Permitting decisions

Variation

We have decided to grant the variation for the Macclesfield Works operated by AstraZeneca UK Limited.

The variation number is EPR/BP3731SR/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

1.0 Environmental risk assessment

We have performed a conservative (worst case) environmental risk assessment of the long and short term impacts of emissions from the five packed scrubber/carbon drum abatement units associated with the multi-purpose plants (air emissions reference points: A120, A134, A148, A169 and A183) at the emission limit values (ELVs) set in the varied and consolidated permit (EPR/BP3731SR/V005). The risk assessment and a summary of the ELVs set in the varied and consolidated permit are presented in Tables 1-4.

Based on our conservative assessment of emissions impacts, emissions of

- volatile organic compounds (VOCs)
- total amines (expressed as dimethylamine)
- benzene
- carbon disulphide
- carbon monoxide
- chlorine
- 1,2-dichloroethane
- formaldehyde

- hydrogen bromide
- hydrogen chloride
- hydrogen cyanide
- hydrogen iodide
- hydrogen sulphide
- iodine
- phosgene
- organic sulphides and mercaptans (expressed as methyl mercaptan)
- total phenols, cresols and xylols (expressed as phenol)
- trimethylamine

have been screened out as insignificant.

We have not included emissions of particulates or active pharmaceutical ingredients (API) in our assessment as we are satisfied that such emissions are minimised and controlled by the operator's techniques to levels which are likely to be insignificant. Justification of this case is presented later in this section.

Applying the conservative criteria in our guidance on environmental risk assessment, emissions of the following substances cannot be screened out as environmentally insignificant:

- ammonia
- bromine
- hydrogen fluoride
- mercury and its compounds
- total acid forming gases of nitrogen (expressed as nitrogen dioxide (NO_2))
- oxides of sulphur (expressed as sulphur dioxide (SO_2)).

Based upon our conservative assessment of impacts, emissions of the above substances breach significance thresholds for impacts on sensitive receptors when emitted at the EPR 4.02 guidance benchmark ELVs from multiple stacks, that is:

- calculated process contributions (PCs) exceed significance thresholds for the relevant environmental assessment level (EAL) for air quality; or
- calculated long term deposition to ground rates exceed the relevant significance threshold; or,
- calculated dry deposition rates exceed the relevant significance thresholds of critical load values for sensitive ecological receptors.

Our assessment shows that limiting emissions to a single packed scrubber/carbon drum stack, ensures that emissions of the following substances do not breach significance thresholds:

- ammonia
- bromine
- oxides of sulphur (expressed as sulphur dioxide (SO_2)).

Our assessment shows however that emissions of hydrogen fluoride, mercury and its compounds, and total acid forming gases of nitrogen (expressed as nitrogen dioxide (NO_2)) do exceed significance criteria for impacts when releases are restricted to a single packed scrubber/carbon drum stack. We have therefore varied the ELVs for these substances to ensure that, in combination with the techniques described in the operator's multi-product protocol (MPP) and revised air emissions risk assessment procedure submitted during this variation (final versions received 23/01/19 and 30/01/19 respectively), emissions do not breach significance thresholds.

The ELVs which have been varied as a result of this assessment are:

- hydrogen fluoride, from 5 mg/Nm^3 to 0.8 mg/Nm^3
- mercury and its compounds from 0.1 mg/Nm^3 to 0.05 mg/Nm^3
- total acid forming gases of nitrogen (expressed as NO_2), from 200 mg/Nm^3 to 55 mg/Nm^3.

Based on our conservative assessment of emissions impacts we have decided that emissions at the ELVs included in the varied and consolidated permit issued with respect to this variation (BP3731SR/V005) will not

exceed the significance thresholds for long or short term impacts for this parameter when emissions are restricted as follows:

- for ammonia and mercury and its compounds:
    - emissions are restricted to an average of one abatement stack source emitting over the course of a year.
- for bromine, hydrogen fluoride, total acid forming gases of nitrogen and oxides of sulphur:
    - emissions are restricted to a single stack source emitting at any one time.

We have varied the permit to allow the operator to perform their own risk assessment to justify relaxation of the above restrictions subject to our approval. The operator must demonstrate that there is no significant risk to sensitive receptors and obtain our agreement in writing before beginning production runs where the above restrictions on emissions are not applied. We anticipate that justification and approval will be conducted under the terms of the new MPP condition included in the varied and consolidated permit (condition 1.5.1).

In performing this assessment we have updated certain sector benchmark ELVs to take into account the ELVs for certain VOCs set out in Part 4 of Annex VII of the Industrial Emissions Directive (IED) 2010/75/EU that is:

- 2 mg/Nm^3 for emissions of VOCs with the following hazard statements H340, H350, H350i, H360D or H360F where the mass flow of the sum of the compounds is greater than, or equal to, 10 g/h.
- 20 mg/Nm^3 for emissions of halogenated VOCs with the hazard statements H341 or H351, where the mass flow of the sum of the compounds causing the hazard statements H341 or H351 is greater than, or equal to, 100 g/h.

We have varied the ELVs for benzene and 1,2-dichloroethane from the EPR 4.02 benchmark level of 5 mg/Nm^3 to 2 mg/Nm^3 as these substances are VOCs with the H350 hazard statement.

We have noted in the varied and consolidated permit that the IED limit of 2 mg/Nm^3 is BAT for combined mass flows at or exceeding 10 g/h. Under the revised MPP, the operator will take this mass flow figure into account in their risk assessment. In the case where the combined mass flows of relevant VOCs do not exceed the thresholds of 10 g/h or 100 g/h the operator may agree in writing with the Environment Agency a higher ELV provided the operator can justify that this does not threaten to breach significance thresholds for long or short term impacts. If we are satisfied that emissions do not threaten to breach significance thresholds for long or short term impacts we may approve the operator's proposal. We anticipate that justification and approval will be conducted under the terms of the new MPP condition included in the varied and consolidated permit (condition 1.5.1).

We performed our conservative environmental risk assessment during the determination of this variation application (BP3731SR/V005) in view of the ongoing reliance of the operator's revised risk assessment technique on the sector benchmark based ELVs set within the 2007 permit as is explained below.

> We reviewed the operator's assessment of the environmental risk from the facility. The operator's assessment submitted with the variation application did not address the requirement to assess potential emissions to air from the remaining multi-purpose plant against current environmental assessment levels (EALs). The operator provided a risk assessment procedure with the variation application ('SOP Emissions to Atmosphere Compliance for Product Accommodations under the MPP document LDMS_001_00018995') which relied on meeting the emission limit values (ELVs) set in the 2007 varied and consolidated permit to demonstrate BAT. We required the operator to update this procedure (version received 30/01/19) to address this.
>
> In accordance with the revised MPP (version submitted on 23/01/19) the operator will follow the revised SOP Emissions to Atmosphere Compliance for Product Accommodations under the MPP document LDMS_001_00018995 (version received 30/01/19) to assess the impacts of proposed production methodologies, abatement techniques and abatement performance standards for each new production run to ensure emissions do not risk significant impacts on sensitive receptors. In order to establish acceptable emissions levels for proposed production runs under the MPP, that is emissions levels which do not risk significant impacts at sensitive receptors, the revised SOP

Emissions to Atmosphere Compliance for Product Accommodations under the MPP document LDMS_001_00018995 (version submitted 30/01/19) takes into account the following:

- the ELVs set within the permit;
- the BAT emission limit values for certain types of hazardous VOCs identified in Part 4 of Annex VII of the Industrial Emissions Directive (2010/75/EU); and,
- published EALs.

The sector benchmark based ELVs included in the 2007 variation and consolidation are the same as those presented in the current sector guidance EPR 4.02. We reviewed the ongoing validity of these sector benchmark based ELVs with respect to BAT for the installation through performance of our own conservative assessment of the impact of emissions at these levels against current published EALs for sensitive human health and ecological receptors within our screening distance of the installation.

As noted earlier in this section, we have not included emissions of particulates or API in our assessment as we are satisfied that such emissions are minimised and controlled by the operator's techniques to levels which are likely to be insignificant. We have based this opinion on the information summarised below.

We have not required monitoring of particulate matter (PM) including API which is in keeping with the current permit and reflects the decision taken by us in the 2007 variation determination process to remove the requirements for monitoring of PM from the:

- packed scrubber emission points associated with the multi-purpose plants (A120, A134, A148, A169 and A183); and,

The 2007 determination decision to remove PM monitoring requirements from these sources was based on our assessment that emissions from these sources were likely to be insignificant and taking into account the difficulties inherent in monitoring emissions of particulate matter from wet scrubbing systems.

All remaining sources of PM and API emissions to air are controlled to prevent or minimise releases to air. All PM and API sources other than the packed scrubber emission points are fitted with continuous liner systems inside glove boxes with extract and HEPA (High Efficiency Particulate Air) filtration on the vent. As described in Table 9 of Part C3 of the variation application (V005), the operator uses continuous liners to contain all PM releases from the processes releasing to the following emission points:

- A110 (vent V3000) Batch Processing Chem Stores HEPA filtration CS0956
- A111 (vent V3001) Batch Processing Chem Stores Misc. Particulate filtration CS0023
- A112 (vent V3002) Batch Processing Chem Stores Misc. Particulate filtration CS0024
- A122 (vent V7786) DA1 DSP1 plant HEPA Filtration DP0183
- A123 (vent V7790) DA1 DSP1 plant HEPA Filtration 68
- A124 (vent V7792) DA1 DSP1 plant HEPA Filtration DP0172
- A135 (vent V7784) DA1 DSP2 plant HEPA Filtration DP0272
- A139 (vent V7922) DA1 DSP1/2 plant HEPA Filtration DP0100
- A149 (vent V7794) DA1 DSP3 plant HEPA Filtration DP0357
- A150 (vent V7795) DA1 DSP3 plant Room Extract HEPA Various Filters
- A152 (vent V7962) DA3 plant HEPA Filtration AT0103, 0203,0311
- A168 (vent V7614) DA3 plant HEPA Filtration AT0804, 0805
- A170 (vent V7638) DA3 plant HEPA Filtration AT0980
- A189 (vent V7979) DPF plant HEPA Filtration DP0418
- A190 (vent V7980) DPF plant HEPA Filtration DP0413
- A191 (vent V7302) DPF plant Particle Size Reduction (PSR) plant HEPA filtration DP0413
- A192 (vent V7303) DPF plant Particle Size Reduction (PSR) plant HEPA filtration LD1506
- A193 (vent V7304) DPF plant Solids Handling Particle Size Reduction (PSR) Plant HEPA Filtration Various Filters.

