

Permitting Decisions- Bespoke Permit

We have decided to grant the permit for Oxford Biomedica operated by Oxford Biomedica PLC

The permit number is EPR/MP3807LH

The application is for an installation which produces a range of gene therapies and a COVID-19 vaccine within 4 processing suites in bioreactors up to 1000 litres volume. There are no emissions direct to air, sewer or surface water from process vessels.

Each suite has its own air handling system with a series of medical grade HEPA filters to remove any particles before most air is returned to the building. On a monthly basis a small amount of hydrogen peroxide is vapourised in each suite, drawn through the handling system and vented to atmosphere via the external vents to destroy bacteria and viruses.

There are no emissions of process water to surface water or sewer. High pH wastewater is collected in a 50kl bunded tank pending removal for appropriate waste treatment.

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 considerations](#) section to show how the main relevant factors have been taken into account
- highlights [key issues](#) in the determination
- 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.

Key issues of the decision

Intermittent Hydrogen Peroxide emissions to air

There are no process related emissions to sewer, surface water or air from the installation. There are 4 gas fired boilers, each of thermal output 260kW. These are smaller than the 1MW threshold for the Medium Combustion Plant so these have been included in the permit as a Directly Associated Activity with no monitoring. Gas usage will included in the annual Energy usage reporting.

However, the production process is conducted in sealed clean rooms with working space negative air extraction through HEPA filters exhausting through 2 louvres on the West side of the building at a height of 7 m. The workspace is cleaned daily, and more thoroughly weekly with disinfectant wipes but once per month the work area and extraction system is disinfected using a small amount of vaporised hydrogen peroxide. During the period of this operation the normal 80% recycle of the extracted air is turned off in favour of 100% exhaust to atmosphere.

The operator submitted a report of the emissions from the rectangular louvre modelled as a row of circular ports using the ADMS5.2 program as well as the software files. The report stated include two key assumptions:

- a) In the absence of monitoring data the hydrogen peroxide background concentration was taken to be the same as the modelled concentration at any location. As it is unlikely there is any hydrogen peroxide background presence this effectively doubles the modelled impact.
- b) The calculated hydrogen peroxide emission concentration of 400ppm is maintained for 6 hours of the 20 hour decontamination period when it is more likely the concentration falls rapidly after the first hour.

These assumptions make the modelling very much a worst case.

There is no published national air quality standard or limit for vaporised hydrogen peroxide. The applicant has therefore compared the calculated concentrations against the Workplace Exposure limits of 1.4mg/m³ (8 hr mean) and 2.8mg/m³ (15 minute mean). We have taken into consideration that these are not environmental exposure limits in our assessment.

We reviewed the report and audited the inputs of the modelling software. These seemed to show that only one of the four modelled sources was modelled for vaporised hydrogen peroxide with a rounded down mass emission rate (the other three had the same emission rate assigned to NO_x) and the receptors were modelled as a ground level grid when the nearest residences across the road from the emission point are at the same 7m height. It was also not fully clear whether the modelled decontamination frequency of once per month applies to each of the four air extraction systems or is a total (only relevant for Long Term effects).

We therefore carried out our own screening using a simplified modelling program with a full range of worst case assumptions. This program is not optimised for horizontal emissions from a building side but the low efflux velocity and ambient temperature (no buoyancy) mean this was acceptable for a screening assessment.

The applicant modelled a maximum ground level 8 hour average process contribution (no background) of 42.6 µg/m³ – 3.0% of the 1400 µg/m³ standard. Our screening showed downdraft from the building was a critical factor in reducing the concentration at the façade of the facing residential properties such that the maximum concentration (24 hr average) was at ground level of the facing residences at 80 µg/m³ – 5.7% of the assumed standard. Even allowing for the uncertainty associated with using a Workplace Exposure limit and the time dependent emission concentration we agree the environmental risk is low.

No emission limits or monitoring have been included in the permit.

Decision considerations

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.

The decision was taken in accordance with our guidance on confidentiality.

Consultation

The consultation requirements were identified in accordance with the Environmental Permitting (England and Wales) Regulations (2016) and our public participation statement.

