

# Permitting decisions

## Bespoke permit

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We have decided to grant the permit for Concept Life Sciences Kilo Facility operated by Concept Life Sciences Integrated Discovery & Development Services Limited.

The permit number is EPR/HP3900BG.

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.

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.

## Decision checklist

Aspect considered	Decision
<b>Receipt of application</b>	
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.
<b>Consultation</b>	
Consultation	<p>The consultation requirements were identified in accordance with the Environmental Permitting Regulations and our public participation statement.</p> <p>The application was publicised on the GOV.UK website.</p> <p>We consulted the following organisations:</p> <ul style="list-style-type: none"> <li>• Local Authority – Environmental Health</li> <li>• Health and Safety Executive</li> </ul> <p>No responses were received.</p>
<b>Operator</b>	
Control of the facility	<p>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 permits.</p> <p>During the determination (31/07/20) the operator changed their registered office address from One St Peter's Square, Manchester, M2 3DE to Heritage House, Church Road, Egham, TW20 9QD.</p>
<b>The facility</b>	
The regulated facility	<p>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', Appendix 1 of RGN 2 'Interpretation of Schedule 1', guidance on waste recovery plans and permits.</p> <p>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.</p> <p>The installation is not a solvent emission activity under Schedule 14 of EPR 2016 as the maximum projected total use of solvents does not exceed the solvent consumption threshold of 50 tonnes/year for manufacturing of pharmaceutical products.</p>
<b>The site</b>	
Extent of the site of the facility	The operator has provided plans which we consider are satisfactory, showing the extent of the site of the. The plan is included in the permit.

Aspect considered	Decision
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.
Biodiversity, heritage, landscape and nature conservation	<p>The application is within the relevant distance criteria of a site of heritage, landscape or nature conservation, and/or protected species or habitat.</p> <p>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.</p> <p>We consider that the application will not affect any sites of nature conservation, landscape and heritage, and/or protected species or habitats identified.</p> <p>We have not consulted Natural England on the application. The decision was taken in accordance with our guidance.</p>
<b>Environmental risk assessment</b>	
Environmental risk	<p>We have reviewed the operator's assessment of the environmental risk from the facility.</p> <p>The operator's risk assessment is satisfactory.</p> <p>The assessment shows that, applying the conservative criteria in our guidance on environmental risk assessment, all emissions may be categorised as environmentally insignificant.</p>
Climate change adaptation	<p>We have assessed the climate change adaptation risk assessment.</p> <p>We consider the climate change adaptation risk assessment is satisfactory.</p> <p>We have decided to include a condition in the permit requiring the operator to review and update their climate change risk assessment over the life of the permit.</p>
<b>Operating techniques</b>	
General operating techniques	<p>We have reviewed the techniques used by the operator and compared these with the relevant guidance notes and we consider them to represent appropriate techniques for the facility.</p> <p>The operating techniques that the applicant must use are specified in table S1.2 in the environmental permit.</p> <p>The operating techniques include the standards for BAT set out in:</p> <ul style="list-style-type: none"> <li>• the sector guidance note EPR 4.02 for the speciality organic chemicals sector which references other relevant European BAT reference documents (BREF); and,</li> <li>• the BREF and BAT conclusions on Common Waste Water and Waste Gas Treatment/management Systems in the Chemical Sector 2016.</li> </ul> <p>The operator will produce active pharmaceutical ingredients (API) to a Multi-product Protocol which meets the standards set out in our guidance on the use of a Multi-product Protocol (MPP) at Chemical production Installations version 5.0</p>