As described in section 4a of Part C3 of the variation application (V005), the operator uses operational monitoring of the pressure drops across all filters to monitor performance and has in place a system of integrity testing for HEPA filters. With respect to the use of continuous liners in all of the above particulates abatement units the operator has stated the following in Table 9 of Section C3 2 of the application:

> 'Vents are still in place but no emissions occur from these points due to the use of continuous liner which contain all particulate releases.'

We are satisfied that there are no significant point source or fugitive releases of API or PM and, in keeping with the 2007 variation determination, we have not set ELVs for PM or APIs from the particulates filter/HEPA filter or abatement stack sources in the varied permit.

The risk assessment is presented in Tables 1-3 with detailed notes describing the various factors taken into account below each table. It should be noted that:

Our assessment is a worst case emissions impact assessment based on ground level discharge heights for discharges from the five packed scrubber/carbon drum abatement stacks. We have assessed impacts using our H1 tool and applying our published[1] annual and hourly dispersion factors for ground level emissions, that is an annual dispersion factor 148 µg/m^3/g/s and an hourly dispersion factor of 3900 µg/m^3/g/s. We have assessed the impact of emissions of each substance for the worst case concurrent emissions from all five stacks and we have also assessed more restricted emissions from a single stack. Where our assessment demonstrated that release of substances from a single stack source at the sector benchmark based ELV risked exceedance of significance thresholds for long or short-term impacts we also assessed revised ELVs.

The annual average and peak short term volumetric flowrates for combined emissions from all five packed scrubber/carbon drum abatement vents are worst case flowrates calculated by us from flow data provided by the operator in the 2006 permit application, that is taking the annual average and short term peak combined volumetric flows of the five multi-product plant scrubber units plus stack A80 (No. 1 Crudes Plant ammonia scrubber) values of 29.19 m^3/h and 984.62 m^3/h. This represents a conservative (worst case) approach as the combined flowrates used in our assessment include a contribution from the now decommissioned A80 stack. The volumetric flowrates applied for the single emission point assessment represent one fifth of the flowrates applied in the worst case assessment of emissions from all five stacks, that is annual average volumetric flow of 5.84 m^3/h and a short term peak flow of 196.92 m^3/h for emissions from a single packed scrubber/carbon drum abatement vent.

[1] Taken from Environment Agency online guidance available on GOV.UK.

Table 1. Worst case impact assessment for concurrent emissions of pollutants from all five packed scrubber/carbon drum stacks at EPR 4.02 benchmark or relevant IED Annex VII Part 4 values

Pollutant	**ELV (mg/Nm^3)**	**Release Rate Long term (g/s)**	**Release Rate Short term (g/s)**	**Process Contribution (PC) annual average [Note 1] (µg/m^3)**	**Process Contribution (PC) hourly average [Note 1] (µg/m^3)**	**EQS/EAL Long term (µg/m^3)**	**EQS/EAL Short term 1 (µg/m^3)**	**EQS/EAL Short term 2 (µg/m^3)**	**PC as % EQS/EAL Long term (µg/m^3)**	**PC as % EQS/EAL Short term**	**Breach of significance thresholds Yes/No [Note 11]**
Total amines (expressed as dimethylamine)	10	8.10811E-05	0.00274	0.012	10.667	N/A	N/A	N/A	N/A	N/A	N/A
Ammonia	10	8.10811E-05	0.00274	0.012	10.667	1 [Note 2]	2500	N/A	1.20	0.43	Yes
Benzene	2 [Note 3]	1.62162E-05	0.00055	0.002	2.133	N/A	195	N/A	N/A	1.09	No
Bromine	10	8.10811E-05	0.00274	0.012	10.667	N/A	70	N/A	N/A	15.24	Yes
Carbon disulphide	5	4.05405E-05	0.00137	0.006	5.333	64	100	N/A	0.01	5.33	No
Carbon monoxide	1 kg/h	0.27778	0.27778	41.111	1083.342	N/A	30,000	10000 [Note 4]	N/A	3.61, 7.58	No
Chlorine	10	8.10811E-05	0.00274	0.012	10.667	N/A	290	N/A	N/A	3.68	No
1,2 Dichloroethane	2 [Note 3]	1.62162E-05	0.00055	0.002	2.133	42	700	N/A	0.01	0.30	No
Formaldehyde	2	1.62162E-05	0.00055	0.002	2.133	5	100	N/A	0.05	2.13	No

Pollutant	ELV (mg/Nm³)	Release Rate Long term (g/s)	Release Rate Short term (g/s)	Process Contribution (PC) annual average [Note 1] (µg/m³)	Process Contribution (PC) hourly average [Note 1] (µg/m³)	EQS/EAL Long term (µg/m³)	EQS/EAL Short term 1 (µg/m³)	EQS/EAL Short term 2 (µg/m³)	PC as % EQS/EAL Long term (µg/m³)	PC as % EQS/EAL Short term	Breach of significance thresholds Yes/No [Note 11]
Hydrogen bromide	5	4.05405E-05	0.00137	0.006	5.333	N/A	700	N/A	N/A	0.76	No
Hydrogen chloride	10	8.10811E-05	0.00274	0.012	10.667	N/A	750	N/A	N/A	1.42	No
Hydrogen cyanide	2	1.62162E-05	0.00055	0.002	2.133	N/A	220	N/A	N/A	0.97	No
Hydrogen fluoride	5	4.05405E-05	0.00137	0.006	5.333	N/A	160	0.5, 5 [Note 5]	N/A	3.33, 251.73, 62.93	Yes
Hydrogen iodide	5	4.05405E-05	0.00137	0.006	5.333	5	520	N/A	0.12	1.03	No
Hydrogen sulphide	5	4.05405E-05	0.00137	0.006	5.333	140	150	N/A	0.00	3.56	No
Iodine	10	8.10811E-05	0.00274	0.012	10.667	N/A	290 [Note 6]	N/A	N/A	3.68	No
Phosgene	1	8.10811E-06	0.00027	0.001	1.067	0.8	25	N/A	0.15	4.27	No
Mercury and its compounds (expressed as mercury)	0.1	8.10811E-07	2.7E-05	0.0001	0.107	0.25	7.5	N/A	0.05	1.42	No

Pollutant	ELV (mg/Nm^3)	Release Rate Long term (g/s)	Release Rate Short term (g/s)	Process Contribution (PC) annual average [Note 1] (µg/m^3)	Process Contribution (PC) hourly average [Note 1] (µg/m^3)	EQS/EAL Long term (µg/m^3)	EQS/EAL Short term 1 (µg/m^3)	EQS/EAL Short term 2 (µg/m^3)	PC as % EQS/EAL Long term (µg/m^3)	PC as % EQS/EAL Short term	Breach of significance thresholds Yes/No [Note 11]
Total acid forming gases of nitrogen (expressed as NO_2)	200	0.001621622	0.05470	0.240	213.333	30	200	75 [Note 7]	0.8	106.67, 167.82	Yes
Organic sulphides and mercaptans (expressed as methyl mercaptan)	2	1.62162E-05	0.00055	0.002	2.133	N/A	N/A	N/A	N/A	N/A	N/A
Oxides of sulphur (expressed as SO_2)	50	0.000405405	0.01368	0.060	53.333	10 [Note 8]	266 [Note 9]	125 [Note 10]	0.60	26.87, 25.17	Yes
Total phenols, cresols and xylols (expressed as phenol)	10	8.10811E-05	0.00274	0.012	10.667	200	3900	N/A	0.01	0.27	No
Trimethylamine	2	1.62162E-05	0.00055	0.002	2.133	N/A	N/A	N/A	N/A	N/A	N/A

Note 1. Worst case emissions impact assessment based on ground level discharge heights for concurrent discharges from all five packed scrubber/carbon drum abatement stacks at the annual average volumetric flow of 29.19 m^3/h and a short term peak of 984.62 m^3/h for concurrent emissions from all five packed scrubber/carbon drum vents. The annual average and peak short term volumetric flowrates for all five packed scrubber/carbon drum abatement vents are worst case flowrates calculated by us from flow data provided by the operator in the 2006 permit application , that is taking the annual average and short term peak

combined volumetric flows of the five multi-product plant scrubber units plus stack A80 (now decommissioned ammonia scrubber) values of 29.19 m^3/h and 984.62 m^3/h. Applying an annual dispersion factor for ground level emissions of 148 µg/m^3/g/s and an hourly dispersion factor for ground level emission of 3900 µg/m^3/g/s. [2]

Note 2. Long term (annual average) environmental quality standard (EQS) for ammonia at sensitive ecological receptors where bryophytes or lichens are present which is relevant to the South Pennine Moors SAC which lies within our screening distance for the site.

Note 3. Revised ELV as a result of this variation determination (EPR/BP3831SR/V005).

Note 4. Short term EQS for carbon monoxide for an 8 hour running average across a 24 hour period (for comparison against an 8 hour running average calculated from the hourly PC multiplied by a conversion factor of 0.7).[3]

Note 5. Short term EQS values for hydrogen fluoride for protected conservations areas: 0.5 µg/Nm^3 as a weekly average and 5 µg/Nm^3 as a daily average (for comparison against PC values calculated from the hourly average PC multiplied by a conversion factor of 0.59 to provide a daily average and multiplying this daily average by a conversion factor of 0.4 to provide a weekly mean value).[4]

Note 6. There is no published EAL for iodine and for the purpose of our conservative assessment of impacts the short-term EAL for chlorine has been applied.

Note 7. Target daily mean predicted environmental concentration (PEC) for oxides of nitrogen (expressed as NO_2) for protected sites (for comparison against PEC values based on the hourly average PC multiplied by a factor of 0.59 to provide a daily average value).

