

Compliance Assessment Report

Report ID:
CAR_NRW0032498

This form will report compliance with your permit as determined by an NRW officer

Site	Distribution Way EPR/DP3832EF	Permit Ref	DP3832EF		
Operator/Permit holder	Biotage GB Limited				
Regime	Installations				
Date of assessment	24/11/2017	Time in	09:00	Out	09:00
Assessment type	Report/Data Review				
Parts of the permit assessed	Monitoring and ELVs				
Lead officer's name	Kemp, Andi				
Accompanied by					
Recipient's name/position	Dr Nick Jenkins/ Chemistry Production Manager	Date issued	24/11/2017		

Section 1 – Compliance Assessment Summary

This is based on the requirements of the permit under the Environmental Permitting Regulations or the licence under the Water Resources Act 1991 as amended by the Water Act 2003. A detailed explanation is captured in "Compliance Assessment Report Detail" (Section 2) and any actions you may need to take are given in the "Action(s)" (section 4). This summary details where we believe any non-compliance with the permit has occurred, the relevant condition and how the non-compliance has been categorised using our Compliance Classification Scheme (CCS). CCS Scores can be consolidated or suspended where appropriate, to reflect the impact of some non-compliances more accurately. For more details of our CCS scheme, contact your local office.

Permit conditions and compliance summary	CCS Category	Condition(s) breached
E1 - Emissions - Air	C3	3.1.2

KEY: See Section 5 for breach categories, suspended scores will be indicated as such.

A = Assessed or assessed in part (no evidence of non-compliance), **X** = Action only,

O = Ongoing non-compliance, not scored.

Number of breaches recorded	1	Total compliance score (see section 5 for scoring scheme)	4
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If the Number of breaches recorded is greater than zero, please see Section 3 for our proposed enforcement response

Section 2 – Compliance Assessment Report Detail

This section contains a report of our findings and will usually include information on:

- The part(s) of the permit that were assessed (eg. Maintenance, training, combustion plant, etc)
- Where the type of assessment was 'Data Review' details of the report/results triggering the assessment
- Any non-compliances identified
- Any non-compliances with directly applicable legislation
- Details of any multiple non-compliances
- Information on the compliance score accrued inc.
- Details of advice given
- Any other areas of concern
- Any actions requested
- Any examples of good practice
- A reference to photos taken

See sull assessment below re. emissions breaches.

There are three main elements to this:

- 1) non-compliance with emissions to air limits - CCS3 minor non-compliance
- 2) Action 1 to address this issue
- 3) Action 1 includes the requirement to propose monitoring (annual) or alternative with justification, going forward

Biotage – DP3832EF Compliance Assessment 20th October 2017

2016 Monitoring Results, Basis of ELVs and Issues

Refer to CAR1 issued on 13th March 2017 covering 2015 and 2016 monitoring data submissions and exceedances. Only 2016 data will be looked at here, because the permit and the emission limit value basis were varied in 2016 and two improvement conditions were included to provide data to demonstrate compliance with the new ELVs.

The 2016 variation, based on additional batch reaction information supplied by the operator, changed the ELVs from mass per unit volume (mg/m^3) to mass released over time (g/hr). This was done by taking the former permit ELVs in mg/m^3 , converting this to g/m^3 by dividing by 1000. This g/m^3 figure is then multiplied by the volumetric flow rate in m^3/hr to give the new ELV in g/hr . The NRW Regulatory Officer (AK) has previously raised the potential for there to be issues around the basis of the former mg/m^3 ELVs, both in terms of the operator having to meet an instantaneous concentration based limit through the entire batch reaction and secondly the basis for the values of the concentration based ELVs in the first place. Refer to the March 2017 CAR1 for a comparison. The root issue here is in the amount and type of information supplied by the operator in the original application – possibly leading to ELVs that the operator cannot meet and that may not be having a significant effect on the environment.

Since then and captured in the 2016 variation, as stated above, the ELVs have been converted to a g/hr basis – the average result over the whole batch not to exceed the ELV. This allows for peak emissions in the batch and lower emissions either side of the reaction peak period. In other words, this is seen as a better way to set limits and measure compliance for this small scale batch process.

The 2016 variation required two improvement conditions (refer to the permit for the actual full wording):

IC1 - *Conduct stack emissions monitoring for stacks A1 – A4 to determine emission rates for each hour of the batch reaction and work out the average emission rates per hour.*

IC2- *If the emissions from the above exercise exceed the new limits, the operator shall investigate reducing these emissions to below the limits and benchmarks.*

Another problem with this site process is the individual batch reaction times and when within the whole production process, emissions are likely to be produced and the fact that the benchmarks (in former EA SGNs for inorganic chemicals) do not necessarily represent the process used, the scale of the process and the intermittent nature of production.

The 2016 variation used the following information off the operator in terms of each of the four processes, what will be released, when and the whole batch reaction and drying time. Only during certain periods of the whole process will emissions of the listed parameters be formed.

