

Permitting decisions

Variation

We have decided to grant the variation for Gargrave Foam Dressing Manufacturing Site operated by Systagenix Wound Management Manufacturing Limited.

The variation number is EPR/SP3535GM/V005.

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 and the variation notice. The introductory note summarises what the variation covers.

Key issues of the decision

Application summary

The operator is transferring equipment and operations from their site in Dunstable to Airebank Mill. Consequently this variation adds a new production line for the manufacture of adhesive coated foam products. The line comprises two sections known as Coater 1A (foam production) and Coater 1B (adhesive coating). Chemicals (powders and liquids) are combined to form a liquid mixture, either polyurethane (PU) or polyvinylchloride (PVC) and then pumped to the head of Coater 1A. Here the mixture is applied to casting papers via a knife-over roller and transferred to a drying oven. On exiting the oven, the product is cooled on chilled rollers before either passing directly to Coater 1B or being wound onto bulk rolls as an intermediate product. Adhesive ingredients, which are all pre-formulated, are pumped directly to the head of Coater 1B. The adhesive is then applied to the foam paper, which then passes through a second drying oven.

Coater 1A is permitted under Section 4.1 A(1)(viii) of the Environmental Permitting Regulations (EPR2016). The majority of the output from Coater 1A is directly fed into Coater 1B; Coater 1B is therefore permitted as a directly associated activity to Coater 1A as well as falling under Section 6.4 B(a)(iv) of EPR2016.

Annual solvent consumption for the new activities is estimated to be approximately 28 tonnes and the adhesive coating activity (Coater 1B) falls under Schedule 14 of EPR2016 (solvent emission activities). The operator is therefore required to submit an annual solvent management plan in order to demonstrate compliance with the requirements of the Industrial Emissions Directive.

Volatile organic compounds (VOC) emissions arise principally from the drying of the adhesive coating, but also from the drying of PU foams, as a result of organic solvent use.

Off-gases from both coater lines are drawn to a common abatement plant (regenerative thermal oxidiser – RTO) with final release to atmosphere at a new emission point A4.

As a result of the new activities the installation boundary is extended to include:

- Building extension to accommodate new activity
- A relocated hazardous waste area
- New chemical storage units.

On 17/10/2018 the registered office address of the operator changed from 2 City Place, Beehive Ring Road, Gatwick Airport, West Sussex, RH6 0PA to 997 Manchester Road, Ashton-Under-Lyne, Lancashire OL7 0ED. The permit has been updated to include the correct details.

Emissions to air

Air Quality Assessment Methodology

The methodology for risk assessment of point source emissions to air is set out in our guidance Air emissions risk assessment for your environmental permit and has the following steps:

- Describe emissions and receptors
- Calculate process contributions
- Screen out insignificant emissions that do not warrant further investigation using the Environment Agency's H1 screening tool
- Decide if detailed air modelling is needed
- Assess emissions against relevant standards
- Summarise the effects of emissions.

We use this methodology to assess the impacts on air quality in the determination of applications.

The methodology uses a concept of "process contribution (PC)", which is the estimated concentration of emitted substances after dispersion into the receiving environmental media at the point where the magnitude of the concentration is greatest. The methodology provides a simple method of calculating PC, primarily for screening purposes, and for estimating process contributions where environmental consequences are relatively low. It is based on using dispersion factors. These factors assume worst-case dispersion conditions with no allowance made for thermal or momentum plume rise and so the process contributions calculated are likely to be an overestimate of the actual maximum concentrations. More accurate calculation of process contributions can be achieved by mathematical dispersion models, which take into account relevant parameters of the release and surrounding conditions, including local meteorology.

Air dispersion modelling enables the PC to be predicted at any environmental receptor that might be impacted by the emissions from a plant. Once short-term and long-term PCs have been calculated in this way, they are compared with Environmental Standards (ES).

PCs are considered insignificant if:

- the long-term process contribution is less than 1% of the relevant ES; and
- the short-term process contribution is less than 10% of the relevant ES.

The long term 1% process contribution insignificance threshold is based on the judgements that:

- It is unlikely that an emission at this level will make a significant contribution to air quality; and
- the threshold provides a substantial safety margin to protect health and the environment.

The short term 10% process contribution insignificance threshold is based on the judgements that:

- spatial and temporal conditions mean that short term process contributions are transient and limited in comparison with long term process contributions; and
- the threshold provides a substantial safety margin to protect health and the environment.

Where an emission is screened out in this way, we would normally consider that the applicant's proposals for the prevention and control of the emission to be acceptable. However, where an emission cannot be screened out as insignificant, it does not mean it will necessarily be significant.

Using H1, the predicted environmental concentration (PEC) is calculated and used to identify emissions that have insignificant environmental impact so they can be 'screened out' at stage 2. PEC is the PC plus the concentration of the substance already present in the environment. PC and PEC are assessed against relevant environmental quality standards (EQS) to decide if detailed air modelling is required.

PECs can be considered as unlikely to give rise to significant pollution at stage 2 if:

- the short term PC is less than 20% of the short term environmental quality standard minus twice the long term background concentration and
- the long term PEC is less than 70% of the long term environmental quality standard.

For those pollutants which do not screen out as insignificant, we determine whether exceedances of the relevant ES are likely. This is done through detailed audit and review of the applicant's air dispersion modelling, taking background concentrations and modelling uncertainties into account.

Where the PC is greater than these thresholds, the assessment must continue to determine the impact by considering the PEC.

The PECs can be considered "not significant" if the assessment has shown that both the following apply:

- proposed emissions comply with associated emission levels (AELs) or the equivalent requirements where there is no AEL; and
- the resulting PECs will not exceed 100% of the environmental standards.

Summary of air quality assessment

At the installation, emissions to air arise from existing emission points:

- A1 – Thermal oxidiser serving hydropolymer manufacturing line
- A2 – Hydropolymer preparation room
- A3 - Methanol store

And new emission point:

- A4 – Regenerative thermal oxidiser serving PU and PVC foam production and adhesive coating

For the purpose of this permit application, the operator undertook a risk assessment of point source emissions to air. The operator undertook a monitoring exercise at the inlet to the RTO at their site at Dunstable; the results are used in the risk assessment as reasonable estimates of emissions from the activities once operational at Gargrave.