Note 8. Target annual mean EQS for sulphur dioxide for protected conservation areas where lichens or bryophytes are present which is relevant to the South Pennine Moors SAC which lies within our screening distance for the site.

Note 9. Short term EQS for sulphur dioxide as a 15 minute limit (for comparison against a 15 minute mean PC calculated from the hourly average PC multiplied by a conversion factor of 1.34).

Note 10. Short term EQS for sulphur dioxide as a 24 hour limit (for comparison against a daily average PC calculated from the hourly average PC value multiplied by a factor of 0.59).

Note 11. If worst case long term PC does not exceed 1% of the relevant long term EQS or EAL and worst case short term PC does not exceed 10% of the relevant short term EQS or EAL, the emission may be screened as insignificant with respect to the risk of long or short term impacts on air quality.

[2] Taken from Environment Agency online guidance available on GOV.UK.
[3] Taken from Environment Agency online guidance available on GOV.UK.
[4] Conversion factor for conversion of daily average to weekly mean for hydrogen fluoride provided by the Environment Agency. Other conversion factors taken from Environment Agency online guidance available on GOV.UK.

Table 2. Worst case impact assessment for emissions of pollutants from a single packed scrubber/carbon drum stack at EPR 4.02 benchmark or relevant IED Annex VII Part 4 values or revised ELVs

Pollutant	**ELV (mg/Nm^3)**	**Release Rate Long term (g/s)**	**Release Rate Short term (g/s)**	**Process Contribution (PC) annual average [Note 1] (µg/m^3)**	**Process Contribution (PC) hourly average [Note 1] (µg/m^3)**	**EQS/EAL Long term (µg/m^3)**	**EQS/EAL Short term 1 (µg/m^3)**	**EQS/EAL Short term 2 (µg/m^3)**	**PC as % EQS/EAL Long term (µg/m^3)**	**PC as % EQS/EAL Short term**	**Breach of significance thresholds Yes/No [Note 8]**
Ammonia	10	1.62E-05	0.00055	0.002	2.133	1 [Note 2]	2500	N/A	0.24	0.09	No
Bromine	10	1.62E-05	0.00055	0.002	2.133	N/A	70	N/A	N/A	3.05	No
Hydrogen fluoride	5	8.11E-06	0.00027	0.001	1.067	N/A	160	0.5, 5 [Note 3]	N/A	0.67, 50.34, 12.59	Yes
Hydrogen fluoride	0.8	1.30E-06	4.4E-05	0.000	0.171	N/A	160	0.5, 5 [Note 3]	N/A	0.11, 8.06, 2.01	No
Total acid forming gases of nitrogen (expressed as NO_2)	200	0.00032	0.01094	0.048	42.667	30	200	75 [Note 4]	0.16	21.33, 33.56	Yes
Total acid forming gases of nitrogen (expressed as NO_2)	55	8.92E-05	0.00301	0.013	11.733	30	200	75 [Note 4]	0.04	5.87, 9.23	No
Oxides of sulphur	50	8.11E-05	0.00274	0.012	10.667	10 [Note 5]	266 [Note 6]	125 [Note 7]	0.12	5.37, 5.03	No

Pollutant	ELV (mg/Nm^3)	Release Rate Long term (g/s)	Release Rate Short term (g/s)	Process Contribution (PC) annual average [Note 1] (µg/m^3)	Process Contribution (PC) hourly average [Note 1] (µg/m^3)	EQS/EAL Long term (µg/m^3)	EQS/EAL Short term 1 (µg/m^3)	EQS/EAL Short term 2 (µg/m^3)	PC as % EQS/EAL Long term (µg/m^3)	PC as % EQS/EAL Short term	Breach of significance thresholds Yes/No [Note 8]
(expressed as SO_2)											

Note 1. Worst case emissions impact assessment based on ground level discharge heights for discharge from a single packed scrubber/carbon drum abatement stacks at the annual average volumetric flow of 5.84 m^3/h and short term peak flow of 196.23 m^3/h for emissions from a single packed scrubber/carbon drum vent. The average annual and peak short term volumetric flow rates from a single packed scrubber/carbon drum abatement vent are worst case flowrates calculated by us from flow data provided by the operator in the 2006 permit application, that is taking the average annual or short term peak combined volumetric flows of the five multi-product plant scrubber units plus stack A80 (now decommissioned ammonia scrubber) value of 29.19 m^3/h or 984.62 m^3/h and dividing by 5. Applying an annual dispersion factor for ground level emissions of 148 µg/m^3/g/s and an hourly dispersion factor for ground level emission of 3900 µg/m^3/g/s.[5]

Note 2. Long term environmental quality standard (EQS) for ammonia at sensitive ecological receptors where bryophytes or lichens are present which is relevant to the South Pennine Moors SAC which lies within our screening distance for the site.

Note 3. Short term EQS values for hydrogen fluoride for protected conservations areas: 0.5 µg/Nm^3 as a weekly average and 5 µg/Nm^3 as a daily average (for comparison against PC values calculated from the hourly average PC multiplied by a conversion factor of 0.59 to provide a daily average and multiplying this daily average by a conversion factor of 0.4 to provide a weekly mean value). [6]

Note 4.Target daily mean predicted environmental concentration (PEC) for oxides of nitrogen (expressed as NO_2) for protected sites (for comparison against PEC values based on the hourly average PC multiplied by a factor of 0.59 to provide a daily average value).

Note 5. Target annual mean EQS for sulphur dioxide for protected conservation areas where lichens or bryophytes are present which is relevant to the South Pennine Moors SAC which lies within our screening distance for the site.

Note 6. Short term EQS for sulphur dioxide as a 15 minute limit (for comparison against a 15 minute mean PC calculated from the hourly average PC multiplied by a conversion factor of 1.34).

Note 7. Short term EQS for sulphur dioxide as a 24 hour limit (for comparison against a daily average PC calculated from the hourly average PC value multiplied by a factor of 0.59).

[5] Taken from Environment Agency online guidance available on GOV.UK.
[6] Conversion factor for conversion of daily average to weekly mean for hydrogen fluoride provided by the Environment Agency. Other conversion factors taken from Environment Agency online guidance available on GOV.UK.

Note 8. If worst case long term PC does not exceed 1% of the relevant long term EQS or EAL and worst case short term PC does not exceed 10% of the relevant short term EQS or EAL, the emission may be screened as insignificant with respect to the risk of long or short term impacts on air quality.

Table 3. Worst case assessment of deposition impacts for emissions of pollutants from a single packed scrubber/carbon drum abatement stacks at EPR 4.02 benchmark or revised ELVs.

Pollutant	**ELV (mg/Nm^3)**	**Release Rate Long term [Note 1] (g/s)**	**Process Contribution (PC) annual average [Note 1] ($\mu g/m^3$)**	**Deposition velocity [Note 2] (m/s)**	**Deposition flux [Note 3]**	**Maximum nutrient N dry deposition flux [Note 4] (kgN/ha/yr)**	**Maximum contribution to acidification (N or S) dry deposition flux [Note 5] (keq/ha/yr)**	**Relevant Critical Load (CL) or deposition flux for conservation sites [Note 6]**	**Deposition rate as % CL or deposition flux at conservation sites [Note 7]**	**Breach of significance thresholds Yes/No [Note 8]**
Ammonia	10	1.62E-05	0.0024	0.02 dry for grassland, 0.03 dry for woodland	0.000048 $\mu g/m^2/s$ dry for grassland, 0.000072 $\mu g/m^2/s$ dry for woodland	0.019 (woodland)	0.0014 (woodland)	5 kgN/ha/yr, 0.321 keq/ha/yr	0.38%, 0.42%	No
Hydrogen fluoride	0.8	1.30E-06	0.000192	0.03 total	0.000498 $mg/m^2/day$ total to ground	N/A	N/A	2.1 $mg/m^2/day$ to ground	0.02%	No
Mercury and its compounds	0.1	1.62E-07	0.000024	0.03 total	0.0000622 $mg/m^2/day$ total to ground	N/A	N/A	0.004 $mg/m^2/day$ to ground	1.56%	Yes
Mercury and its compounds	0.05	8.11E-08	0.000012	0.03 total	0.0000311 $mg/m^2/day$ total to ground	N/A	N/A	0.004 $mg/m^2/day$ to ground	0.78%	No

Pollutant	ELV (mg/Nm^3)	Release Rate Long term [Note 1] (g/s)	Process Contribution (PC) annual average [Note 1] ($\mu g/m^3$)	Deposition velocity [Note 2] (m/s)	Deposition flux [Note 3]	Maximum nutrient N dry deposition flux [Note 4] (kgN/ha/yr)	Maximum contribution to acidification (N or S) dry deposition flux [Note 5] (keq/ha/yr)	Relevant Critical Load (CL) or deposition flux for conservation sites [Note 6]	Deposition rate as % CL or deposition flux at conservation sites [Note 7]	Breach of significance thresholds Yes/No [Note 8]
Total acid forming gases of nitrogen (expressed as NO_2)	55	8.92E-05	0.0132	0.0015 dry for grassland, 0.003 dry for woodland	0.0000198 $\mu g/m^2/s$ dry for grassland, 0.0000396 $\mu g/m^2/s$ dry for woodland	0.003801 (woodland)	0.000271 (woodland)	5 kgN/ha/yr, 0.321 keq/ha/yr	0.08%, 0.09%	No
Oxides of sulphur (expressed as SO_2)	50	8.11E-05	0.012	0.012 dry for grassland, 0.024 dry for woodland	0.000144 $\mu g/m^2/s$ dry for grassland, 0.000288 $\mu g/m^2/s$ dry for woodland	N/A	0.00284 (woodland)	0.428 keq/ha/yr	0.66%	No

Note 1. Worst case emissions impact assessment based on ground level discharge heights for discharge from a single packed scrubber/carbon drum abatement stack at the annual average volumetric flow of 5.838 m^3/h and short term peak flow of 196.23 m^3/h for emissions from a single packed scrubber/carbon drum vent. The average annual and peak short term volumetric flows from a single packed scrubber/carbon drum abatement vent are worst case flowrates calculated by us from flow data provided by the operator in the 2006 permit application, that is taking the average annual or short term peak combined volumetric flows of the five multi-product plant scrubber units plus stack A80 (now decommissioned ammonia scrubber) value of 29.19 m^3/h or 984.62 m^3/h and dividing by 5. Applying an annual dispersion factor for ground level emissions of 148 $\mu g/m^3/g/s$.[7]

Note 2. Deposition velocities applied for screening of the significance of deposition impacts of ammonia, nutrient nitrogen and sulphur or nitrogen related acidification effects at conservation sites are based on dry deposition velocity for different receptor groundcover (grassland or woodland) relevant to protected sites within

[7] Taken from Environment Agency online guidance available on GOV.UK.

screening distance of the installation, that is South Pennine Moors SAC (5.74 km) and Peak District Moors (South Pennine Moors Phase 1) SPA (5.74 km).[8] Deposition velocities for screening of the significance of other pollutants (fluoride and mercury) are total deposition velocities.[9]

Note 3. Deposition flux applied for screening of the significance deposition impacts of ammonia, nutrient nitrogen and sulphur or nitrogen related acidification effects at conservation sites are based on dry deposition flux in units of µg/m^2/s. Deposition flux for screening of the significance of other pollutants (fluoride and mercury) are total deposition flux in units of mg/m^2/day. Deposition flux values are calculated by multiplying the maximum annual mean PC by the deposition velocity taking into account the reporting units.