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	<p>May 2019. The MPP Version 2 (June 2020) is a key operating technique which restricts the activity to the scope of the MPP which includes the raw materials, production equipment, production capacity, annual operating hours, raw material consumption rates, emissions control and abatement techniques, emissions and emissions impacts included in the envelope of emissions assessed for the application. The envelope of emissions and emissions impacts, and the risk assessment methodology for assessment of emissions to air is described in the Environmental Risk Assessment version 3, revision 2 (17/07/20) which is also a key operating technique.</p>
<p>Operating techniques for emissions that screen out as insignificant</p>	<p>Emissions of the following pollutants have been screened out as insignificant, and so we agree that the applicant's proposed techniques are BAT for the installation:</p> <ul style="list-style-type: none"> <li>• Inorganic substances: <ul style="list-style-type: none"> <li>○ ammonia</li> <li>○ hypochlorite (as chlorine)</li> <li>○ hydrazine</li> <li>○ hydrogen bromide</li> <li>○ hydrogen chloride</li> <li>○ oxides of nitrogen (NO and NO<sub>2</sub> expressed as NO<sub>2</sub>)</li> <li>○ phosphoryl chloride</li> <li>○ sulphur dioxide</li> <li>○ thionyl chloride</li> </ul> </li> <li>• Organic substances <ul style="list-style-type: none"> <li>○ acetone</li> <li>○ acetonitrile</li> <li>○ acetyl chloride</li> <li>○ benzyl chloroformate</li> <li>○ BOC anhydride( di-tert-butyl dicarbonate)</li> <li>○ borane tetrahydrofuran</li> <li>○ n-butyl lithium</li> <li>○ dichloromethane</li> <li>○ diethyl ether</li> <li>○ diethyl ketone</li> <li>○ di-i-propyl ether</li> <li>○ dimethyl formamide</li> <li>○ dimethyl sulphoxide</li> <li>○ 1,4 dioxane</li> <li>○ ethanol</li> <li>○ ethyl acetate</li> </ul> </li> </ul>

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	<ul style="list-style-type: none"> <li>○ n-hexane</li> <li>○ n-heptane</li> <li>○ iodomethane</li> <li>○ methanol</li> <li>○ methyl chloroform</li> <li>○ methyl chloroformate</li> <li>○ methylethyl ketone</li> <li>○ methylpropyl ketone</li> <li>○ methyl-t-butyl ether</li> <li>○ propan-1-ol</li> <li>○ propan-2-ol</li> <li>○ pyridine</li> <li>○ tetrahydrofuran</li> <li>○ toluene</li> <li>○ trifluoroacetic acid</li> <li>○ m-Xylene VOC total;</li> <li>● particulate matter (PM); and,</li> <li>● noise.</li> </ul> <p>We consider that the emission limits included in the installation permit reflect the BAT for the sector.</p>
<b>Permit conditions</b>	
Use of conditions other than those from the template	Based on the information in the application, we consider that we do not need to impose conditions other than those in our permit template.
Pre-operational conditions	<p>Based on the information in the application, we consider that we need to impose pre-operational conditions.</p> <p>We have imposed pre-operational measure 1 requiring the operator to validate the key assumptions made in developing the envelope of assessed emissions for the MPP. We have imposed this measure because the projected emissions concentrations are based on the assumptions that the techniques described in the application can limit emissions to these levels. We are satisfied that the techniques described will ensure the predicted levels are achievable however we have required the operator to deliver a validation report in keeping with the commitments made in their application to perform this validation during commissioning. Including this pre-operational measure in the permit will confirm that the envelope of assessed emissions for the MPP is appropriate and that the emissions to air associated to operating to the MPP are at levels which are insignificant with respect to the potential for impacts on human health and ecological receptors within our screening distances.</p> <p>We have imposed pre-operational measure 2 requiring the operator to review their environmental management system (EMS) and identify any improvements</p>

