Permitting decisions

Bespoke permit

We have decided to grant the permit for MSD Animal Health (Milton Keynes) operated by MSD Animal Health UK Limited.

The permit number is EPR/UP3801PH.

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:

- 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

Emissions to air

The operator used the H1 software tool to assess the emissions to air. The substances assessed were:

- Outputs from the hot water and steam boilers from the burning of natural gas
    - Nitrogen dioxide
    - Nitrogen monoxide, and
    - Carbon monoxide
- Output from the production of the API
    - Formaldehyde
    - Methanol, and
    - Binary Ethyleneimine (BEI)

The assessment showed that nitrogen dioxide, nitrogen monoxide and formaldehyde did not screen out as insignificant (i.e. process contribution (PC) less that 1% of the long term environmental assessment level (EAL) and less than 10% of the short term EAL). These parameters were therefore further assessed in

relation to the background pollution levels and only formaldehyde screened out as part of this further assessment.

The operator then undertook a detailed modelling assessment for nitrogen dioxide, nitrogen monoxide, carbon monoxide, sulphur dioxide, and VOCs (as benzene from combustion processes) to assess the potential impact on specific receptors. The results of this modelling are discussed below.

Emissions from boilers

The operator utilises four natural gas fired boilers at the site for the production of steam and hot water for site use. The site operates four gas-fired boilers: two identical boilers of 4.22 MWth for the production of hot water and two identical steam boilers of 4.00 MWth. The total installed capacity is 16.44 MWth

The main pollutants of concern from the combustion of natural gas are nitrogen oxides and carbon monoxide. The purpose of the assessment was to determine whether, under the current operating regime, releases to atmosphere from the boiler plant are likely to impact the environment or not.

Assumptions and modelling scenarios made for the assessment of the emissions to air:

a) A worst case operational regime is considered where both the steam boilers and one of the hot water boilers operate at full load.

b) The exhaust gas conditions for full load operation have been estimated assuming natural gas combustion at conditions measured during routine monitoring.

c) Oxides of nitrogen (NO_x) are considered to comprise primarily of nitrogen monoxide (NO) and nitrogen dioxide (NO_2).

   Nitrogen oxides from road transport is a major contributor to ground level concentrations, emissions from combustion processes can also be significant. Emissions from combustion primarily consist of nitrogen monoxide, although reaction in the atmosphere results in conversion to nitrogen dioxide, which is the primary nitrogen oxide of interest with respect to ambient pollution. The emission of nitrogen oxides and their transformation products can cause a wide range of environmental effects including acidification and eutrophication as well as harm to human health.

d) Carbon monoxide (CO) is a product of incomplete combustion of the fuel and is therefore related to combustion efficiency. It reacts with other pollutants to form ground level ozone and has implications for neurological health.

e) With incomplete combustion there is also the risk of elevated levels of volatile organic compounds (VOCs) which can give rise to odours and influence ground level ozone formation.

f) Release of sulphur dioxide (SO_2) will be dependent on the sulphur content of the fuel, however as the fuel is natural gas this will be very low.

g) The modelling scenarios were as follows:

   (i) The plant load utilised in the model is 50% for the hot water boiler and 100% for the two steam boilers

   (ii) The modelling system used is ADMS 5.2 (however AERMOD was used when undertaking the sensitivity analysis)

   (iii) Meteorological data used for the five years from 2014 – 2018

   (iv) NOx limit would be 250mg/m^3.

The operator undertook sensitivity analysis looking at meteorological conditions, model selection and boiler load. The operator predicts the maximum long term NO_2 PC and predicted environmental concentration (PEC) at sensitive locations to be 10.0% and 49.1%, respectively. The operator has modelled all volatile organic compounds as benzene. We note that this is a conservative approach and that benzene formation from natural gas combustion is unlikely.

We have audited the air quality assessment and have made observations to their methodology and assumptions.

We performed our emission rate calculations and where emission rates could not be exactly replicated, the most conservative value was selected for modelling. Additionally, we have conducted our own modelling and sensitivity analysis to our observations. We found that PCs of NO_2, SO_2, CO and VOC (assessed as benzene) from the site combustion processes are either insignificant or PECs are unlikely to exceed the

Environmental Standards (ES) set for the protection of human health. Therefore, we largely agreed with the conclusions of operator's modelling report.

Although the operator states that only one hot water boiler is in operation at any one time we, to reflect the worst case scenario, we assumed all four sources operate continuously throughout the year in our sensitivity checks.