Note 4. Maximum nutrient N dry deposition flux for screening of the significance of deposition impacts of ammonia and nutrient nitrogen is calculated from the maximum deposition flux for woodland for each pollutant converting the deposition flux in µg/m^2/s to kgN/ha/yr.

Note 5. Maximum contribution to acidification (N or S) dry deposition flux for screening of the significance of deposition impacts of N or S is calculated from the maximum deposition flux for woodland for N or S and converting the deposition flux in µg/m^2/s to keq/ha/yr.

Note 6. Relevant Critical Load (CL) or deposition flux for screening of deposition impacts of ammonia, nutrient nitrogen and sulphur or nitrogen related acidification effects at the protected conservation sites within screening distance of the installation , that is the South Pennine Moors SAC and Peak District Moors (South Pennine Moors Phase 1) sites.[10]

Note 7. Worst case screening assessment of deposition rates as % CL or deposition flux at conservation sites for ammonia, nutrient nitrogen and sulphur or nitrogen acidification impacts, or, as % of our published thresholds for fluoride and mercury deposition to ground.[11]

Note 8. If worst case deposition rate does not exceed 1% of the relevant long term Critical Load or deposition flux for the protected site or does not exceed 1% of our published thresholds deposition to ground, the emission may be screened as insignificant with respect to the risk of long term impacts from deposition.

[8] Provided by the Environment Agency.
[9] Taken from Environment Agency online guidance available on GOV.UK.
[10] Data taken from the APIS website.
[11] Taken from Environment Agency online guidance available on GOV.UK.

Table 4. Emission Limit Values (ELVs) set in the varied and consolidated permit as a result of variation EPR/BP3731SR/V005

Parameter	Limit (including unit)	Derivation of limit	Comment
VOC	Annual total mass release limits (in tonnes per year): acetonitrile 3, dichloromethane 1, Class A solvents 5, Class B solvents 35	Limits set in 2006 permit and retained in 2007 variation	Whilst solvent consumption has considerably reduced since the 2006 permit determination due to decommissioning/demolition of single product plant, annual mass emission limits for certain VOCs (acetonitrile, dichloromethane, total Class A solvents and Total Class B solvents) have been retained to maintain operator's flexibility within the MPP scope. We assessed impacts at these levels during the 2006 determination and this assessment remains valid.
VOC	IED Annex VII limits: total emission limit value 5% of solvent input and specific limits of 2 mg/Nm^3 and 20 mg/Nm^3 for certain VOCs	EPR Schedule 14 (transposes IED Chapter V and Annex VII which replaces SED)	The operator has chosen to continue to manage VOC emissions to air through the total mass emission limit of 5% of solvent input for VOC emissions to air from manufacturing of pharmaceutical products which is regulated under Schedule 14 of the EPR as a solvent emission activity. This limit was set in the 2006 permit to attain compliance with the Solvent Emissions Directive (SED) which has since been replaced by Chapter V of the IED. This total emission limit value includes both fugitive and point source emissions to air with solvent 'input' as defined in Article 57 of the IED. We have set the following additional IED Annex VII limits in Table S3.1 of the varied permit: • Emission limit values for VOCs specified in Article 58 and Part 4 of Annex VII of the IED substances: o 2 mg/Nm^3 for emissions of VOCs with the following hazard statements H340, H350, H350i, H360D or H360F where the mass flow of the sum of the compounds is greater than, or equal to, 10 g/h. o 20 mg/Nm^3 for emissions of halogenated VOCs with the hazard statements H341 or H351, where the mass flow of the sum of the compounds causing the hazard statements H341 or H351 is greater than, or equal to, 100 g/h.

Parameter	Limit (including unit)	Derivation of limit	Comment
Particulates	No limit set	2007 variation	As for 2007 variation, we have not set the EPR 4.02 sector benchmark for emissions of particulate matter as active ingredients of 0.15 mg/m^3 or the EPR 4.02 particulate matter benchmark range of 5-20 mg/Nm^3. We have not set ELVs as, based on the information provided in the variation application EPR/BP3731SR/V005, we are satisfied that the emissions from these sources are minimised and controlled by the operator's techniques to levels which are likely to be insignificant.
Total amines (expressed as dimethylamine)	10 mg/Nm^3	EPR 4.02 sector benchmark	We have retained the EPR 4.02 benchmark for emissions of total amines (expressed as dimethylamine) in the varied permit. We have not reassessed emissions at this benchmark level as there are no published EALs for total amines and the operating techniques specified within the varied and consolidated permit require the operator to assess releases of specific substances against any current environmental assessment levels [Note 2].
Ammonia	10 mg/Nm^3 [Note 1]	EPR 4.02 sector benchmark	We have reviewed the assessment performed in the 2006 permit determination to screen emissions at the EPR benchmark value of 10 mg/Nm^3 against the current long term and short term EALs for ammonia: • ammonia human health: o 180 µg/Nm^3 as an annual average o 2500 µg/Nm^3 as an hourly limit • ammonia protected ecological receptors where lichens or bryophytes are present: o 1 µg/Nm^3 as an annual average The reassessment is a conservative (worst case) assessment, based on the combined average and worst case short term flowrates used in the 2006 determination. For the long and short term assessment the combined emissions of the five remaining abatement unit stacks was assessed. Based on this assessment, the ELV in the current permit which is based on the current EPR 4.02 benchmark ELV of 10 mg/Nm^3 would be required to be reduced to a maximum value of 2 mg/Nm^3 to ensure emissions will not breach the long term significance threshold for ammonia levels in air at sensitive ecological receptors. We have noted that the South Pennine Moors SAC, which is within our screening

Parameter	Limit (including unit)	Derivation of limit	Comment
			distance from the site, is a protected habitat for ammonia sensitive lichens and bryophytes and has a lower critical load value of 5 kgN/ha/yr for nutrient nitrogen deposition. Taking this into account in our conservative assessment, emissions of ammonia at the benchmark ELV of 10 mg/Nm^3 will not breach significance thresholds when emissions are restricted to an average output from one stack only over the course of a year and we have retained the current permit ELV for this scenario [Note 2].
Benzene	2 mg/Nm^3 [Note 3]	IED Annex VII Part 4(1) limit	We assessed emissions at the EPR 4.02 sector benchmark for emissions of chlorobenzene during the 2006 determination process for emissions from single and multi-purpose plants and found the predicted concentrations based on zero stack height of discharges did not breach significance thresholds. Chlorobenzene is not currently used within the installation and we have therefore reassessed impacts using benzene as a worst case analogue for this type of substance. As a VOC with hazard statement H350, we have reduced the ELV from the sector benchmark of 5 mg/Nm^3 to bring into compliance with the IED Annex VII Part 4 (1) limit of 2mg/Nm^3 for IED Article 58 substances emitted at mass flows at or exceeding 10 g/h. We have reassessed emissions at this ELV in this current variation to confirm that emissions will not breach significance thresholds for benzene for an ELV of 2 mg/Nm^3 [Note 2].
Bromine	10 mg/Nm^3 [Note 1]	EPR 4.02 sector benchmark	We have retained the EPR 4.02 benchmark for emissions of bromine in the varied permit. We have reassessed emissions at this ELV in this current variation. The reassessment is a conservative (worst case) assessment, based on the combined average and worst case short term flowrates used in the 2006 determination. Based on this assessment we have confirmed that emissions of bromine will not breach significance thresholds for bromine for an ELV of 10 mg/Nm^3 when emissions are restricted to one stack only and we have retained the current permit ELV for this scenario [Note 2].
Carbon disulphide	5 mg/Nm^3	EPR 4.02 sector benchmark	We have retained the EPR 4.02 benchmark for emissions of carbon disulphide in the varied permit. We have reassessed emissions at this ELV in this current variation to confirm that emissions will not breach significance thresholds for carbon disulphide for an ELV of 5 mg/Nm^3 [Note 2].