The risk assessment comprises screening of two scenarios using our H1 screening tool followed by air dispersion modelling:

1. 'Base case': evaluation of existing emissions (A1, A2 & A3) plus new emissions (A4) without abatement.
2. 'New RTO': evaluation of existing emissions plus new emissions with abatement (RTO).
3. Air dispersion modelling and assessment of environmental impacts of oxides of nitrogen (NO_x) and carbon monoxide (CO) from the RTO.

The operator entered the 'top ten' speciated volatile organic compounds (VOCs) into the H1 tool: 2-methylhexane, propan-2-ol, 3-methylhexane, ethyl acetate, n-heptane, propane, toluene, 2,3-dimethylpentane, dimethyl cyclopentane and methyl cyclohexane. The remaining VOCs were considered together - TVOC Class B. Other parameters entered were hydrogen chloride (HCl), chlorine (Cl₂), nitrogen dioxide (NO₂), CO and Total Particulate Matter (TPM).

The operating mode entered into H1 was 96% of total annual hours (i.e. 8,400 operational hours per annum). The site does not currently operate at this number of hours but could potentially in the future. Hence, this figure provides a worst-case and is calculated on the basis of 2 weeks per year allowed for maintenance activities with plant out of operation.

The operator's 'base case' assessment showed that all parameters except NO₂, toluene and TVOC Class B screened out as insignificant at stage 1 (PC is <1 % of the long term EQS and < 10% of the short term EQS). We have audited the operator's assessment. We could not replicate the operator's conclusions for a number of reasons:

- the following parameters were input into the H1 tool without associated air quality standards: 2-methylhexane, 2-methylhexane, ethyl acetate, n-heptane, propane, 2,3-dimethylpentane, dimethyl cyclopentane and methyl cyclohexane. This meant the assessment was incomplete.
- An incorrect EAL was input for TVOCs Class B
- Incorrect EALs were input for Total Particulate Matter.

We undertook our own H1 assessment using the operator's data. EALs were calculated for ethyl acetate and n-heptane using occupational exposure standards (OES) stated in the Health and Safety Executive's guidance document EH40/2001. It was not possible to calculate EALs for the remaining speciated VOCs as OESs are not available in EH40/2001. These VOCs were therefore grouped with the other TVOCs Class B and an EAL applied as stated in Environment Agency Technical Guidance document IPC S2 4.04, Table 4.1.

The short-term and long-term ambient air directive limit values stated within our guidance were applied for particulates (PM₁₀).

Table 1 below shows the emissions which can be screened out at stage 1 of the base case assessment as insignificant (PC is <1 % of the long term EQS and < 10% of the short term EQS):

Table 1 – Process contributions insignificant at stage 1 – H1 base case				
Pollutant	Averaging period	EQS / EAL $\mu\text{g}/\text{m}^3$	PC $\mu\text{g}/\text{m}^3$	PC % of EQS / EAL
Long term impacts				
Propan-2-ol	Annual average	9,990	35.3	0.353
n-heptane	Annual average	20,850	55.8	0.268
Short term impacts				
Hydrogen chloride	Hourly average	750	2.03	0.271
n-heptane	Hourly average	62,500	1,532	2.46
Chlorine	Hourly average	290	2.03	0.699
Carbon monoxide	8 hour running average across a 24 hour period)	10,000	477	4.77
Propan-2-ol	Hourly average	125,000	928	0.743

As the PC screens out at this stage, these emissions can be considered to have no significant environmental impact and therefore no further assessment is required.

There are no specific standards for screening of the following emissions for human health therefore no assessment is required:

- Long term hydrogen chloride
- Long term chlorine
- Long term carbon monoxide

Table 2 below shows the emissions which can be screened out at stage 2 of the base case assessment as insignificant (PEC < 70% of the long term EQS):

Table 2 – process contributions considered unlikely to give rise to significant pollution at stage 2 – H1 base case						
Pollutant	Averaging period	EQS / EAL $\mu\text{g}/\text{m}^3$	Background $\mu\text{g}/\text{m}^3$	PC $\mu\text{g}/\text{m}^3$	PEC $\mu\text{g}/\text{m}^3$	PEC % of EQS / EAL
Long term impacts						
TVOC Class B	Annual mean	80,000	0.23	1,441	1,441	1.81
Ethyl acetate	Annual mean	210	0.23	68.3	65.8	32.7
Nitrogen dioxide	Annual mean	40	9.21	17.4	26.6	66.5
Toluene	Annual mean	1,910	0.23	235	235	12.3
Particulates (PM 10)	Annual mean	40	8.66	11.2	19.9	49.6

The following emissions did not screen out at Stage 2 because the short term PC was greater than 20% of the short term EQS minus twice the long term background and further assessment is therefore required:

- TVOC – Class B (short term)
- Ethyl acetate (short term)
- nitrogen dioxide (short term)
- toluene (short term)
- particulates (PM10) (short term)

The operator subsequently used H1 to predict emissions with RTO abatement, 'New RTO'. Emissions of carbon monoxide and long-term nitrogen dioxide were also assessed because emissions from the RTO comprise products of combustion – nitrogen dioxide and CO).

We also undertook a subsequent H1 assessment following the same approach. Emissions that did not screen out of the H1 base case were assessed. Table 3 below shows the emissions with RTO abatement which can be screened out at stage 1 of the assessment as insignificant (PC is <1 % of the long term EQS and < 10% of the short term EQS):

Table 3 – Process contributions insignificant at stage 1 – H1 New RTO				
Pollutant	Averaging period	EQS / EAL $\mu\text{g}/\text{m}^3$	PC $\mu\text{g}/\text{m}^3$	PC % of EQS / EAL
Long term impacts				
Toluene	Annual average	1,910	2.37	0.124
TVOC Class B	Annual average	80,000	15.0	0.0187
Ethyl acetate	Annual average	210	0.683	0.26

Table 3 – Process contributions insignificant at stage 1 – H1 New RTO				
Pollutant	Averaging period	EQS / EAL $\mu\text{g}/\text{m}^3$	PC $\mu\text{g}/\text{m}^3$	PC % of EQS / EAL
Short term impacts				
Toluene	Hourly average	8,000	64.9	0.811
TVOC Class B	Hourly average	80,000	410	0.512
Ethyl acetate	Hourly average	210	18.8	4.47

As the PC screens out at this stage, these emissions can be considered to have insignificant environmental impact and therefore no further assessment is required.