A1 Chlorosilation – *The main process and a variation of it collectively release methanol, other VOCs and HCl. The overall process (loading, reaction, washing and drying) takes 5 days. The principle process releases peak VOC (washing / purification solvents) and HCl over the first 2 – 3 hours, although HCl can be released over the first 2 days of the process. In 2015 this process was carried out 32 times in 1 kg – 12 kg batches.*

A2 Sulphonation – *Again VOCs and HCl are released; peak concentrations being in the first hour. The process takes up to 8 days, with HCl only being released in the first 2 days. In 2015 this process was carried out on 4 occasions in 2 – 3 kg batches.*

A3 Oxidation – *NO₂ and VOCs are released, with peaks in the first hour. The process takes 5 days, but NO_x is only produced in the first 2 – 3 hours. In 2015 this was carried out on 50 occasions in 6 – 7 kg batches.*

A4 Bromination – *HBr is the principle emission here, with peaks at the 3 hour period, although emissions are produced over the first half of a three day process. In 2015 this process was carried out 22 times in 2.4 – 3 kg batches.*

In October 2016 NRW, Biotage and their appointed monitoring contractor met to discuss the new permit and the Improvement Conditions (IC) and how to go about them. This resulted in a specification tender from the contractors, which appeared to design the exercise so as to satisfy the objectives of IC1 – AK extended the deadline of the IC to allow the operator time to conduct this monitoring and assess and present the data.

It should be pointed out that the data and its assessment conclusions and proposals (should the results

exceed the ELV, which they do) have not been formally submitted in the format prescribed by the IC to NRW – the operator simply passed on the raw data in the monitoring report, with no descriptive or explanatory text to present the results and comparison to ELVs. AK had another meeting in March 2017 to discuss the results and look at the monitoring report and data, with a view to determine compliance or otherwise and advise on the way forward. The results for 2015 and 2016 are assessed in the March 2017 CAR1, where warning of non-compliances and the potential necessity for further actions to address the exceedances was given.

This assessment is based on examining the various ELVs, their derivation, the monitoring report, what impact these new releases could have and how to establish either:

1. new ELVs and the basis

and / or

1. abatement or production process alterations (number of batches, amount and type of raw materials used, reaction chemistry and conditions etc.)

with a view to reducing emissions or setting a different basis for compliance.

AK also stressed to the operator that exceedances and permit breaches need to be notified formally to the regulator using the form in Schedule 5 of the permit, as per permit condition 4.3.1(b)(i)(ii) – steps taken to remedy the situation should also be taken. Since the March 2017 meeting Biotage have submitted the Schedule 5 notices. The exceedances were informally submitted on the annual emission reporting, received 9th February 2017 – hence the meeting and CAR1 for March 2017 to capture the situation around the potential breaches.

AK has to stress that Biotage have not led on developing a remedy to the situation, but they are waiting more detailed assessment and advice from NRW – they have initially declared in the March 2017 meeting, that if production and / or processes have to be altered to reduce emissions, they will do so. Before any such decisions are reached, AK did say that he would go back to the original limits, the conversion in the 2016 variation and the results of the monitoring exercise from November 2016. AK wants to be absolutely sure that the limits have a sound basis, the data gathered is representative of typical processes and that any impact assessment takes account of these releases, but based on when and how often during the year the processes are carried out. If emission concentrations cannot be altered through adjusting flow rates or abatement, then there is the potential to reduce the mass of raw material or type of raw materials used or limit the number of batches. NRW would need to explore all other options first and only if the current emissions pose an unacceptable risk to the environment and human health, should production alterations be proposed and limiting the number of batches would be the last resort of all.

Typically impact is assessed as a comparison of an instantaneous emission concentration (mg/m³) against a recognised environmental assessment level, such as a legal air quality standard or a non statutory limit. Sometimes in place of or in addition to, limits may be set on mass release per year – although typically

concentration predominates, even if the release period is of short duration. However, depending on the level of concentration peaks, over what duration, the nature of the substance concerned and possibly taking on board existing background concentrations, this may allow for very short duration peak releases infrequently.

To set out the issues, this is a summary of exceedances from 2016. As stated the 2015 exceedances are based on the former instantaneous ELV in mg/m^3 and will not be useful for demonstrating compliance as an average hourly release.

A1 – HCl – ELV – 15.12 g/hr – 2016 result = 56.93 g/hr – average over whole batch

A1 – Methanol – ELV – 4.08 g/hr – 2016 result = 22.7 g/hr

A4 – HBr – ELV 0.626 g/hr – 2016 result = 15.54 g/hr

With just one data round – albeit the sampling was extended over the various batches for differing periods – the above may not be a statistically sound basis to assume that it is only the three breaches above that can occur and indeed at or around these values. The previous data results, albeit in different units, do not follow the pattern of values and exceedances of the 2016 data.