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	<p>required to enable compliance with the permit conditions. We have imposed this measure because the operator proposed to review the EMS policies and to test procedures supporting the EMS during the commissioning phase of the site development. The operator has committed to developing an EMS based on the requirements of the ISO14001 standard and the relevant technical standards (sections 2 and 6 of the application support document). We have reviewed the EMS policy and we are satisfied that the operator will develop an EMS to enable it to comply with the permit conditions. Including this pre-operational measure in the permit will ensure that any improvements required are identified by the operator and agreed with us before commencing operations.</p> <p>We have imposed pre-operational measure 3 requiring the operator to submit a commissioning plan to us for approval to ensure we understand the extent, duration and the potential emissions of the commissioning process.</p> <p>We have imposed pre-operational measure 4 requiring the operator to review and validate during commissioning the methodology to be applied in determining the monitoring frequency for the measurement of the abatement scrubber fluid pH and oxidant concentration. We have imposed this measure because we need to ensure that the monitoring of the process is sufficient irrespective of whether the operator runs one or all of the reactors together and that there will be an adequate amount of protection provided by the scrubber.</p>
Improvement programme	<p>Based on the information on the application, we consider that we need to impose an improvement programme.</p> <p>We have imposed an improvement programme to ensure that the frequency of emissions monitoring continues to reflect BAT standards for this installation.</p> <p>We have included an improvement condition in the permit (IC1) to allow the operator to justify reductions in the frequencies of monitoring emissions to air from the pharmaceutical production process. We anticipate that over the first 12 months of operation the operator will collate adequate data to confirm that emissions are at or below the levels assessed as insignificant in their H1 risk assessment. Inclusion of this improvement condition facilitates the use of this data to justify reducing the monitoring frequency for some/all parameters to instances where changes (made under the MPP or by way of the 'minor operational change' route) could affect emissions e.g. when a solvent is proposed to be used which was not included in the envelope of assessed emissions for the MPP but which has similar characteristics to other solvents which have been assessed.</p>
Emission limits	<p>ELVs have been set for the following substances.</p> <ul style="list-style-type: none"> <li>• Inorganic substances: <ul style="list-style-type: none"> <li>○ ammonia</li> <li>○ hypochlorite (as chlorine)</li> <li>○ hydrazine</li> <li>○ hydrogen bromide</li> <li>○ hydrogen chloride</li> <li>○ oxides of nitrogen (NO and NO<sub>2</sub> expressed as NO<sub>2</sub>)</li> <li>○ phosphoryl chloride</li> </ul> </li> </ul>

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	<ul style="list-style-type: none"> <li>○ sulphur dioxide</li> <li>○ thionyl chloride</li> <li>• Organic substances <ul style="list-style-type: none"> <li>○ acetyl chloride</li> <li>○ benzyl chloroformate</li> <li>○ BOC anhydride( di-tert-butyl dicarbonate)</li> <li>○ n-butyl lithium</li> <li>○ n-hexane</li> <li>○ iodomethane</li> <li>○ methanol</li> <li>○ methyl chloroformate</li> <li>○ pyridine</li> <li>○ tetrahydrofuran</li> <li>○ toluene</li> <li>○ trifluoroacetic acid</li> <li>○ Volatile Organic Compounds (VOCs) Total Class A (acetonitrile, dichloromethane, 1,4 dioxane, dimethyl formamide, n-heptane, methyl chloroform, m-xylene);</li> <li>○ VOCs Total Class B (expressed as carbon)(acetone, borane tetrahydrofuran, diethyl ether, diethyl ketone, di-i-propyl ether, dimethyl sulphoxide, ethanol, ethyl acetate, methylethyl ketone, methylpropyl ketone, methyl-t-butyl ether, propan-1-ol, propan-2-ol and tetrahydrofuran); and,</li> </ul> </li> <li>• particulate matter (PM).</li> </ul> <p>Where appropriate, we have set ELVs at the sector benchmark emissions levels for groups of volatile organic compounds (VOCs) set out in the sector guidance EPR 4.02 for the Speciality organic Chemicals Sector for Class A and Class B VOCs. We have identified Class A and B VOCs in keeping with our sector guidance EPR 4.02 and with reference to 'The Categorisation of Volatile Organic Compounds, 1995 HMIP Research Report No DOE/HMIP/RR/95/009'.</p> <p>The sector benchmark limits are:</p> <ul style="list-style-type: none"> <li>• 100 g/hr or 20 mg/m<sup>3</sup> for Total Class A VOCs; and,</li> <li>• 2 kg/hr or 5 tonnes per annum (TPA) expressed as carbon (whichever is the lower) and 75 mg/m<sup>3</sup> above these mass emission thresholds.</li> </ul> <p>The sector benchmark limits are more relaxed than the achievable emission levels assessed by the operator in the permit application. Emissions of the Class A and Class B VOCs at the sector benchmark levels screen out as insignificant using our H1 assessment tool, we have therefore decided it is BAT to apply the sector benchmark limits in the permit. This approach ensures that the operator's and our efforts may be focussed on management of the emissions of more hazardous substances to maintain compliance with the permit.</p> <p>We have specified the VOCs to which the benchmark limits apply and checked</p>