The following emissions with RTO abatement did not screen out at Stage 2 of the assessment because the short term PC was greater than 20% of the short term EQS minus twice the long term background and further assessment is therefore required:

- nitrogen dioxide (long term)
- nitrogen dioxide (short term)
- carbon monoxide (short term)
- particulates PM 10 (short term)

We did not agree with the applicant's choice of EALs, and therefore their conclusions, regarding emissions of particulates using the H1 screening tool. We have therefore assessed the emissions further using our own internal screening assessment tool. Table 4 presents the predicted PCs and PEC at the most impacted human receptor:

Table 4 – Predicted impacts at most impacted human receptors						
Pollutant	Environmental standard (ES)	Background	Process Contribution (PC)		Predicted Environmental Concentration (PEC)	
Unit	$\mu\text{g}/\text{m}^3$	$\mu\text{g}/\text{m}^3$	$\mu\text{g}/\text{m}^3$	% of Environmental standard	$\mu\text{g}/\text{m}^3$	PEC % of Environmental standard
Particulates (PM10) Long term (human receptor: Mill Lane)	40	8.66	0.28	0.7	8.94	22.35
Particulates (PM10) Short term (human receptor: Mill Lane)	50	17.32	1.1	2.64	17.42	34.84

Long term particulate emissions are insignificant at the most impacted human receptor because the PC is less than 1% of the relevant ES.

Short term particulate emissions are insignificant at the most impacted human receptor because the PC is less than 10% of the relevant ES.

No further assessment of particulate emissions is required.

The applicant subsequently undertook detailed air dispersion modelling to assess emissions of NO_x and CO to air against the relevant environmental standards and the potential impact upon local human health and ecological receptors. This assessment predicts the potential effects on local air quality from stack emissions using the ADMS-5.2 dispersion model, which is a commonly used computer model for dispersion modelling.

The model used five years of meteorological data collected from the weather station at Bingley. The impact of the terrain surrounding the site upon plume dispersion was considered in the model.

The model assumes continuous operation and includes emissions from the existing thermal oxidiser, the new RTO as well as an existing boiler. This is a conservative approach as in practice the site is unlikely to operate on a continuous basis all year round. The report is titled 'Air Quality Assessment for Environmental Systagenix Wound Management Permit Variation', dated October 2019.

We have assessed the applicant's dispersion model and we agree with the consultant's conclusions for human health and ecological receptors.

Predicted impacts at human receptors

The applicant's modelling looks at the impact of NO_x and CO emissions on human receptors within the proximity of the site. Relevant receptors are situated in either background locations (set back from the main road) or adjacent to the main roads (A65 northwest of the site).

For receptors that are not at roadside locations the background value of 8.3 µg/m³ has been used which is the highest concentration from the mapped background concentrations in the study area.

For receptors that are at roadside locations the background value of 23 µg/m³ has been used which is the highest concentration from nearby roadside measurements.

Baseline CO concentrations were not determined by the applicant. Background CO concentrations were therefore obtained from DEFRA's background maps and used in the table below.

The PCs from the site at the most impacted human receptors (and therefore represent the worst case) are given in table 5 below.

Table 5 – Predicted impacts at most impacted human receptors						
Pollutant	Environmental standard (ES)	Background	Process Contribution (PC)		Predicted Environmental Concentration (PEC)	
Unit	µg/m ³	µg/m ³	µg/m ³	% of ES	µg/m ³	PEC % of ES
NO _x annual mean (human receptor: roadside property, adjacent to A65)	40	23	<0.8	<2	<23.8	<59.5
NO _x annual mean (human receptor: non-roadside location, Mill Lane)	40	8.3	<1.2	<3	9.5	<23.75
NO _x hourly mean (human receptor: any location)	200	26	<10	<5	<36	<18
CO 8 hour running average across a 24 hour period (human receptor: any location)	10,000	199	260.9	2.6	459.9	4.60

The long-term PC of NO_x could not be screened out as insignificant. We therefore look to determine whether exceedances of the relevant ES are likely. Whilst the long-term PEC for the roadside property is up to 59.5% of the ES, less than 2% is attributable to the emissions from the site. The background, which includes emissions from traffic from the local road network, contributes 57.5% of the PEC.

It is our view that emissions of NO_x from the RTO are unlikely to cause an exceedance of the long-term ES.

Short-term PCs of NO_x could be screened out as insignificant because the PC is less than 10% of the ES.

Short-term PCs of CO could be screened out as insignificant because the PC is less than 10% of the ES.

Predicted impacts at ecological receptors

The applicant's modelling looked at the impact of NO_x emissions on ecological receptors within relevant screening distances of the site. There are a number of internationally designated ecological receptors within relevant screening distances: Craven Limestone Complex Special Area of Conservation (SAC), North Pennine Dales Meadows SAC and North Pennine Moors SAC and Special Protection Area (SPA), which is the closest, approximately 4.7 km to the North East of the site.

There are eight Ancient Woodlands (AW) within relevant screening distances. The closest is Rom Side/Lords Wood approximately 1.2 km to the North East of the site.

PCs are presented in the following tables for North Pennine Moors SAC/SPA and Rom Side/Lords Wood AW; together they therefore represent the worst case.

Table 6 – Predicted impacts at most impacted ecological receptors

Pollutant	Environmental standard (ES)	Background	Process Contribution (PC)		Predicted Environmental Concentration (PEC)	
			µg/m ³	% of Environmental standard	µg/m ³	PEC % of Environmental standard
NO _x annual mean (Rom Side/Lords Wood)	30	N/A	<0.6	<2	N/A	N/A
NO _x annual mean (North Pennine Moors SAC/SPA)	30	9.8	<0.3	<1	N/A	N/A
NO _x daily mean (Rom Side/Lords Wood)	75	N/A	<7.5	<10	N/A	N/A
NO _x daily mean (North Pennine Moors SAC/SPA)	75	19.6	<7.5	<10	N/A	N/A
Nutrient nitrogen deposition (Rom Side/Lords Wood)	3	N/A	<0.05	<1.67	N/A	N/A
Nutrient nitrogen deposition (North Pennine Moors SAC/SPA)	5	N/A	<0.05	<1	N/A	N/A

Table 6 – Predicted impacts at most impacted ecological receptors						
Pollutant	Environmental standard (ES)	Background	Process Contribution (PC)		Predicted Environmental Concentration (PEC)	
Unit	µg/m ³	µg/m ³	µg/m ³	% of Environmental standard	µg/m ³	PEC % of Environmental standard
Acid deposition (Rom Side/Lords Wood)	3.169 ¹	N/A	<0.01	<0.315	N/A	N/A
Acid deposition (North Pennine Moors SAC/SPA)	0.491	N/A	<0.001	<0.2	N/A	N/A

¹ The applicant did not provide the critical load for ancient woodland. The figure quoted is CLmaxN as stated on the UK Air Pollution Information System APIS.