Parameter	Limit (including unit)	Derivation of limit	Comment
Carbon monoxide	1 kg/h	2006 permit and 2007 variation	We have retained the emission rate ELV assessed and set in the 2006 permit. We have reassessed emissions at this ELV in this current variation to confirm that emissions will not breach significance thresholds for carbon monoxide for an ELV of 1 kg/h [Note 2].
Chlorine	10 mg/Nm^3	EPR 4.02 sector benchmark	We have retained the EPR 4.02 benchmark for emissions of chlorine in the varied permit. We have reassessed emissions at this ELV in this current variation to confirm that emissions will not breach significance thresholds for chlorine for an ELV of 10 mg/Nm^3 [Note 2].
1,2 Dichloroethane	2 mg/Nm^3 [Note 3]	IED Annex VII Part 4(2)	1,2 Dichloroethane is a VOC with hazard statement H350 therefore we have reduced the ELV in the varied permit from the EPR 4.02 sector benchmark of 5mg/Nm^3 to 2 mg/Nm^3. This lower ELV is in compliance with the limit set in Annex VII Part 4 (1) of the IED limit for IED Article 58 substances emitted at mass flows at or exceeding 10 g/h. This limit applies to the combined emissions in mg/m^3 of all Article 58 substances. We have reassessed emissions at this ELV in this current variation to confirm that emissions will not breach significance thresholds for 1,2-dichloroethane for an ELV of 2 mg/Nm^3 [Note 2].
Formaldehyde	2 mg/Nm^3	2007 variation	We have retained the ELV for emissions of formaldehyde from 2007 variation. This ELV is lower than the EPR 4.02 sector benchmark of 5mg/Nm^3 which was set in the 2006 permit. We have reassessed emissions at this ELV in this current variation to confirm that emissions will not breach significance thresholds for formaldehyde for an ELV of 2 mg/Nm^3 [Note 2].
Hydrogen bromide	5 mg/Nm^3	EPR 4.02 sector benchmark	We have retained the EPR 4.02 benchmark for emissions of hydrogen bromide in the varied permit. We have reassessed emissions at this ELV in this current variation to confirm that emissions will not breach significance thresholds for hydrogen bromide for an ELV of 5 mg/Nm^3 [Note 2].
Hydrogen chloride	10 mg/Nm^3	EPR 4.02 sector benchmark	We have retained the EPR 4.02 benchmark for emissions of hydrogen chloride in the varied permit. We have reassessed emissions at this ELV in this current variation to

Parameter	Limit (including unit)	Derivation of limit	Comment
			confirm that emissions will not breach significance thresholds for hydrogen chloride for an ELV of 10 mg/Nm^3 [Note 2].
Hydrogen cyanide	2 mg/Nm^3	EPR 4.02 sector benchmark	We have retained the EPR 4.02 benchmark for emissions of hydrogen cyanide in the varied permit. We have reassessed emissions at this ELV in this current variation to confirm that emissions will not breach significance thresholds for hydrogen cyanide for an ELV of 2 mg/Nm^3 [Note 2].
Hydrogen fluoride	0.8 mg/Nm^3 [Note 1]	Permit variation EP/BP3731SR/V005 review of ELVs	We have reviewed the assessment performed in the 2006 permit determination to screen emissions at the EPR benchmark value of 5 mg/Nm^3 against the most stringent current long term and short term EALs for hydrogen fluoride: • hydrogen fluoride human health: o 160 µg/Nm^3 as an hourly limit • hydrogen fluoride protected ecological receptors: o 0.5 µg/Nm^3 as a weekly average o 5.0 µg/Nm^3 as a daily average. The reassessment is a conservative (worst case) assessment, based on the combined average and worst case short term flowrates used in the 2006 determination. Based on this assessment we have varied the ELV from the current EPR 4.02 benchmark ELV of 5 mg/Nm^3 to 0.8 mg/Nm^3 to ensure emissions will not breach significance thresholds for hydrogen fluoride or fluoride deposition to ground when emissions are restricted to one stack only [Note 2].
Hydrogen iodide	5 mg/Nm^3	EPR 4.02 sector benchmark	We have retained the EPR 4.02 benchmark for emissions of hydrogen iodide in the varied permit. We have reassessed emissions at this ELV in this current variation to confirm that emissions will not breach significance thresholds for hydrogen iodide for an ELV of 5 mg/Nm^3 [Note 2].
Hydrogen sulphide	5 mg/Nm^3	EPR 4.02 sector benchmark	We have retained the EPR 4.02 benchmark for emissions of hydrogen sulphide in the varied permit. We have reassessed emissions at this ELV in this current variation to confirm that emissions will not breach significance thresholds for hydrogen sulphide for an ELV of 5 mg/Nm^3 [Note 2].

Parameter	Limit (including unit)	Derivation of limit	Comment
Iodine	10 mg/Nm^3	EPR 4.02 sector benchmark	We have retained the EPR 4.02 benchmark for emissions of iodine in the varied permit. We have reassessed emissions at this ELV in this current variation. There is no published EAL for iodine and for the purpose of our conservative assessment of impacts the short-term EAL for chlorine has been applied (290 µg/Nm^3). Our conservative assessment confirms that emissions will not breach significance thresholds for iodine for an ELV of 10 mg/Nm^3 [Note 2].
Phosgene	1 mg/Nm^3	EPR 4.02 sector benchmark	We have retained the EPR 4.02 benchmark for emissions of phosgene in the varied permit. We have reassessed emissions at this ELV in this current variation to confirm that emissions will not breach significance thresholds for phosgene for an ELV of 1 mg/Nm^3 [Note 2].
Mercury and its compounds (expressed as mercury)	0.05 mg/Nm^3 [Note 1]	Permit variation EP/BP3731SR/V005 review of ELVs	No mercury is used as a raw material and reducing mercury as a contaminant in sodium hydroxide has been addressed in completed improvement programme deliverable IP5 and ongoing raw material management. We have reviewed the assessment performed in the 2006 permit determination to screen emissions at the EPR 4.02 benchmark value of 0.1 mg/Nm^3 against the current long term and short term EALs and ground deposition critical load. The reassessment is a conservative (worst case) assessment, based on the combined average and worst case short term flowrates used in the 2006 determination. Based on this assessment we have varied the ELV from the current EPR 4.02 benchmark ELV of 0.1 mg/Nm^3 to 0.05 mg/Nm^3 to ensure emissions will not breach significance thresholds for mercury deposition to ground when emissions are restricted to one stack only [Note 2].
Total acid forming gases of nitrogen (expressed as NO_2)	55 mg/Nm^3 [Note 1]	Permit variation EP/BP3731SR/V005 review of ELVs	We have reviewed the assessment performed in the 2006 permit determination to screen emissions at the EPR 4.02 benchmark value of 200 mg/Nm^3 against the current long term and short term EALs for nitrogen dioxide and oxides of nitrogen: • Nitrogen dioxide human health: o 40 µg/Nm^3 as an annual average o 200 µg/Nm^3 as an hourly limit • Oxides of nitrogen protected ecological receptors: o 30 µg/Nm^3 as an annual average

Parameter	Limit (including unit)	Derivation of limit	Comment
			o 75 µg/Nm^3 as a daily average The reassessment is a conservative (worst case) assessment, based on the combined average and worst case short term flowrates used in the 2006 determination. Based on this assessment, the ELV in the current permit which is based on the current EPR 4.02 benchmark ELV of 200 mg/Nm^3 is required be reduced to a maximum value of 55 mg/Nm^3 to ensure emissions will not breach significance thresholds for NOx or NO_2 levels in air with emissions restricted to a single stack. We have noted that the South Pennine Moors SAC, which is within our screening distance from the site, is a protected habitat for raised and blanket bogs and has a lower critical load value of 5 kgN/ha/yr for nutrient nitrogen deposition and a critical load value of 0.321 Keq/ha/yr for nitrogen related acidification. The Peak District Moors (South Pennine Moors Phase 1) SPA, which is within our screening distance from the site, is also a protected habitat which has features sensitive to nutrient nitrogen deposition and acidification. Based on our conservative assessment we have varied the ELV from the current EPR 4.02 benchmark ELV of 200 mg/Nm^3 to 55 mg/Nm^3 to ensure emissions of total acid forming gases of nitrogen (expressed as NO_2) will not breach significance thresholds for air quality or deposition to ground when emissions are restricted to one stack only [Note 2].
Organic sulphides and mercaptans (expressed as methyl mercaptan)	2 mg/Nm^3	EPR 4.02 sector benchmark	We have retained the EPR 4.02 benchmark for emissions of organic sulphides and mercaptans. We have not reassessed emissions at this benchmark level as there are no published EALs for non-specified organic sulphides and mercaptans and the operating techniques specified within the varied and consolidated permit require the operator to assess releases of specific substances against any current environmental assessment levels [Note 2].
Oxides of sulphur (expressed as SO_2)	50 mg/Nm^3 [Note 1]	EPR 4.02 sector benchmark	We have reviewed the assessment performed in the 2006 permit determination to screen emissions at the EPR 4.02 benchmark value of 50 mg/Nm^3 against the current long term and short term EALs for sulphur dioxide and sulphuric acid: • Sulphur dioxide human health: o 266 µg/Nm^3 as a 15 minute mean o 350 µg/Nm^3 as an hourly limit o 125 µg/Nm^3 as a 24 hour average

Parameter	Limit (including unit)	Derivation of limit	Comment
			• Sulphur dioxide protected ecological receptors: o 10 µg/Nm^3 as an annual average where lichens or bryophytes are present The reassessment is a conservative (worst case) assessment, based on the combined average and worst case short term flowrates used in the 2006 determination for the combined emissions of the five remaining abatement unit stacks. Based on this assessment we have confirmed that emissions will not breach significance thresholds for oxides of sulphur in air for an ELV of 50 mg/m^3 when emissions are restricted to a single stack. We have noted that the South Pennine Moors SAC, which is within our screening distance from the site, is a protected habitat for raised and blanket bogs which have a lower critical load for sulphur related acid deposition of 0.248 Keq/ha/yr. The site is also protected due to the presence of Old Sessile Oak Wood which has a lower critical load for sulphur related acid deposition of 0.428 Keq/ha/yr. Based on our conservative assessment, emissions of oxides of sulphur (expressed as SO_2) from a single stack at the current EPR 4.02 benchmark ELV of 50 mg/Nm^3 will not breach significance thresholds for air quality or deposition to ground when emissions are restricted to one stack only [Note 2].
Total phenols, cresols and xylols (expressed as phenol)	10 mg/Nm^3	EPR 4.02 sector benchmark	We have retained the ELV for emissions of phenols, cresols and xylols in the varied permit. We have reassessed emissions at this ELV in this current variation to confirm that emissions will not breach significance thresholds for phenol for an ELV of 10 mg/Nm^3 [Note 2].
Trimethylamine	2 mg/Nm^3	EPR 4.02 sector benchmark	We have retained the EPR 4.02 benchmark for emissions of trimethylamine. We have not reassessed emissions at this benchmark level as there are no published EALs for trimethylamine [Note 2].

