.
Consultation	
Consultation	The consultation requirements were identified in accordance with the Environmental Permitting Regulations and our public participation statement. The application was publicised on the GOV.UK website. We have consulted with • HSE • Cambridge Council Environmental Health Department The comments and our responses are summarised in the consultation section.
Operator	
Control of the facility	We are satisfied that the applicant (now the operator) is the person who will have control over the operation of the facility after the grant of the permit. The decision was taken in accordance with our guidance on legal operator for environmental

Aspect considered	Decision
	permits.
The facility	
The regulated facility	We considered the extent and nature of the facility at the site in accordance with RGN2 'Understanding the meaning of regulated facility', Appendix 2 of RGN 2 'Defining the scope of the installation'. The extent of the facility is defined in the site plan and in the permit. The activities are defined in table S1.1 of the permit.
The site	
Extent of the site of the facility	The operator has provided a plan which we consider is satisfactory, showing the extent of the site of the facility. The plan is included in the permit.
Site condition report	The operator has provided a description of the condition of the site, which we consider is satisfactory. The decision was taken in accordance with our guidance on site condition reports and baseline reporting under the Industrial Emissions Directive. The site condition report consists of the Applicant completion of our H5 site condition report template and a wider environmental assessment within document reference dated 20/03/18 P162-R03-F1.The assessment covers: • Site Details • Site Description • Environmental Setting • Land Pollution History • Fugitive emission controls including detail of metallic containers for external drum storage as discussed above in key issues section of this document under Containment Site Management have confirmed that they are not aware of any pollution incidents at the site. The site is not currently completing intrusive ground sampling at this stage as the Operator considers the site operations are well contained, small scale and with a high level of operating procedures to minimize risk of ground water and land contamination. They have accepted the risk of not taking such baseline monitoring prior to the EPR permit being granted. <u>Conclusion</u> We are satisfied that the controls within the installation as detailed within the above site condition report are satisfactory to minimize the risk of ground water and land contamination from the installation activities.
Biodiversity, heritage, landscape and nature conservation	The application is within the relevant distance criteria of a site of heritage, landscape or nature conservation, and/or protected species or habitat. There are no European/Ramsar Sites or Sites of Special Scientific Interest within the relevant screening distance of the installation. There are eight Other Conservation Sites within the 2km screening distance from the installation. We have assessed the application and its potential to affect all known sites of nature conservation, landscape and heritage and/or protected species or habitats identified in the nature conservation screening report as part of the permitting process.

Aspect considered	Decision
	We consider that the application will not affect any sites of nature conservation, landscape and heritage, and/or protected species or habitats identified. We have not consulted Natural England on the application. The decision was taken in accordance with our guidance.
Environmental risk assessment	
Environmental risk	We have reviewed the operator's assessment of the environmental risk from the facility. The operator's risk assessment is satisfactory.
Operating techniques	
Operating techniques for emissions that screen out as insignificant	Emissions of all atmospheric and effluent parameters listed above after H1 assessment have been screened out as insignificant, and so we agree that the applicant's proposed techniques are BAT for the installation.
Permit conditions	
Emission limits	We have decided that emission limits are not required in the permit.
Reporting	We have specified reporting in the permit under Table S4.1.
Operator competence	
Management system	There is no known reason to consider that the operator will not have the management system to enable it to comply with the permit conditions. The decision was taken in accordance with the guidance on operator competence and how to develop a management system for environmental permits.
Growth Duty	
Section 108 Deregulation Act 2015 – Growth duty	We have considered our duty to have regard to the desirability of promoting economic growth set out in section 108(1) of the Deregulation Act 2015 and the guidance issued under section 110 of that Act in deciding whether to grant this permit. Paragraph 1.3 of the guidance says: "The primary role of regulators, in delivering regulation, is to achieve the regulatory outcomes for which they are responsible. For a number of regulators, these regulatory outcomes include an explicit reference to development or growth. The growth duty establishes economic growth as a factor that all specified regulators should have regard to, alongside the delivery of the protections set out in the relevant legislation." We have addressed the legislative requirements and environmental standards to be set for this operation in the body of the decision document above. The guidance is clear at paragraph 1.5 that the growth duty does not legitimise non-compliance and its purpose is not to achieve or pursue economic growth at the expense of necessary protections. We consider the requirements and standards we have set in this permit are reasonable and necessary to avoid a risk of an unacceptable level of pollution. This also promotes growth amongst legitimate operators because the standards applied to the operator are consistent across businesses in this sector and have been set to achieve the required legislative standards.

Consultation

There were no responses from organisations to our consultation and no responses from the public to our www.gov.uk website advertising.