Our guidance presents the following screening criteria for local nature sites (includes Ancient Woodland):

The emissions are insignificant if:

- the PC is less than 100% of the ES

The short and long term NO_x emissions and nutrient nitrogen deposition are insignificant at Rom Side/Lords Wood because the PCs are less than 100% of the relevant ES. No further assessment is required.

The operator's air quality assessment confirms that for acid deposition the PC is less than 0.01 keq/ha/year at all designated sites. Acid deposition is therefore insignificant at Rom Side/Lords Wood because the PC is less than 100% of the CLmaxN. No further assessment is required.

The guidance present screening criteria for internationally designated sites:

The emissions are insignificant if:

- the short-term PC is less than 10% of the short-term environmental standard for protected conservation areas
- the long-term PC is less than 1% of the long-term environmental standard for protected conservation areas

Both short and long term NO_x emissions are insignificant at North Pennine Moors SAC/SPA because the short-term PC is less than 10% and the long-term PC is less than 1% of the relevant ES. No further assessment is required.

The impact of nutrient nitrogen deposition is insignificant at North Pennine Moors SAC/SPA because the PC is less than 1% of the relevant ES. No further assessment is required.

The impact of acid deposition is insignificant at North Pennine Moors SAC/SPA because the PC is less than 1% of the relevant ES. No further assessment is required.

Monitoring

Paragraph 1, Part 6 of Annex VII of the Industrial Emissions Directive requires “*channels to which abatement equipment is connected, and which at the final point of discharge emit more than an average of 10 kg/h of total organic carbon, shall be monitored continuously for compliance*”. The operator has confirmed that following abatement, at the final point of discharge, the level of TVOC (expressed as carbon) is estimated to be 0.332 kg/h. Therefore, continuous monitoring is not deemed to be required. We have specified annual monitoring for TVOC in Table S3.1 of the varied permit.

Operating techniques – process control

We have reviewed the measures proposed by the operator and compared them against the indicative BAT set out in our guidance note EPR 4.02 Speciality Organic Chemicals Sector and DEFRA’s Process Guidance Note 6/32(11) Statutory guidance for adhesive coating (Solvent Emissions Activity). A summary of the key operating techniques is provided below. We are satisfied that these measures represent BAT for the installation.

The operator is transferring coating operations from their site in Dunstable to the Gargrave site. The production methods are standard production methods for this type of activity.

The company operates in accordance with an ISO 14001:2015 certified Environmental Management System (EMS). Under the EMS the company has established objectives and targets for environmental performance. Raw material usage, water usage and waste generation arising from new activities are routinely monitored, reported and assessed in accordance with the EMS. Opportunities to improve efficiency are evaluated and plans established to implement improvements where appropriate.

Training is provided in accordance with operational processes relevant to job specification. The company’s Quality Management System (QMS) includes a training matrix and training completed is recorded via a software system that also provides notifications for refresher training etc.

Environmental impact is minimised by detailed production planning, chemical usage, efficient operation and maintenance to maximise resource efficiency and minimise waste. Each production run is completed according to a specific production plan which includes details on volumes of materials to be used. This includes consumption of coatings, adhesives and solvent as “Coat Weights” (specific weight on substrate). Process equipment is set to deliver specific volumes for each production run. This approach minimises the amount of excess organic solvent and coating used.

In support of the application the operator submitted an environmental risk assessment of the new activity and has identified the main potential impacts as arising from:

- fugitive emissions from storage and handling of chemicals
- point source emissions to air from RTO abatement on the coater lines
- fugitive emissions from the adhesive coating process.

Foam ingredients are mixed in dedicated 600 litre mobile cylindrical metal mixing vessels within internally located formulation rooms in accordance with established procedures. Containers are opened using the caps located at the top of the container (i.e. a minimal area will be exposed), transfer pipes inserted into the containers and the contents pumped to the mixing vessel based on specific quantities required. The mixer is lowered into, and sealed to, the mixing vessel thus providing a complete cover. Emissions are therefore expected to be minimal and local exhaust ventilation is in place for health and safety reasons only.

As the PU or PVC foam exits the drying ovens, it passes over chilled rollers to cool the product before winding onto bulk rolls as an intermediate product. The rollers form part of a recirculating cooling system linked to an existing on-site chiller.

The adhesive coating process is a potential source of fugitive VOC emissions, due to the solvents used. However, all adhesives are pre-mixed and pumped direct from drum or IBC to the coating head via pipework (i.e. closed transfer systems), thus minimising the potential for fugitive emissions.

Off-gases from both Coater 1 and Coater 2 are to be drawn to an RTO providing abatement of VOC emissions by combustion, providing >99% destruction efficiency, prior to release to atmosphere via a 12m stack (emission point A4). The exit velocity has been designed as 15m/s under normal operating conditions. The stack design does not include a cap or other restriction. The products of combustion comprise oxides of nitrogen and carbon monoxide; see Point Source Emissions section for more information on the predicted environmental impacts of these substances.

Installation and commissioning of the RTO will be completed in conjunction with the site engineering team during which full instruction will be provided on set-up, operation and maintenance. The operation of the RTO will be documented on Work Instructions. We have included pre-operational condition PO1 which requires the operator to submit a commissioning plan to the Environment Agency for approval at least four weeks before commencement of commissioning of the coating lines. The commissioning plan shall detail the expected emissions to the environment during the different stages of commissioning, the expected durations of each stage of the commissioning activities and the actions to be taken to protect the environment, any sampling and testing to be undertaken, and the mechanism for reporting to the Environment Agency in the event that actual emissions exceed the expected emissions. Commissioning shall then be carried out in accordance with the commissioning plan as approved.