Aspect considered	Decision
	<p>that maximum emissions for each individual VOC at the relevant benchmark limit are insignificant with respect to relevant environmental assessment levels (EALs). We are satisfied that the techniques proposed by the operator to control, minimise and abate emissions of the Class A and Class B VOCs specified in the permit will ensure these limits are achievable.</p> <p>Certain Class B VOCs do not screen out as insignificant at the sector benchmark emissions levels. These VOCs are:</p> <ul style="list-style-type: none"> <li>• n-hexane;</li> <li>• methanol; and,</li> <li>• toluene.</li> </ul> <p>For these VOCs we have set ELVs at the achievable emissions proposed and assessed as insignificant by the operator.</p> <p>All other ELVs set in the permit are those proposed and assessed by the applicant as achievable emissions based on operational techniques used to manage, minimise and abate emissions.</p> <p>We have reviewed the applicant's H1 screening assessment of emissions and their ecological impact assessment. We have confirmed that the long and short term process contributions do not exceed thresholds for insignificance set out in our online guidance i.e. long term PCs represent less than 1% of relevant environmental assessment levels (EALs) and short term PCs represent less than 10% of the relevant EALs. We are satisfied that emissions of substances at the limits set in the permit are insignificant with respect to the impact on air quality for human health and do not risk significant impacts through contribution to acidification, nutrient enrichment or toxic contamination at statutory and non-statutory protected sites within our screening distance of the site. Our assessment of the impact of emissions to air on sites protected under the Habitats Directive has been submitted to Natural England for information purposes.</p> <p>We have also set an ELV for the volumetric flowrate from the process stack emission source A1. This limits the flowrate to 106.03 m<sup>3</sup>/hr which is the flowrate used in the H1 screening assessments.</p> <p>We have not set emission limits for emissions from stack emission sources other than sources A1 (the process scrubber abatement system) and A4 (the oven tray dryer vacuum pump). We have made these decisions on the basis of the justifications provided by the operator in the application and their responses to the Schedule 5 Notice dated 27/05/20, in summary:</p> <ul style="list-style-type: none"> <li>• A2 is an emergency vent serving the reaction vessel bursting disc release tank and there are no emissions from this vent under normal operations;</li> <li>• A3 serves the fume hoods and building heating and ventilation system for the building 901. <ul style="list-style-type: none"> <li>○ the heating and ventilation system releases air from the occupied parts of the building and will not be contaminated under normal operating conditions.</li> <li>○ the fume hoods are those serving the API production reactors and there are no significant routine emissions from the reactors and processes as: <ul style="list-style-type: none"> <li>- liquids and powders are transferred to and from the reaction</li> </ul> </li> </ul> </li> </ul>