Note 1: Based on our conservative assessment of emissions impacts we have decided that emissions at this emissions limit value will not exceed the significance threshold for long or short term impacts for this parameter when emissions are restricted as follows:

- For ammonia and mercury and its compounds: emissions are restricted to an average of one abatement stack source emitting over the course of a year.

- For bromine, hydrogen fluoride, total acid forming gases of nitrogen and oxides of sulphur: emissions are restricted to a single stack source emitting at any one time.

Under the MPP, the operator may perform their own risk assessment to justify relaxation of these restrictions and may therefore justify lifting of the above restrictions if they can demonstrate there is no significant risk to sensitive receptors. The operator must obtain our agreement in writing before beginning production runs where these restrictions on emissions are not applied.

Note 2: Under the MPP the above emissions limit values (ELVs) are factored into the operator's emissions to air risk assessment for proposed production of development and commercial API in the multi-purpose plants as described in the document: 'SOP Emissions to Atmosphere Compliance for Product Accommodations under the MPP document LDMS_001_00018995' (version received 30/01/19). This risk assessment procedure requires the operator to take into account current published environmental assessment levels (EALs) and critical loads for sensitive receptors in assessing potential long and short term impacts and take action to ensure emissions do not threaten exceedance of EALs or risk significant impacts. Actions to be considered by the operator include: review of the proposed production process; scheduling of production campaigns to limit short term emission rates from multiple sources; and/or, use of abatement to prevent significant impacts. Under the MPP, monitoring of emissions from the abatement plant is required at least once during the campaign to demonstrate performance of the abatement technique.

Note 3: The IED limit of 2 mg/Nm^3 is BAT for emissions of VOCs with the following hazard statements H340, H350, H350i, H360D or H360F where the mass flow of the sum of the compounds is greater than, or equal to, 10 g/h. The operator will take the mass flow figure of 10g/h into account in their risk assessment. In the case where the combined mass flows do not exceed the thresholds of 10 g/h or 100 g/h the operator may agree in writing with the Environment Agency a higher ELV provided the operator can justify that this does not threaten to breach significance thresholds for long or short term impacts.

2.0 Revised multi-product protocol (MPP)

The 2006 IPPC permit replaced the previous IPC permit for the installation and permitted AstraZeneca UK Limited to continue to operate bulk pharmaceuticals manufacturing plants at the Macclesfield site including a range of single purpose plants and 5 multi-purpose plants for the development, synthesis and manufacture of pharmaceutical chemicals. To facilitate production of commercial development products the permit allows operation of the multi-purpose plants to an MPP. At the time of the determination of the permit in 2006, and the subsequent variation and consolidation in 2007, the majority of the output from the installation was established (commercial) product produced in a range of single purpose plants. A smaller quantity of development products were produced mainly in the multi-purpose plants.

This decision document relates to the current variation (EPR/BP3731SR/V005) which consolidates the 2007 permit (variation NP3034UB) with the two administrative variations issued in 2010 and 2016 and also updates the permit to our current chemicals sector template conditions. This variation updates the consolidated permit in line with the changes to the limits of the activities that have taken place over recent years as a result of demolition of a number of buildings and significantly reduced commercial pharmaceutical production. There are no changes to the actual activities undertaken as a result of the changes to the site and the site remains a Lower Tier COMAH site due to the quantities of hazardous materials stored on the site

The changes included in this variation (EPR/BP3731SR/V005) reduce the consumption of raw materials, the quantities of hazardous substances stored on the site and cease all emissions associated with the established commercial production processes within certain demolished and/or decommissioned plants, , that is:

- Decommissioned and demolished production plants:
  - the single product plant No.1 Plant Crude's/Semi Pures
  - multi-product plants: SSMF and DA2.
- Decommissioned multi-product plants:
  - SRP, NPP, DPF Unit 2.

As a result of this variation (EPR/BP3731SR/V005) all future API production will be performed under a revised MPP for the installation in the remaining multi-purpose plants:

- DHP, DA1 DPF, DA1 DSP1, DA1 DSP2, DA1 DSP3, DA1 DSP4, DA3

As a result of this variation (EPR/BP3731SR/V005), the existing MPP has been updated (version submitted 23/01/19) to meet our MPP guidance report reference GEHO0511BTUN-E-E, and now requires the operator to notify us and seek approval before beginning production of API intended for commercial use (with commercial use as defined in our guidance note RGN 2[12] and including production associated with a commercial research and development contracts as well as product).

In accordance with the definition of commercial use and production in RGN 2, API product intended for commercial use includes Phase III API and all stages of product: from crude though to pure. The operator will also follow the MPP for the production of API for in-house R&D related 'development production' of API, that is, products not intended for commercial use. The operator is not required to notify us and seek approval for this 'non-commercial production' as this is beyond the scope of our MPP guidance. The revised MPP for the installation acknowledges this and the differing notification requirements.

[12] RGN 2: Understanding the meaning of regulated facility (https://www.gov.uk/government/publications/rgn-2-understanding-the-meaning-of-regulated-facility)

Non-commercial product development remains within the EPR Schedule 14 solvent emission activity and the revised MPP therefore provides the operator with a methodology for managing EPR permit compliance and is supported by the revised SOP Emissions to Atmosphere Compliance for Product Accommodations under the MPP document LDMS_001_00018995, final version received 30/01/19.

We have carried forward from the 2006 permit and 2007 variation, the requirement for the operator to perform periodic stack monitoring of emissions of certain substances from the packed scrubber/carbon drum abatement units (emission points A120, A134, A148, A169 and A183). Periodic monitoring is to be performed as required in section 6.2.5.2 of the revised MPP AZDoc0116277 document received 23/01/19, that is:

> 'Emission monitoring is performed to MCERT accredited methodology and is undertaken once during the campaign to demonstrate the performance of the abatement for the duty / abatement technique.'

The substances included are certain substances having a sector benchmark emission level listed in the sector guidance EPR 4.02[13].

3.0 Improvement programme

Current permit version V004

We reviewed the status of the existing improvement programme during the determination process for this variation V005. We required the operator to submit evidence of completion of the improvement conditions through issue of a Schedule 5 Notice (issued 05/11/18). The operator provided evidence of delivery, and our acceptance of delivery, of all outstanding improvement programme items to the date identified in the permit except for IP10 and IP11:

- IP10: The Operator shall undertake a waste minimisation audit. The options shall comply with the requirements of Sections 2.4.2 of Sector Guidance Note S4.02. Where appropriate the plan shall contain dates for the implementation of individual improvements. The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the plan. The plan shall be implemented by the operator from the date of approval by the Agency.
- IP11: The Operator shall review their written Site Closure Plan with regard to the requirements set out in Section 2.11 of the Agency Guidance Note IPPC S6.11, October 2003. Upon completion of the plan a summary of the document shall be submitted to the Agency in writing.

The operator was unable to provide evidence to confirm that IP10 or IP11 were completed for the due date of 01/01/09 and our records for this period are incomplete.

The operator has however described a recent detailed waste minimisation assessment to the sector BAT standard (EPR 4.02) in the variation application report for this variation (V005). This description was provided by the operator in responses to section 6e of Part C3 of the application. This assessment identified a number of improvement options which the operator intends to complete as part of the continuous improvements to environmental performance required under their Environmental Management System (EMS). In view of this evidence we have recorded that IP10 has been completed in the varied permit.

The operator has provided a Site Closure Plan with the variation application within Appendix C2 5.0, document reference AZ SOP LDMS_001_0016010136 V2. This plan is maintained under the operator's EMS and has been implemented during the decommissioning activities undertaken on-site over recent years. In view of this evidence we have recorded that IP11 has been completed in the varied permit.

[13] How to comply with your environmental permit, Additional guidance for: Speciality Organic Chemicals Sector (EPR 4.02) (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/298096/geho0209bpiv-e-e.pdf)

New improvement programme items relating to this variation (EPR/BP3731SR/V005)

We have included a new improvement programme item, IP12, requiring the operator to agree in writing with us the format and content of the notification documentation required by condition 1.5.1 and the multi-product protocol (MPP) with respect to the intention to produce API for commercial purposes within the multi-purpose plants. We have required the operator to submit a written plan to us for agreement. The plan must contain a summary of the information to be provided to us to meet the notification requirements of condition 1.5.1 and in accordance with our guidance on multi-product protocol (MPP) report reference GEHO0511BTUN-E-E. The written plan must be submitted to us by prior to production of API for commercial purposes. The operator must implement this plan as agreed, and from the date stipulated by the Environment Agency.

We have included a new improvement programme item, IP13, requiring the operator to submit a written plan to us for technical assessment and approval. The plan must detail the proposed changes to make a permanent access point for monitoring emissions to air from emission reference point A148 (vent V7555): Batch Processing DA1 DSP3 (Packed Scrubber Column/ Carbon Drums DP01212). The proposed changes must meet the standards outlined in our guidance: TGN M1 Sampling requirements for stack emissions monitoring. The written plan must be submitted to us by 01/09/19. The operator must implement this plan as agreed in writing with us, and from the date stipulated by us.

4.0 Change in description of the effluent treatment plant activity

The operator has decided to retain the effluent treatment activity within the permit although there is currently no physico-chemical treatment of trade effluent undertaken and the effluent treatment tanks are currently used for surface water balancing and settlement prior to discharge to sewer under the Trade Effluent Discharge Consent. Due to the scale of the plant and the volume of wastewater which may be discharged to sewer under the Trade Effluent Discharge Consent we have altered the status of this activity from a directly associated activity to an EPR Schedule 1 Part A activity:

> S5.4 A1 (a) (ii) Disposal of non-hazardous waste with a capacity exceeding 50 tonnes per day involving physico-chemical treatment.

The operator has agreed with this description of the effluent treatment plant activity. We have previously assessed the risks from this activity during the 2006 permit variation and set emission limits to prevent risk of significant impacts on receiving waters, that is the discharge to surface water from the receiving sewage treatment works. We have decided that there is no change in the potential impact of this activity in varying the description from a directly associated activity to an EPR Schedule 1 Part A activity and no further assessment of risk is required.