The operator has evaluated impacts at a single ecological receptor. Within our checks, we have identified six additional nature sites within the 2 km screening distance criterion, however our results indicate that the site will cause no significant pollution at any of these nature sites.

The results of our audit, we found that;

- Although short term NO_2, long-term NO_2 and long term VOC (assessed as benzene) PCs at relevant human health receptors are not insignificant, considering there is headroom, we are satisfied that PECs are below the ES.
- All remaining pollutant PCs at relevant human health receptors screen out as insignificant.
- Impacts of long and short term NO_x emissions, nutrient nitrogen deposition and acid deposition are likely to be insignificant compared to site relevant critical levels and loads at the ecological sites we identified.

The operator also uses three diesel powered back-up generator which are only utilised in the event of a power failure. They also have two diesel powered emergency firewater pumps which will be used in the event of a fire. All of these are routinely tested to ensure their operability but are limited to <50 hours per year.

We have included emission limits in the permit for certain parameters, see Table S3.1 of the permit. We have limited the oxides of nitrogen to 250 mg/m^3 in line with the Environment Agency guidance[1] taking into consideration that the size of the boilers are <5MWth. As already noted, our audit found that emissions of NO_X from the boilers are not insignificant (i.e. PCs are not less than 1% of long-term EAL and 10% of the short term EAL), therefore emission limits need to be included in the permit to ensure that the emissions are not contributing to the background concentrations of the pollutants.

The boilers are regularly maintained as part of a planned preventative maintenance (PPM) programme and utilise low NOx fitted burners. We have required monitoring every three years as we consider these techniques together with the emission limits to represent appropriate techniques for the facility.

Emissions from API production

The operator uses solvents such as formalin (37% formaldehyde), methanol and BEI in the production of the API, and also in the cleaning (fumigation) of parts of the facility between production cycles. Emission of these will be mainly from the isolator plant and HVAC equipment as well as potential diffusion emissions from cleaning materials such as wipes and sprays used in the laboratories and production areas.

The operator has calculated and assessed the potential emission of these substances to air from two point sources: the HVAC systems for Buildings 71 and 73 (A8 and A9).

We requested verification of these calculations via a Schedule 5 notice (dated 11/11/19). The operator submitted additional information and evidence to confirm the accuracy of the calculation in the response dated 28/11/19 and also submitted additional information (Addendum Report dated 08/07/20[2]) describing the prevention measures employed to reduce and control solvent emissions from cleaning of the facility as well as clarifying the emission points, the emissions from the isolators in Buildings 71 and 73 and the HVAC system in Building 72 (A15).

The operator submitted a revised screening assessment for the emission of formaldehyde, methanol and BEI in the Addendum Report (Section 4). This showed that the emissions of the long term formaldehyde, and

[1] IED chapter 2 permits affected by the regulations - https://www.gov.uk/guidance/medium-combustion-plant-and-specified-generators-environmental-permits

[2] Environmental Permit Application – Addendum 1 received on 08/08/20

both long term and short term methanol and BEI[3] (EAL for benzene used as a surrogate) screened out as insignificant. The short term formaldehyde screened out at the PEC (at 10.3%, i.e. less than 20% of the available headroom).

The operator submitted an inventory of cleaning products used such as wipes and sprays. We are satisfied that the operator is employing appropriate measures to reduce and control fugitive emissions of solvents from the cleaning products and that these products do not contain solvents with hazard statements specified in Article 58 of the Industrial Emissions Directive (IED) Annex VII limit for VOCs.

We are satisfied that the calculations showing the emission of formalin (37% formaldehyde), methanol and BEI are accurate and represent the maximum potential emissions to air from operations (see Section 4 of Addendum Report). As formaldehyde and BEI are solvents that have hazard statements specified in Article 58 of the Industrial Emissions Directive (IED) the limits on emissions of VOCs in Annex VII of the IED are applicable. We have required the operator to undertake monitoring to verify that they will not exceed the limit of 10 g/h[4] twice a year, and for the Class B solvent (methanol) we have set a limit of is 2 kg/hr or 5 TPA (expressed as carbon) whichever is lower in keeping with our sector guidance. However, we have, via improvement condition IC 1, required the operator to undertake one round of monitoring to verify the calculations submitted in Addendum Report and submit a report to allow the operator to revise the monitoring frequencies specified in the permit for VOCs and demonstrate that these can be monitored by calculation.