Operating parameters have been established for the RTO – the RTO self-monitors and optimises operation, for example to limit CO generation. The RTO automatically shuts down if operating parameters are out of range. The system is linked to the production process; if the RTO shuts down an alarm sounds and a controlled shutdown of the coater lines is automatically initiated. Foam and adhesive ceases to be dispensed onto the lines. However the lines will continue to run until products have cleared the ovens (for health and safety reasons - exposure to VOCs and to manage/control fire risk).

The RTO inlet and outlet manifolds and the 12m exhaust stack will be externally insulated. This is to prevent condensation on internal surfaces that could lead to corrosion and ductwork failure or to droplet emission. Flue and ductwork cleaning will be included in the site's existing inspection and maintenance programme.

The maintenance of the RTO will be recorded and controlled using the operator's existing computer-based maintenance management system and a maintenance contract established with the supplier to include monthly inspection visits, remote PLC (programmable logic controller) interrogation and an annual inspection and service. Spares and consumables will be held on site based on advice from the supplier.

The RTO's performance will be monitored and periodically reviewed to identify any potential enhancements in line with developments in BAT. We have included improvement conditions IC8 and IC9 that require the operator to undertake further monitoring once the RTO is operational, to verify the assumptions made in the application air quality risk assessment. If the results of the monitoring are higher than those provided in the application assessment, the operator is required to undertake an environmental impact risk assessment of all point source releases to air to demonstrate that the emissions will not result in a significant impact. If the environmental impact risk assessment shows potential long or short term impacts from the emissions, the operator must agree with the Environment Agency amendments to existing procedures and/or for the implementation of additional measures to reduce the impacts of the substances identified. The measures must subsequently be implemented to agreed timescales.

Storage and handling of chemicals and wastes

The operator has provided information on the storage and use of chemicals on site including impermeable pavement and bunding across all areas where storage, mixing, or processing occurs. Storage of chemicals is in designated site areas. Incompatible substances will be stored separately (e.g. segregation of flammable liquids and oxidising substances). Whilst in storage, all drums / IBCs / bulk bags will be sealed to prevent escape. Powders are stored internally within a purpose-built storage facility. Temperature control will be incorporated into the storage area for use as required dependent on the chemicals stored at any one time. Storage areas will be subject to routine inspection and maintenance organised via the operator's existing computer based maintenance management system.

The relocated hazardous waste storage area benefits from impermeable surfacing and will be used to store nominally empty chemical containers, drummed production line washing wastes (predominantly washing of coater heads), and drummed materials contaminated with solvents (i.e. rags used in cleaning operations). All wastes are stored within a dedicated storage cabinet with integral bunding and is subject to routine inspection and cleared regularly under contract. Volatilisation of chemical residues will be managed by ensuring waste containers are sealed whilst pending collection.

All waste packaging is stored within enclosed skips in dedicated waste storage areas and removed from site on a regular basis under contract.

The new activities involve the use of several chemicals classed as flammable liquids. These chemicals will be received in drums or IBCs and will be stored externally from the site buildings within four integrally bunded, lockable containers which provide containment equivalent to 110% of the volumes stored within and feature ATEX certified lighting, temperature control and ventilation. Whilst in storage, all containers will be sealed to prevent oxygen ingress to manage Lower Explosive Limit (LEL).

Solvents are also used to wash off residual material from the coater lines during planned cleaning. The washed off solvents and process residues are drummed up and sent for treatment at a permitted facility.

Mains water is used within the internally located wash area for the washing out of mixing vessels and chemical containers. Used wash water will be emptied to IBCs pending disposal off-site.

We are satisfied that the operating techniques used constitute BAT for the site.

Energy Efficiency

The new activities use electricity and natural gas supplied by the national grid. As the operations are being transferred from one site (Dunstable) to another (Gargrave) there is not expected to be an overall increase in contribution of greenhouse gas emissions from the sector/UK as a result of the proposed activities.

The energy performance of the site is routinely monitored, recorded and evaluated both under a Climate Change Agreement and in accordance with the existing environmental permit; energy audits are completed where appropriate. This will include the new activities. Energy efficiency will continue to be reviewed at least every 4 years and as per the existing permit.

Accidents

Fire

The operator has identified the following fire risks: arson; plant & equipment condition; electrical faults including damaged or exposed electrical cables; discarded smoking materials; hot works; ignition sources; leaks and spillages of flammable chemicals; incompatibilities / reactions between stored chemicals; build-up of combustible material.

The new activities involve the use of flammable chemicals, which are to be stored in specially designed designated areas (see Storage of chemicals section above).

Existing controls to minimize the risk of fire include:

- No smoking is permitted across the site (except at designated smoking areas away from chemical storage / hazardous areas)
- Routine inspection and maintenance of all plant and equipment to minimise risk of faults
- Policies are in place for the management of electrical installations / equipment and all electrical work, including inspection and testing, is undertaken by a competent electrician / electrical engineer
- A permit to work system is in place and all hot works subject to specific risk assessment and control measures, including fire watch on completion of works
- The operator maintains an up-to-date inventory of substances including identification of environmental hazards
- Incompatible substances are stored separately (e.g. segregate flammable liquids and oxidising substances) to minimise pollution risk in the event of incident.
- If a fault occurs on the RTO system an alarm will sound and a controlled shutdown of the coater lines will automatically be initiated. The lines will continue to run until products have cleared the ovens to manage / control fire risk.
- Routine housekeeping / cleaning is undertaken to minimise build-up of dusts, etc with special attention paid to hot parts of production equipment.

To facilitate an early response to a potential fire incident, the site incorporates:

- Fire detectors throughout
- Sprinkler system throughout
- CCTV
- Alarms linked to the fire detection system. Manually activated alarm call points are also located throughout the site. The fire alarm system is linked to the local fire service.
- Fire extinguishers are located throughout the site for use on small fires and several fire hydrants are located across the site for use by the Fire & Rescue Service.

Testing of the detection and alarm system is completed on a weekly basis and fire safety checks are completed as part of routine site inspections. Fire response procedures are in place under the site Business Continuity Plan and personnel are trained in response procedures with drills being completed periodically.