Decision checklist

Aspect considered	Decision
Receipt of application	
Confidential information	A claim for commercial or industrial confidentiality has been made. This claim was made by AstraZeneca UK Limited and is restricted to the details included in Appendix 2 Part 2 C3.3.1 of the application for variation which provide the Chemicals Sector Block Diagrams and associated information for Fulvestrant and Acalabrutinib production. The level of technical detail regarding the reaction schematics provided in the document exceeds that required for determination of the permit variation application EPR/BP3731SR/V005 and does not provide information which we can use to assess the emissions or impacts of the described production schemes. The information is therefore not material to this variation application and it is not relevant to the public interest to include this information on the public register. In the event that the operator proposes to produce either of the products in future this will be performed under the multi-product protocol (MPP) for the installation and, in keeping with the MPP, the operator must submit detailed information to us for our approval before beginning production. This detailed information may include a revised version of the information submitted with the application regarding the proposed production process and will include projected emissions and emissions control techniques. On receipt of this information we will decide to what extent such information may be regarded as confidential. In summary, we have reviewed the document and decided that the information contained is not material to determination of this variation application. We have removed this document from our electronic records and returned the hard copy version of the information to the operator.
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: • Local Authority Environmental Health (Cheshire East Environmental Protection) • Health and Safety Executive (HSE) • Sewage Authority – United Utilities plc • Local Authority Public Health (Cheshire East Director of Public Health) • Public Health England (PHE)

Aspect considered	Decision
	No responses were received from: • Local Authority Environmental Health (Cheshire East Environmental Protection) • Health and Safety Executive (HSE) • Sewage Authority – United Utilities plc • Local Authority Public Health (Cheshire East DPH) The comments from PHE and our responses are summarised in the consultation section.
The facility	
The regulated facility	We considered the extent and nature of the facilities at the site in accordance with RGN2 'Understanding the meaning of regulated facility', Appendix 2 of RGN 2 'Defining the scope of the installation', Appendix 1 of RGN 2 'Interpretation of Schedule 1', guidance on waste recovery plans and permits. The extent of the facilities are defined in the site plan and in the permit. The activities are defined in table S1.1 of the permit. The operator has decided to retain the effluent treatment activity within the permit although there is currently no physico-chemical treatment of trade effluent undertaken and the effluent treatment tanks are currently used for surface water balancing and settlement prior to discharge to sewer under the Trade Effluent Discharge Consent. Due to the scale of the plant and the volume of wastewater which may be discharged to sewer under the Sewer Discharge Consent we have altered the status of this activity from a directly associated activity to an EPR Schedule 1 Part A activity: S5.4 A1 (a) (ii) Disposal of non-hazardous waste with a capacity exceeding 50 tonnes per day involving physico-chemical treatment. See key issues section for further details.
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. There is no change to the installation boundary however the plan identifies the buildings which remain in use within the installation boundary and reflects the changes due to decommissioning and demolition of certain facilities since issue of the 2007 permit variation and consolidation.
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.

Aspect considered	Decision
	We consider that the application will not affect any sites of nature conservation, landscape and heritage, and/or protected species or habitats identified. We have not consulted Natural England on the application. The decision was taken in accordance with our guidance.
Environmental risk assessment	
Environmental risk	We have reviewed the operator's assessment of the environmental risk from the facility. The operator's risk assessment was unsatisfactory and required additional Environment Agency assessment. The operator's assessment submitted with the variation application did not address the requirement to assess potential emissions to air from the remaining multi-purpose plant against current environmental assessment levels (EALs). The operator provided a risk assessment procedure with the variation application ('SOP Emissions to Atmosphere Compliance for Product Accommodations under the MPP document LDMS_001_00018995') which relied on meeting the emission limit values (ELVs) set in the 2007 varied and consolidated permit to demonstrate BAT. We required the operator to update this procedure (final version received 30/01/19) to address this. In accordance with the revised multi-product protocol submitted as a result of this variation (version submission on 23/01/19 and discussed in the key issues section) the operator will follow the revised SOP Emissions to Atmosphere Compliance for Product Accommodations under the MPP document LDMS_001_00018995 (version submitted on 30/01/19) to assess the impacts of proposed production methodologies, abatement techniques and abatement performance standards for each new production run to ensure emissions do not risk significant impacts on sensitive receptors. In order to establish acceptable emissions levels for proposed production runs under the MPP , that is emissions levels which do not risk significant impacts at sensitive receptors, the revised SOP Emissions to Atmosphere Compliance for Product Accommodations under the MPP document LDMS_001_00018995 (version submitted on 30/01/19) takes into account following: • the ELVs set within the permit; • the BAT emission limit values for certain types of hazardous VOCs identified in Annex VII of the Industrial Emissions Directive (2010/75/EU); and, • published EALs. In view of the ongoing reliance of the operator's risk assessment technique on the sector benchmark based ELVs set within the 2007 permit we have reviewed the ELVs during the determination of this variation application (BP3731SR/V005). The sector benchmark ELVs included in the 2007 variation and consolidation are the same as those presented in the current sector guidance EPR 4.02 and we have reviewed the ongoing validity of these sector benchmark based ELVs with respect to BAT for the installation through performance of our own conservative assessment of the impact of emissions at these levels against current published EALs for sensitive

Aspect considered	Decision
	human health and ecological receptors within our screening distance of the installation. Our conservative (worst case) assessment of the long and short term impacts of emissions at the EPR 4.02 benchmark values from the five packed scrubber/carbon drum abatement units associated with the remaining multi-purpose plants (air emissions reference points: A120, A134, A148, A169 and A183) is presented in the key issues section. The assessment shows that, applying the conservative criteria in our guidance on environmental risk assessment, all emissions may be categorised as environmentally insignificant with respect to long and short term impacts with the exception of: • ammonia • bromine • hydrogen fluoride • mercury and its compounds • total acid forming gases of nitrogen (expressed as nitrogen dioxide (NO_2)) • oxides of sulphur (expressed as sulphur dioxide (SO_2)). Based upon our conservative assessment of impacts, emissions of the above substances at the EPR 4.02 benchmark ELVs in the current EPR permit from all five stack sources concurrently breach significance thresholds for impacts on sensitive receptors , that is • calculated process contributions (PCs) exceed significance thresholds for the relevant EAL for air quality; or • calculated long term deposition to ground rates exceed the relevant significance threshold; or, • calculated dry deposition rates exceed the relevant significance thresholds of critical load values for sensitive ecological receptors. The measures to control these emissions are described in the operating techniques section below.
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	The operator proposes to continue to operate to the standards set out in the sector guidance EPR 4.02 for the speciality organic chemicals sector and the BREF, and associated BAT conclusions, for common waste water and waste gas treatment/management systems in the chemical sector (CWW, BAT conclusions published January 2017 and BREF published June 2016 respectively). Emissions of • ammonia • bromine

Aspect considered	Decision
	• hydrogen fluoride • mercury and its compounds • total acid forming gases of nitrogen (expressed as nitrogen dioxide (NO_2)) • oxides of sulphur (expressed as sulphur dioxide (SO_2)) at the EPR 4.02 benchmark values from all five stack sources concurrently cannot be screened out as insignificant. We have assessed whether the proposed techniques are BAT. Under the operator's revised multi-product protocol (MPP) submitted during this variation (version received 23/01/19 and discussed in the key issues section), ELVs are factored into the operator's emissions to air risk assessment for proposed production of development and commercial API in the multi-purpose plants as described in the document: 'SOP Emissions to Atmosphere Compliance for Product Accommodations under the MPP document LDMS_001_00018995' (version received 30/01/19). This risk assessment procedure requires the operator to take into account current published environmental assessment levels (EALs) in assessing potential long and short term impacts and take action to ensure emissions do not threaten exceedance of EALs or risk significant impacts. Actions to be considered by the operator include: review of the proposed production process; scheduling of production campaigns to limit short term emission rates from multiple sources; and/or, use of abatement to prevent significant impacts. As noted in the key issues section, concurrent emissions of the above substances at ELV concentrations set in the current permit, from all five packed scrubber/carbon drum units breach significance thresholds for impacts on sensitive receptors. Based on our conservative assessment: o Emissions of ammonia from all five packed scrubber/carbon drum abatement plant over the course of a year exceeds the threshold for significance of long term impacts at sensitive conservation receptors where lichens or bryophytes are present and risks exceedance of the significance threshold for nutrient nitrogen deposition at such sites. o Concurrent emissions of bromine, hydrogen fluoride and total acid forming gases of nitrogen from multiple stacks exceed the relevant significance thresholds for short term impacts on air quality. o Concurrent emissions of oxides of sulphur from multiple stacks exceeds the significance threshold for short term impacts on air quality and the significance threshold for acid deposition impacts on sensitive conservation areas. o Concurrent emissions of mercury and its compounds from multiple stacks exceed the significance threshold for deposition to ground. The operator will use the techniques described in the MPP and revised air emissions risk assessment procedure submitted during this variation (final versions received 23/01/19 and 30/01/19 respectively) to ensure that the short term impacts of substances are minimised through scheduling of production runs. Our assessment, which is presented in the key issues section, demonstrates that limiting emissions to a single packed scrubber/carbon