In addition, we have required the operator, via improvement condition IC 2, to submit a report reviewing all the substances used at the facility with the hazard statements specified in Article 58 of the IED, reviewing their viability and where appropriate submit plans for the replacement of these substances, any additional measure (e.g. abatement) and timescales i.e.in the shortest possible time as required by Article 58 for doing so. However, we do acknowledge that in some areas in the production of the API (e.g. inactivation), that the scope for replacing solvents such as formaldehyde may be limited.

Other emission points (A10 - A14) are from local exhausts or ventilation systems. The operator assessed these and they have concluded that that the emissions of formaldehyde, methanol, BEI and hydrogen peroxide would be minor. We are satisfied with the assessment undertaken and have therefore not set emission limits for these point sources.

The operator has also listed additional emission points for the onsite emergency firewater (2 x 322kW diesel pumps) that have been installed in Building 42. These are not listed in the permit as they are only for emergency use and only subject to routine testing.

Emissions to Water

Point Source Emissions to Surface Water

Rainwater run-off from non-process areas is collected within the surface water drains and discharges to the municipal surface water system (emission points W1 and W2), which flow to the River Ouzel located 215m west of the installation. There are no other point source emissions to surface water from the installation.

The site surface water system (including areas outside of the installation boundary) can be isolated, and the drain contents contained, via the operation of five surface water isolation points (consisting of valves and/or bladders).

We are satisfied that the appropriate measures employed by the operator will minimise the potential for pollutant to be discharged via the surface water system.

Point Source Emissions to Sewer

Process waste water from the manufacturing processes is treated in an onsite waste water conditioning plant employing equalisation (buffering) and pH adjustment. Treated waste water is discharged to sewer in

[3] EAL for benzene used as a surrogate

[4] Limit set by Article 58, Annex VII of the Industrial Emissions Directive

accordance with the conditions specified in a Trade Effluent Discharge Consent held by MSD AH with Anglian Water via point source S1. This is summarised in Table 9.3 of the Application Report[5]

The operator has used the Environment Agency H1 software tool to assess treated effluent.

Assumptions made:

a) that there would be no treatment of formaldehyde in the sewage treatment works therefore the sewage reduction factor is 1,

b) flow was 172.8 m^3 per day, and

c) as no background data was accessible, the operator assumed the background for formaldehyde was 2.5 µg, i.e.is half of the environmental quality standard (EQS) of 5 µg as per Environment Agency guidance.

All the pollutants other than formaldehyde screened out as insignificant when assessed at the emission limits specified in the Trade Effluent Discharge Consent. Formaldehyde screened out at PEC i.e. less than 10% of the annual average EQS and maximum available concentration (MAC).

However, we are not fully satisfied with the screening undertaken as the operator is permitted by the trade effluent consent to be able to discharge up to 300 m^3 per day. Therefore, we reassessed emissions at 300 m^3 per day and again all but formaldehyde screens out as insignificant. We have therefore set an emission limit of 0.97 mg/l for formaldehyde which screens out at PEC level.

Formaldehyde is not a priority hazardous or specified substance, but has an operational (non-statutory) EQS and, in keeping with our processes, we have assessed this pollutant. We are satisfied that the limit set will minimise the impact of emissions, ensure there is no deterioration of the receiving water course and further ensure protection of the goal for the UK to protect aquatic life by controlling formaldehyde discharge at source as required by Environment Agency guidance[6].

We have not set emission limits or mass emission limits for cadmium and mercury as these screen out as insignificant i.e. less that 4% of the annual average and MAC EQS (Cd: 0.21% (AA-EQS) and 0.738% (MAC-EQS); Hg: 0.504% (MAC-EQS)). The significant load also screens out for cadmium and mercury as less that 0.018 kg and 0.003 kg per year respectively, therefore passing the significant load test of less than 5 kg (Cd) and 1 kg (Hg) per annum.

We have required process monitoring of discharge to sewer (pH and chemical oxygen demand (COD)) to ensure that the effluent remains within the parameters set in the application details[7]. The parameters and monitoring frequency have been set in line with the Environment Agency guidance[8].

[5] Environmental Permit Application MSD Milton Keynes – dated 18/06/19

[6] Environment Agency guidance: Operational instruction: LIT 13134, Section 6.