In the event of a fire, the Fire & Rescue Service will determine the most appropriate fire-fighting strategy including consideration of how to minimise environmental harm. Contaminated firefighting water / foam presents a potential pollution risk to surface waters, the ground and groundwater. Surface water run-off from the site discharges via point "W1" to Mill Race which flows to the River Aire.

Existing measures in place to contain firewater include:

- Impermeable pavement is present across all operational site areas and a drainage plan is in place and maintained – locations and runs of all drains are known.
- Drain bladders are held on site for blocking off surface water drainage system and retaining contaminated water and a shut-off valve is installed at surface water emissions point W1- Mill Race passing to the River Aire.
- Other pollution control measures are also available on site including: drain covers; booms; cushion, cloths and absorbent matting.
- The site is fully surrounded by an earth mound / kerb which provides both containment of water / liquids on-site and acts as a flood defence

We are satisfied that the measures in place to minimise the risks of a fire to the environment constitute BAT for the site.

Chemical Spills

Escape of chemicals presents a potential pollution risk resulting from:

- Poor handling and storage of chemicals
- Poor practice in chemical mixing / formulation
- Leaks on process equipment
- Poor practice in the cleaning of process equipment (use of solvent containing chemicals)
- Poor waste management particularly hazardous waste.
- Failures in primary / secondary containment provisions
- Accidental vehicle strike of storage areas

A description of storage controls is provided above under the Storage and handling of chemicals and wastes sub-heading.

The primary risks from such incidents is pollution of surface water, the ground and groundwater via the surface water drainage system. As such the fire procedures outlined above also apply to chemical spills. Spill control measures are held on site including inert absorbent material. Established spill control procedures are in place under the operator's EMS.

We are satisfied that the measures in place to contain spills constitute BAT for the site.

Air Emissions Abatement System Failure

As described above, if the RTO fails, there is the risk of releasing significant VOC emissions to atmosphere. However the process is controlled by an automated system and the coater lines must receive a signal to confirm the RTO is ready to receive fume. Should a fault occur on the RTO system an alarm will sound and a controlled shutdown of the coater lines will automatically be initiated. See Operating techniques – process control section above for further explanation.

We are satisfied that the systems in place to minimise emissions of VOCs constitute BAT for the site.

Odour

Release of VOCs presents a potential odour risk. However, based on operational experience at the operator's Dunstable site and the management measures in place, significant odour issues are not anticipated with the chemicals used in the process.

Mixing is undertaken internally within the factory building in dedicated formulation rooms – see Operating techniques – process control section above.

Adhesives are a potential source of odour due to solvent content and therefore VOC release. However all the adhesives used on site are pre-mixed and pumped direct to the coating head (i.e. closed transfer systems).

All off-gases from both coater lines are drawn to a common RTO abatement system (RTO) which combusts >99% of VOCs.

Qualitative assessment for odour from operations forms part of routine site inspections. Established complaints procedures are in place and will be followed in the event of an odour nuisance complaint.

We are satisfied that the measures in place constitute BAT for the site. Consequently, we have not required an odour management plan as part of this determination. However, we have included our standard odour condition in the variation notice, which allows us to ask for an odour management plan if we become aware of odour-related problems on site.

Noise

Based on operational experience at the operator's Dunstable site and the management measures in place, significant issues are not anticipated; coater line operations, which are not considered to be significant sources of noise or vibration, and the RTO, which incorporates a fan, are located internally within site buildings which will provide noise attenuation.

Qualitative assessment of noise from operations forms part of routine site inspections; established complaints procedures are in place and will be followed in the event of a noise / vibration nuisance complaint.

We are satisfied that the measures in place constitute BAT for the site. Consequently, we have not required a noise management plan as part of this determination. However, we have included our standard noise condition in the variation notice, which allows us to ask for a noise management plan if we become aware of noise-related problems on site.

Requirements under the Industrial Emissions Directive with respect to solvent use

Schedule 14 of the Environmental Permitting Regulations 2016, together with Chapter V and Annex VII of the Industrial Emissions Directive, sets out the permitting requirements for installations and activities using organic solvents to prevent or reduce the direct and indirect effects of emissions of volatile organic compounds into the environment, mainly into air, and the potential risks to human health, by providing measures and procedures to be implemented for certain activities. Parts 1 and of Annex VII lists adhesive coating with solvent consumption greater than 5 tonnes per year as a relevant activity.

Organic solvents are primarily present in the adhesive used on Coater 1B. The operator has estimated that annual solvent use associated with the new activities will be approximately 28 tonnes and confirms that the adhesive coating activity falls within the threshold and description of a Chapter V activity.

The operator has confirmed that none of the solvents used classified as carcinogens, mutagens or toxic to reproduction under Regulation (EC) No 1272/2008 i.e. are assigned or need to carry hazard statements:

- H340 (may cause genetic defects),
- H350 (may cause cancer),
- H350i (may cause cancer by inhalation),
- H360D (may damage the unborn child)
- H360F (may damage fertility)

None of the solvents containing chemicals are halogenated.

As such, the provisions of Chapter V, Article 58 and Article 59 (5) of the IED (which requires the substitution for less harmful substances or mixtures) do not apply.

In accordance with Schedule 14 of the EPR2016, condition 4.2.5 of the varied permit requires the operator to submit an annual solvent management plan in order to demonstrate compliance with the requirements of Chapter V of the Industrial Emissions Directive.

The operator has elected to adopt the emissions limit values for VOCs as specified in Annex VII, Part 2 of the IED for the relevant activity. For adhesive coating activities that use more than 15 tonnes of organic solvent per year the applicable emission limit value in waste gas is 50 mg carbon/Nm³.