The application was publicised on the GOV.UK website.

We consulted the following organisations:

Food Standards Agency
Local Authority – Environmental Health
Health and Safety Executive
Local Director of Public Health
United Kingdom Health Security Agency

The comments and our responses are summarised in the [consultation responses](#) section.

Operator

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.

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 RGN2 'Defining the scope of the installation', Appendix 1 of RGN 2 'Interpretation of Schedule 1'

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 storage of alkaline wastewater in a 55,000 litre bunded tank is a Directly Associated Activity rather than a S5.6A(1)(a) scheduled activity as it is a waste produced on site awaiting collection.

Direct abatement of emissions from process plant would generally be included as part of the scheduled activity but the HEPA filter extracted ventilation system in this case is for the room air. It has been included as a Directly Associated Activity (DAA) because it is part of the Stationary Technical Unit and could have an effect on emissions to air. Similarly the four boilers (each <1MWth input) have been included as a DAA as their main load is to heat the room air ventilation system and they could have an effect on emissions to air.

The site

The operator has provided a plan which we consider to be satisfactory.

This shows 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

Nature conservation, landscape, heritage and protected species and habitat designations

We have checked the location of the application to assess if it is within the screening distances we consider relevant for impacts on nature conservation, landscape, heritage and protected species and habitat designations. The application is within our screening distances for these designations.

Oxford Meadows Special Area of Conservation (>5km from installation)
Cothill Fen Special Area of Conservation (>8km from installation)

Lye Valley Site of Special Scientific Interest
Iffley Meadows Site of Special Scientific Interest
Brasenose Wood and Shotover Hill Site of Special Scientific Interest

We have assessed the application and its potential to affect sites of nature conservation, landscape, heritage and protected species and habitat designations identified in the nature conservation screening report as part of the permitting process.

We consider that the application will not affect any site of nature conservation, landscape and heritage, and/or protected species or habitats identified.

We have sent our Habitats Regulation assessment for the SACs to Natural England for information.

We have not consulted on the SSSIs.

The decision was taken in accordance with our guidance.

Environmental risk

We have reviewed the operator's assessment of the environmental risk from the facility.

The operator's risk assessment is satisfactory.

The assessment shows that, applying the conservative criteria in our guidance on environmental risk all emissions may be determined as not environmentally significant.

See Key issues above.

General operating techniques

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.

The operating techniques that the applicant must use are specified in table S1.2 in the environmental permit.

Operating techniques for emissions that screen out as insignificant

Intermittent emissions of hydrogen peroxide have been screened out as insignificant, and so we agree that the applicant's proposed techniques are Best Available Techniques (BAT) for the installation.

Improvement programme

Based on the information on the application, we consider that we need to include an improvement programme.

A Multi-Product Protocol ST18804 RPT 10 v0.1 February 2022 authored by Wardell Armstrong was submitted in response to the request for further information for Duly Making. This addresses the scope outlined in Section 7.2 of Environment Agency Guidance on the use of a Multi-Product Protocol (MPP) at Chemical Production Installations May 2019 and outlines how it will be used in practice.

We have included an improvement programme to submit evidence of how the submitted Multi-Product Protocol will be integrated into the Installation Environmental management System in line with Sections 7.3-7.5 of the guidance.

Emission Limits

We have decided that emission limits are not required in the permit.

There are no process related emissions to sewer or land. For assessment of emissions to air see Key Issues above.

Reporting

We have specified reporting in the permit for annual water, energy and raw material usage. There is no emissions monitoring to report.

Management System

We are not aware of any 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

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 Responses

The following summarises the responses to consultation with other organisations and our notice on GOV.UK for the public and the way in which we have considered these in the determination process.

Responses from organisations listed in the consultation section:

Response received from United Kingdom Health Security Agency

Brief summary of issues raised: No significant concerns regarding the risk to the health of the local population from the installation if the permit holder shall take all appropriate measures to prevent or control pollution, in accordance with the relevant sector guidance and industry best practice.

Summary of actions taken: No actions required

No others responses received.

Representations from individual members of the public

No responses received