[7] Environmental Permit Application MSD Milton Keynes – dated 18/06/19

[8] Monitoring discharges to water: guidance on selecting a monitoring approach - https://www.gov.uk/guidance/monitoring-discharges-to-water-guidance-on-selecting-a-monitoring-approach#approaches-to-monitoring-discharges

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 consulted the following organisations: • Milton Keynes Council - Planning Department - Director of Public Health - Environmental Health Department • Public Health England • Food Standards England • Health and Safety Executive • Anglian Water We received comments from Public Health England and Anglian Water. The comments and our responses are summarised in the consultation section. No responses were received from the other consultees.
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 permits. During the determination the operator changed their name from Intervet UK Limited to MSD Animal Health UK Limited. The company number and the name of the installation remains the same.
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', Appendix 1 of RGN 2

Aspect considered	Decision
	'Interpretation of Schedule 1', guidance on waste recovery plans and permits. 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. Plans that include the emissions and discharge points are referenced 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.
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. 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. We consider that the application will not affect any sites of nature conservation, landscape and heritage, and/or protected species or habitats identified. Please see key issues for further details.
Environmental risk assessment	
Environmental risk	We have reviewed the operator's assessment of the environmental risk from the facility. The large majority of the operator's risk assessment is satisfactory. However, one part of the operator's risk assessment is unsatisfactory and required additional Environment Agency assessment. The operator evaluated the impacts from air emissions to a single ecological receptor. Within our checks, we have identified six additional nature sites within the 2 km screening distance criterion. We carried out our own modelling and included the additional nature sites and concluded that the impacts of long and short term NO_x, nutrient nitrogen deposition and acid deposition are likely to be insignificant compared to site relevant critical levels and loads at the ecological sites identified. Therefore the Environment Agency assessment shows that, applying the conservative criteria in our guidance on environmental risk assessment, all emissions may be categorised as environmentally insignificant at all of these nature sites. Please see key issues for further details.

Aspect considered	Decision
Operating techniques	
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 do not screen out as insignificant	Emissions of short term NO_2, long-term NO_2, short term formaldehyde and long term VOCs (assessed at EALs for benzene) from the combustion process cannot be screened out as insignificant. We have assessed whether the proposed techniques are BAT. See key issues – Air Emissions.
Operating techniques for emissions that screen out as insignificant	Emissions of carbon monoxide, sulphur dioxide, nitrogen monoxide, BEI, methanol and long term formaldehyde, as well as noise and odour have been screened out as insignificant, and so we agree that the applicant's proposed technique are BAT for the installation. Noise Impact Assessment Noise emissions have been assessed and are considered to not present a risk of significant impacts at sensitive receptors. We consider that the emission limits included in the installation permit reflect the BAT for the sector. Also, see key issues – Air Emissions.
Permit conditions	
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.
Raw materials	We have specified limits and controls on the use of raw materials and fuels.
Improvement programme	Based on the information in the application, we consider that we need to impose an improvement programme. See key issues for improvement conditions IC 1 and IC 2. Potential Changes to Onsite Drainage Discussion with the operator revealed that they wish to make improvements to storage of waste on site which may require changes to the site drainage. Therefore, we have required the operator via improvement condition (IC 3) to provide an updated drainage plan to the Environment Agency.
Emission limits	See key issues.
Monitoring	See key issues.

Aspect considered	Decision
Reporting	We have specified reporting in the permit. We made these decisions in accordance with Environment Agency technical guidance: How to comply with your environmental permit, Additional guidance for: Speciality Organic Chemicals Sector (EPR 4.02).
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. The installation operates under an environmental management third party certification scheme to ISO14001:2015.
Relevant convictions	The Case Management System have been checked to ensure that all relevant convictions have been declared. No relevant convictions were found. The operator satisfies the criteria in our guidance on operator competence.
Financial competence	There is no known reason to consider that the operator will not be financially able to comply with the permit conditions.
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

The following summarises the responses to consultation with other organisations, 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
Public Health England
Brief summary of issues raised
Response received on the 29/10/19. The consultee stated that they would consider the air emissions as the main concern and these had showed that the predicted concentration was below the relevant health based air quality standards. Therefore, they have no concerns assuming the operator takes appropriate measure to prevent pollution, in accordance with the relevant sector guidance and industry best practice.
Summary of actions taken or show how this has been covered
No actions required

Response received from
Anglian Water
Brief summary of issues raised
Anglian Water have had discussions with the operator and consider that no changes need to be made to the current trade effluence consent. They noted an error in the grid reference in the application.
Summary of actions taken or show how this has been covered
We have checked the grid reference and discussed this with Anglian Water.