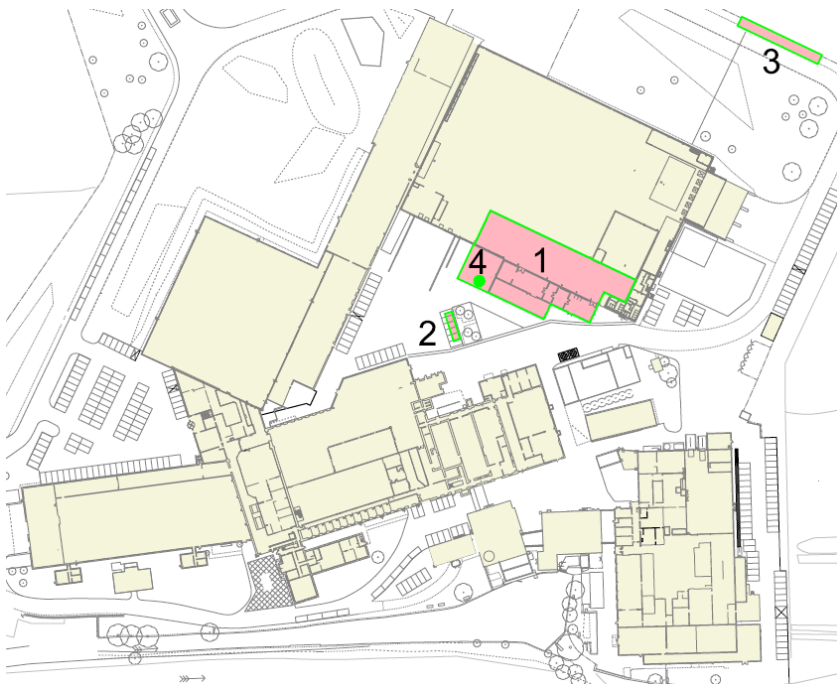
All potential fugitive emissions will be identified by a combination of direct measurement and calculation with data entered into the Solvent Management Plan and be assessed against the applicable emission limit value for fugitive emissions (20% or 25% of the solvent input dependant on quantity used).

Extension of installation boundary

As a result of the variation, the installation boundary is extended to include the areas of land, which are located within with operator's wider site boundary, outlined in green on Drawing 1 below:

1. New coater lines (1A and 1B) and ancillary activities
2. Relocated hazardous waste area
3. New chemical storage units
4. Emission point A4 – RTO serving Coater 1A and 1B

Drawing 1 – new areas of land to be included within the installation boundary



The operator has provided an updated site condition report that includes reference to the new activities, and a site plan (reference MERS/MSE/3835-4, dated 31/07/2019) that indicates the full extent of the revised installation boundary. The plan is included at Schedule 7 of the varied permit.

Additional substances used in each of the new processes are identified, along with relevant hazard codes, in Appendix B-2 to the report.

As described above, storage of chemicals will be in designated areas that are appropriately contained, inspected and maintained.

The site condition report references the site report prepared by ERM in March 2006, reference 0040225, submitted in support of the original permit application completed for Johnson & Johnson Wound Management Ltd.

The site condition report also references sampling of groundwater from 3 existing on-site boreholes (BH1, BH2 and BH3), the locations of which are shown in Drawing 2 below.

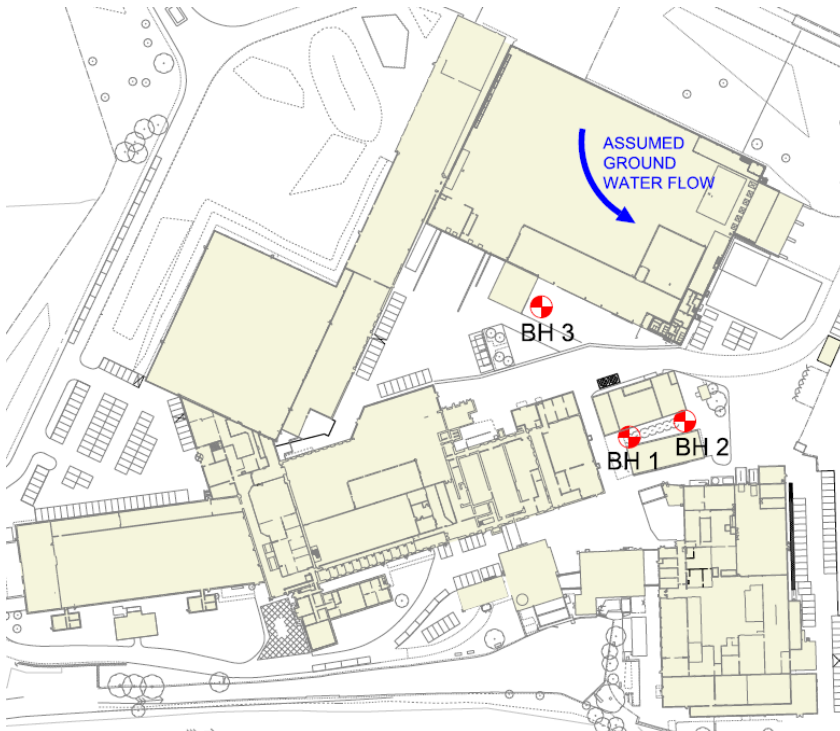
The boreholes are understood to have been formed as part of a site investigation conducted in 1990 to assess pollution impact at the time.

Groundwater samples were analysed for:

- Total petroleum hydrocarbons (TPH) – all results for aliphatic TPH were below the laboratory limit of detection. Low levels of aromatic TPH were detected in all boreholes across several hydrocarbon fractions.
- individual volatile organic compounds – all results were below the laboratory limit of detection.
- individual semi volatile organic compounds – all results were below the laboratory limit of detection.

A copy of the laboratory results for the groundwater analysis is included at Appendix B-3 of the site condition report.

Drawing 2 – location of 3 existing on-site groundwater sampling boreholes



We are satisfied that the updated site condition report provides a baseline of soil and groundwater condition at the time of the variation.

Drainage

During determination, the operator confirmed that it will not be necessary to reconfigure drainage at the site because there are no drainage points present beneath the coater room, waste area, materials storage area, wash area, banded storage / pumping room or the mixing room. Any spillages inside the building would be contained within the building - i.e. there are no discharge points / drains to either foul or surface water systems in the coater line building. Operational control measures include spill response and all necessary measures would be deployed in the event of a spill within the building. Surface water run-off from the site will continue to discharge via point W1 to Mill Race, which can be controlled via a shut-off valve

Impermeable pavement and bunding is present across all areas where storage, mixing, or processing occurs.

Deletion of obsolete text

In 2015 the operator applied to replace a bioreactor with a thermal oxidiser (application reference: EPR/SP3535GM/V004). During the current consolidation of the permit we noticed a number of references to the bioreactor that have remained in the permit. These references have now been deleted in the consolidated permit:

Table S1.2 – operating techniques for the bioreactor (variation notice ref: EPR/SP3535GM/V004)

Table S3.1 – monitoring frequency for emission point A1 (variation notice ref: EPR/SP3535GM/V002)

Table S3.3 – point source emission of bioreactor discharge (variation notice ref: EPR/SP3535GM/V002)

There is one other reference to the bioreactor within Table S1.3 (improvement condition IC7). This has not been deleted as improvement conditions are retained within the permit.