Aspect considered	Decision
	<p>vessels using closed transfer lines;</p> <ul style="list-style-type: none"> <li>- the reactors are equipped with over pressure burst disc release to a dedicated catch tank with level detection (this tank vents to atmosphere from air emission release point A2);</li> <li>- reaction vessels and vacuum systems are fitted with condensers to capture volatile substances;</li> <li>- reactors, and reactor associated vacuum pump condensers, vent to the building process scrubber that provides further emissions abatement and vents to air emission release point A1.</li> </ul> <p>We have not set emission limits for emissions to water from the installation. There are no emissions of trade effluents to sewer or surface water from the site. Domestic wastewater arising from the site is discharged to foul sewer and treated in the Discovery Park WWTP before release to the River Stour. Uncontaminated rainwater run-off from the main building roof is segregated, collected and released to the River Stour by connection to the wider Discovery Park site drainage system. Surface water collected in roadway drains is passed by the site drainage system to an off-site catch pit (reference 287) located within the boundary of the Sandwich Pharmaceuticals Pilot Plant which is managed by Pfizer R&amp;D UK Ltd under permit reference EPR/RP3734QE. This catch pit is not linked to the Discovery Park drainage system and collected water is tested by Pfizer R&amp;D UK Limited before transfer by road tanker for disposal either at the Discovery Park WWTP or at another suitable facility. Surface waters falling within bunds associated with waste and chemicals storage on the site are collected in local blind sumps and tested before transfer to the Pfizer catch pit or transfer off-site for other suitable treatment and disposal. The operator has management procedures in place to minimise the risk of contamination of surface waters and to liaise with Pfizer R&amp;D UK Limited in the event of an incident affected the quality of surface waters collected in the Pfizer catch pit.</p> <p>The emissions and ELVs set in the permit form the envelope of assessed emissions for the MPP.</p>
Monitoring	<p>We have decided that monitoring should be carried out for the parameters listed in the permit, using the methods detailed and to the frequencies specified.</p> <p>These monitoring requirements have been imposed in order to ensure the effectiveness of operational techniques to control, minimise and abate emissions to levels which are insignificant.</p> <p>We made this decision in accordance with our sector guidance for the speciality organic chemicals sector (EPR 4.02), our monitoring and certification scheme (MCERTS) and our standards for monitoring stack emissions: techniques for periodic monitoring available from:  <a href="https://www.gov.uk/government/publications/monitoring-stack-emissions-techniques-and-standards-for-periodic-monitoring/monitoring-stack-emissions-techniques-and-standards-for-periodic-monitoring">https://www.gov.uk/government/publications/monitoring-stack-emissions-techniques-and-standards-for-periodic-monitoring/monitoring-stack-emissions-techniques-and-standards-for-periodic-monitoring</a>.</p> <p>Based on the information in the application we are not satisfied that the operator's techniques, personnel and equipment have either MCERTS certification or MCERTS accreditation as appropriate. This is not an issue as the operator proposes to sub-contract monitoring of stack emissions and the permit requires</p>

Aspect considered	Decision
	that this monitoring is performed to MCERTS standards.
Reporting	<p>We have specified reporting in the permit.</p> <p>We have required annual reporting of emissions to air from the main process stack emissions sources. Annual reporting of emissions to air is the normal reporting frequency set out in our permit template for the chemicals sector.</p> <p>We have required reporting of the following production and performance parameters annually:</p> <ul style="list-style-type: none"> <li>• production of API (clinical grade product);</li> <li>• water usage;</li> <li>• energy usage;</li> <li>• total raw material used; and,</li> <li>• total solvent consumption (with solvent consumption as defined in Article 57 of the Industrial Emissions Directive).</li> </ul> <p>Annual reporting of these parameters is the normal reporting frequency set out in our permit template for the chemicals sector.</p> <p>We made these decisions in accordance with our sector guidance for the speciality organic chemicals sector (EPR 4.02).</p>
<b>Operator competence</b>	
Management system	<p>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.</p> <p>The decision was taken in accordance with the guidance on operator competence and how to develop a management system for environmental permits.</p>
Relevant convictions	<p>The Case Management System and National Enforcement Database have been checked to ensure that all relevant convictions have been declared.</p> <p>No relevant convictions were found. The operator satisfies the criteria in our guidance on operator competence.</p>
Financial competence	<p>There is no known reason to consider that the operator will not be financially able to comply with the permit conditions.</p>
<b>Growth Duty</b>	
Section 108 Deregulation Act 2015 – Growth duty	<p>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.</p> <p>Paragraph 1.3 of the guidance says:</p> <p>“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</p>

<b>Aspect considered</b>	<b>Decision</b>
	<p>in the relevant legislation.”</p> <p>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.</p> <p>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.</p>