Aspect considered	Decision

	drum stack, ensures that emissions of the following substances at the ELVs set in the current permit do not breach significance thresholds:
	• ammonia
	• bromine
	• oxides of sulphur (expressed as sulphur dioxide (SO_2)).
	Our assessment shows that emissions of hydrogen fluoride, mercury and its compounds, and total acid forming gases of nitrogen (expressed as nitrogen dioxide (NO_2)) do exceed significance criteria for impacts even when releases are restricted to a single packed scrubber/carbon drum stack. We have therefore varied the ELVs for these substances to ensure that, in combination with the techniques described in the operator's multi-product protocol (MPP) and revised air emissions risk assessment procedure submitted during this variation (final versions received 23/01/19 and 30/01/19 respectively), and our restriction of emissions, emissions of these substances do not breach significance thresholds.
	The ELVs which have been varied as a result of this assessment are:
	• hydrogen fluoride, from 5 mg/Nm^3 to 0.8 mg/Nm^3
	• mercury and its compounds from 0.1 mg/Nm^3 to 0.05 mg/Nm^3
	• total acid forming gases of nitrogen (expressed as nitrogen dioxide), from 200 mg/Nm^3 to 55 mg/Nm^3.
	Based on our conservative assessment of emissions impacts we have decided that emissions at the ELVs included in the varied and consolidated permit issued with respect to this variation (BP3731SR/V005) will not exceed the significance threshold for long or short term impacts for this parameter when emissions are restricted as follows:
	• For ammonia and mercury and its compounds:
	  • emissions are restricted to an average of one abatement stack source emitting over the course of a year.
	• For bromine, hydrogen fluoride, total acid forming gases of nitrogen and oxides of sulphur:
	  • emissions are restricted to a single stack source emitting at any one time.
	Under the MPP, the operator may perform their own risk assessment to justify relaxation of the above restrictions if they can demonstrate there is no significant risk to sensitive receptors. The operator must obtain our agreement in writing before beginning production runs where the above restrictions on emissions are not applied. We anticipate that justification and approval will be conducted under the terms of the new MPP condition included in the varied and consolidated permit (condition 1.5.1).
	Under the MPP, monitoring of emissions from the abatement plant is required at least once during the campaign to demonstrate performance of the abatement technique.
	The proposed techniques/ ELVs for emissions that do not screen out as insignificant are in line with the techniques and benchmark levels contained in the technical guidance and we consider them to represent appropriate techniques for the facility. The permit conditions ensure compliance with relevant BREFs and BAT Conclusions, and ELVs deliver compliance with BAT-AELs.

Aspect considered	Decision
Operating techniques for emissions that screen out as insignificant	Based on our conservative assessment of emissions impacts, emissions of • VOCs • total amines (expressed as dimethylamine) • benzene • carbon disulphide • carbon monoxide • chlorine • 1,2-dichloroethane • formaldehyde • hydrogen bromide • hydrogen chloride • hydrogen cyanide • hydrogen iodide • hydrogen sulphide • iodine • phosgene • organic sulphides and mercaptans (expressed as methyl mercaptan) • total phenols, cresols and xylols (expressed as phenol) • trimethylamine have been screened out as insignificant, and so we agree that the applicant's proposed techniques are BAT for the installation. We consider that the emission limits included in the installation permit reflect the BAT for the sector. We have not included the sector benchmark emission limits for particulates or API as we are satisfied that emissions are minimised and controlled by the operator's techniques to levels which are likely to be insignificant.
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.
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.
Improvement programme	Based on the information on the application, we consider that we need to impose an improvement programme. We have imposed an improvement programme as discussed in the key issues section.
Emission limits	ELVs or equivalent parameters or technical measures based on BAT have been amended/deleted for the following substances: • benzene, amended from 5 mg/Nm^3 to 2 mg/Nm^3 • 1,2-dichloroethane, amended from 5 mg/Nm^3 to 2 mg/Nm^3 • hydrogen fluoride, amended from 5 mg/Nm^3 to 0.8 mg/Nm^3

Aspect considered	Decision
	• mercury and its compounds, amended from 0.1 mg/Nm^3 to 0.05 mg/Nm^3 • total acid forming gases of nitrogen (expressed as nitrogen dioxide), amended from 200 mg/Nm^3 to 55 mg/Nm^3 • total VOC (as toluene) batch average mass release rate limit of 2 kg/hr has been deleted. We have amended the ELVs set out in the current permit for benzene and 1,2-dichloroethane to reflect the BAT limits, identified in Part 4 of Annex VII of the IED, for VOCs specified in Article 58 of the IED, , that is: • 2 mg/Nm^3 for emissions of VOCs with the following hazard statements H340, H350, H350i, H360D or H360F where the mass flow of the sum of the compounds is greater than, or equal to, 10 g/h. • 20 mg/Nm^3 for emissions of halogenated VOCs with the hazard statements H341 or H351, where the mass flow of the sum of the compounds causing the hazard statements H341 or H351 is greater than, or equal to, 100 g/h. Benzene and 1,2-dichloroethane are VOCs with the hazard statement H350 and therefore the ELV of 2 mg/Nm^3 applies to the combined emissions. The IED limit of 2 mg/Nm^3 is BAT for combined mass flows at or exceeding 10 g/h. The operator will take this mass flow figure into account in their risk assessment. In the case where the combined mass flows do not exceed the thresholds of 10 g/h or 100 g/h the operator may agree in writing with the Environment Agency a higher ELV provided the operator can justify that this does not threaten to breach significance thresholds for long or short term impacts. If we are satisfied that emissions do not threaten to breach significance thresholds for long or short term impacts we may approve the operator's proposal. We anticipate that justification and approval will be conducted under the terms of the new MPP condition included in the varied and consolidated permit (condition 1.5.1). As noted in the operating techniques section, we have varied ELVs for the hydrogen fluoride, mercury and its compounds and total acid forming gases of nitrogen (expressed as nitrogen dioxide). We have varied the ELVs for these substances to ensure that, in combination with the techniques described in the operator's multi-product protocol (MPP) and revised air emissions risk assessment procedure submitted during this variation (final versions received 23/01/19 and 30/01/19 respectively), emissions do not breach the significance thresholds. Based on our conservative risk assessment we have restricted emissions of these substances to: o an average of one abatement stack emitting over the course of a year for mercury and its compounds; and o a single abatement stack source emitting at any one time for hydrogen fluoride and total acid forming gases of nitrogen (expressed as nitrogen dioxide). Under the MPP, monitoring of emissions from the abatement plant is required at least once during the campaign to demonstrate performance of the abatement technique. We have removed the 2 kg/hr mass release rate limit for total VOC (expressed as toluene). This limit was included in the permit to meet the

Aspect considered	Decision
	Solvent Emissions Directive (SED) compliance requirements which have been superseded by Chapter V and Annex VII of the IED concerning solvent emission activities. As identified in the Operator's response to question 4a of Part C3 and in section 4.1.3 of the operator's revised 'SOP Emissions to Atmosphere Compliance for Product Accommodations under the MPP document LDMS_001_00018995' (final version received 30/01/19), the operator has chosen to comply with the total emission limit value for new installations identified in Annex VII of the IED, that is 5% of annual solvent input. In keeping with Article 59 of the IED, we are not requiring the operator to also comply with the waste gas ELVs identified in part 1 of Annex VII of the IED or to develop a reduction scheme as described in Part 5 of Annex VII of the IED. Under this variation (V005) the operator has amended their emissions assessment methodology, described in the 'SOP Emissions to Atmosphere Compliance for Product Accommodations under the MPP document LDMS_001_00018995' (final version received 30/01/19), to require the application of the most recently published EALs in assessments of estimated emissions from proposed production of development and commercial API in the multi-purpose plants under the multi-product protocol (MPP). We have included this revised SOP within Table S1.2 (operating techniques) of the varied permit (V005) and the operator must therefore ensure that emissions of substances to air from all API production do not exceed EALs, ELVs or sector benchmarks. The ELVs set in the permit provide a conservative basis to ensure that emissions from the five packed scrubber/carbon drum abatement units will not breach significance thresholds for long and short term impacts.
Monitoring	Based on the information in the application we are not fully satisfied that the operator's techniques, personnel and equipment have either MCERTS certification or MCERTS accreditation as appropriate. We are not fully satisfied as the operator proposes to identify the MCERTS accredited contractors and specific MCERTS compliant analysis methods for monitoring of emissions to air on a case by case basis. We have accepted this approach as, under the MPP: • the monitoring requirements and suitable analytical methods will be identified for each API production run or campaign; and, • information on the proposed monitoring techniques will be submitted to us with the MPP notification documentation for our approval.
Reporting	We have added reporting in the permit for the following parameters: • an annual solvent management plan. The annual solvent management plan has been required by new condition 4.2.5 of the varied and consolidated permit with reference to Article 62 of Chapter V of the IED (reporting on compliance). The annual solvent management plan is required in order to demonstrate compliance with Chapter V and Annex VII of the IED in particular: • the requirement for substitution of hazardous substances (Article 58); and, • control of emissions (Article 59):

Aspect considered	Decision
	o the total emission limit value of 5% of solvent input o the specific ELVs identified in Part 4 of Annex VII of the IED. We have amended the descriptions of API products required to be reported in table S4.2 (Performance parameters) from 'established products' and 'development products' to: • product for commercial purpose; and, • product for development purpose Where such products are as defined in our guidance RGN 2. We have retained the requirement for annual reporting of these parameters to enable comparison with data from previous years. We made these decisions in accordance with: • emissions compliance requirements for installations carrying out a solvent emission activity as defined in Schedule 14 of EPR 2016; and, • our guidance RGN 2 which defines commercial and non-commercial production for activities listed in Section 4.5 of Part 2 of Schedule 1 of EPR 2016.
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	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

Aspect considered	Decision
	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, Centre for Radiation, Chemical and Environmental Hazards, received by email attachment 01/10/18.
Brief summary of issues raised
Public Health England made the following recommendation: 'any Environmental Permit issued for this site should contain conditions to ensure that the following potential emissions do not impact upon public health: point source and fugitive emissions to air.' Public Health England raised the following concern: 'the applicant has provided limited fire prevention and accident management scenarios. Due to the combustible nature of materials stored on site, we recommend that further consideration is given to the implementation of fire prevention measures to minimize the public health impact in the event of a fire at the site.' Public Health England stated: 'Based solely on the information contained in the application provided, Public Health England has no significant concerns regarding risk to health of the local population from this proposed activity, providing that the applicant takes all appropriate measures to prevent or control pollution, in accordance with the relevant sector technical guidance or industry best practice.'
Summary of actions taken or show how this has been covered
We have taken into consideration point source and fugitive emissions to air in our determination of this variation application and are satisfied that the operating techniques employed, which are in line with appropriate sector and BAT guidance, and the conditions set in the varied and consolidated permit prevent risk of significant impact on public health. The changes material to this variation application do not increase the risk of fire on the site and we have not performed a detailed assessment of risks from fire or fire prevention measures as part of this variation determination. The site remains a Lower Tier COMAH facility and measures are in place to minimise the potential for major accidents including fire.