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. The decision was taken in accordance with our guidance on confidentiality.
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: Director of Public Health – North Yorkshire County Council Public Health England Health & Safety Executive Craven District Council Environmental Health The comments and our responses are summarised in the consultation section .
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 '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 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.
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.

Aspect considered	Decision
	<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>
Environmental risk assessment	
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 not significant.</p>
Operating techniques	
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>
Operating techniques for emissions that screen out as insignificant	<p>Emissions of the following substances have been screened out as insignificant, and so we agree that the applicant's proposed techniques are BAT for the installation.</p> <p>Toluene</p> <p>Ethyl acetate</p> <p>n-heptane</p> <p>Total VOC Class B</p> <p>Propan-2-ol</p> <p>Hydrogen chloride</p> <p>Chlorine</p> <p>Oxides of nitrogen</p> <p>Carbon monoxide</p> <p>Particulates</p> <p>We consider that the emission limits included in the installation permit reflect the BAT for the sector.</p>

Aspect considered	Decision
Permit conditions	
Updating permit conditions during consolidation	We have updated permit conditions to those in the current generic permit template as part of permit consolidation. The conditions will provide the same level of protection as those in the previous permit(s).
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 included pre-operational condition PO1 which requires the operator to submit a commissioning plan to the Environment Agency for approval at least four weeks before commencement of commissioning of the coating lines. The commissioning plan shall detail the expected emissions to the environment during the different stages of commissioning, the expected durations of each stage of the commissioning activities and the actions to be taken to protect the environment, any sampling and testing to be undertaken, and the mechanism for reporting to the Environment Agency in the event that actual emissions exceed the expected emissions. Commissioning shall then be carried out in accordance with the commissioning plan as approved.</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 included improvement conditions IC8 and IC9 that require the operator to undertake further monitoring once the RTO is operational, to verify the assumptions made in the application air quality risk assessment. If the results of the monitoring are higher than those provided in the application assessment, the operator is required to undertake an environmental impact risk assessment of all point source releases to air to demonstrate that the emissions will not result in a significant impact. If the environmental impact risk assessment shows potential long or short term impacts from the emissions, the operator must agree with the Environment Agency amendments to existing procedures and/or for the implementation of additional measures to reduce the impacts of the substances identified. The measures must subsequently be implemented to agreed timescales.</p>
Emission limits	<p>ELVs have been added for the following substances:</p> <ul style="list-style-type: none"> • Total Volatile Organic compounds (expressed as carbon) emitted from emission point A4 – Table S3.1 • Solvents – annual fugitive emission limit value set – Table S3.4 <p>We made these decisions in accordance with the Speciality Organic Chemicals Sector (EPR4.02) guidance and Schedule 14 of the Environmental Permitting Regulations 2016, together with Chapter V and Annex VII of the Industrial Emissions Directive.</p>
Monitoring	<p>We have decided that monitoring should be added for the following parameters at the new emission point A4, using the methods detailed and to the frequencies specified:</p> <ul style="list-style-type: none"> • Total Volatile Organic compounds (expressed as carbon)

Aspect considered	Decision
	<p>These monitoring requirements have been imposed in order to ensure the emissions from the process are in accordance with the ELVs assigned to protect the environment.</p> <p>Based on the information in the application we are satisfied that the operator's techniques, personnel and equipment have either MCERTS certification or MCERTS accreditation as appropriate.</p> <p>We made these decisions in accordance with the Speciality Organic Chemicals Sector (EPR4.02) guidance and Schedule 14 of the Environmental Permitting Regulations 2016, together with Chapter V and Annex VII of the Industrial Emissions Directive.</p>
Reporting	<p>We have added reporting in the permit for the following parameters:</p> <ul style="list-style-type: none"> • Total Volatile Organic compounds (expressed as carbon) emitted from emission point A4 • Fugitive emissions; percentage of solvent input. • Submission of an annual solvent management plan in order to demonstrate compliance with the requirements of the Industrial Emissions Directive (enacted by Schedule 14 of EPR 2016). <p>We made these decisions in accordance with the Speciality Organic Chemicals Sector (EPR4.02) guidance and Schedule 14 of the Environmental Permitting Regulations 2016, together with Chapter V and Annex VII of the Industrial Emissions Directive.</p>
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.
Growth Duty	
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 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</p>

Aspect considered	Decision
	<p>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>

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
The main potential concerns are health and odour impacts on nearby residential receptors arising from aerial emissions of gases and particulates arising from combustion and emissions abatement activities.
Summary of actions taken or show how this has been covered
<p>We have undertaken an audit of the operator's air quality assessment. As explained in the Key Issues section above, all emissions screen out as environmentally insignificant.</p> <p>We have included improvement conditions IC8 and IC9 that require the operator to undertake further monitoring once the RTO is operational, to verify the assumptions made in the application air quality risk assessment. If the results of the monitoring study are higher than those provided in the application, the operator is required to undertake an environmental impact risk assessment and, if deemed necessary, to implement measures to reduce environmental impacts. Refer to Key Issues section for further explanation.</p> <p>ELVs have been added for the following substances:</p> <ul style="list-style-type: none"> • Total volatile organic compounds (expressed as carbon) emitted from emission point A4 – Table S3.1 – monitored annually. • Solvents – annual fugitive emission limit value – Table S3.4 - the operator is required to report fugitive emissions as a percentage of solvent input. <p>We have included a condition in the variation notice, which requires the operator to submit an annual solvent management plan in order to demonstrate compliance with the requirements of the Industrial Emissions Directive.</p> <p>We have included our standard condition in the variation notice, which allows us to ask for an emissions management plan if we become aware of problems on site related to emissions of substances not controlled by emission limits (e.g. particulates).</p> <p>Based on operational experience at the operator's Dunstable site and the management measures in place (see Key Issues section for further detail), significant odour issues are not anticipated with the chemicals used in the process. We have therefore not required an odour management plan as part of this determination but, we have included our standard odour condition in the variation notice, which allows us to ask for an odour management plan if we become aware of odour-related problems on site.</p>