The next item to assess is the monitoring report and how the spot concentrations were converted into g/hr release rates averaged over the whole batch. Things that will be looked at are:

- monitoring methods, MCerts, corrections
- Flow rates
- Duration of exercise
- Defining within the overall batch when the emissions and peak emissions are
- Does the raw data correlate with the batch profiles asserted by the operator
- Converting the concentrations over the batch into average g/hr for compliance purposes

Ultimately what is required to make a reasonable environmental impact assessment of the releases at this site, which would factor in the varying and potentially high concentrations against potentially low volumetric flow rates, is:

- Accurately define the batch timings
- Accurately derive when emissions are released
- Does monitoring data correlate to the predicted peaks and do emissions cease when the operator said they would
- Is the flow rate fairly stable and is the velocity sufficient for accurate / reliable sampling
- Work out based on the above the batch profile and concentrations the average g/hr mass releases
- Assess the impact of the release rates in g/s using either the H1 tool or other more sophisticated (less conservative tools, e.g. modelling)

A comparison will now be made of the batch release timings as supplied by the operator in the 2016 variation application, with the timings and measurements from the November / December 2016 monitoring exercise.

<u>Emission Point</u>	<u>Parameter</u>	<u>ELV g/hr</u>	<u>Batch Time Hours (days)</u>	<u>Emission Period Hours (days)</u>	<u>Emission Peak Hours</u>	<u>Volumetric Flow Rate m³/s Av.</u>	<u>Monitoring Periods</u>	<u>Min Max Average mg/m³</u>	<u>Average g/hr</u>
A1	HCl	15.12	120 (5)	48 (2)	2 – 3 (start of reaction)	0.40	09:05 – 15:59	18.57 68.05 39.21	56.93
	VOC	4.0824	120 (5)	48 (2)	2 - 3	As above	As above	8.38 26.06 16.60	22.70
A2	HCl	49.068	192 (8)	48 (2)	1 (start of reaction)	0.54	08.03 – 10.48	0.36 20.22 9.21	17.90
	VOC	45.684	192 (8)	48 (2)	1	As above	07:56 – 10:51	12.72 27.03 19.79	38.00
A3	NO _x	48.84	120 (5)	2 – 3	1 (start of reaction)	0.37	10:30 (29 th) – 07.18 (30 th)	2832.08 9.42	12.55
	VOC	355.68	120 (5)	2 - 3	1	As above	10:30 – 14:53	12.43 178.45 54.87	70.00
A4	HBr	0.6264	72 (3)	36 (1.5)	3 (during heating)	0.43	07:41 – 14:16	0.13 25.40 9.73	15.54

Emission Benchmarks – From the EA SGNs 4.02 & 4.03

HCl – 10 mg/m³

Class B VOC (e.g. methanol) – 75 mg/m³

NO_x – 50 mg/m³ (low end of the range)

HBr – 5 mg/m³

The table of data above was taken from the permit limits in g/hr and the data provided in the 2016 monitoring exercise. There is additional data within the monitoring report that shows methanol via FTIR and TVOC via a FID; NO_x via a portable analyser; HBr via FTIR. This data is presented in graphical format in the figures section of the monitoring report. These figures reveal information about the reaction profile. A comparison of information about the batch processes supplied by the operator and these graphs from the monitoring exercise show a broad correlation (over the monitoring times) with the peak emission timing described by the operator and the graphs showing emissions.

This 2016 monitoring exercise completes IC1, but as the emissions are not compliant, the operator must proceed onto IC2:

If the results of the stack emissions monitoring exercise required by Improvement Condition IC 1 show that emissions of any of the parameters listed in Table S3.1 of Schedule 3 exceed:
(i) The emission limit values (ELV) given in Table S3.1 in Schedule 3; and / or
(ii) The relevant emissions to air benchmark values given in Annex 1 of the the Environment Agency's 'How to Comply with Your Environmental Permit' guidance documents EPR 4.02 'Speciality organic chemicals sector' and EPR 4.03 'The inorganic chemicals sector'

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The operator shall investigate methods for reducing these emissions below the ELVs and / or benchmarks and provide a report on this assessment to Natural Resources Wales for approval. The operator shall consider the applicability and efficacy of installing abatement plant in this assessment.

Action 1 Biotage 24th November 2017: *The operator must use the data gathered in the monitoring exercise, along with knowledge of the batch process timings and emissions, and:*

- i. *Conduct an impact assessment of the parameters that have exceeded the ELVs. This can be done initially using the H1 tool, or a more accurate, less conservative assessment, could be made by modelling these releases using known atmospheric dispersion models (e.g. ADMS, AERMOD). This assessment must:*

- a. *confirm the batch timings – the monitoring exercise did not necessarily cover the full batch emission period – it is essential to define the emission period*
 - b. *assess the maximum concentration of exceeding parameters against relevant environmental assessment levels*
 - c. *assess the average concentration over a batch (based on accurate batch timing as in (i) a.)*
 - d. *Estimate a mass release per year based on expected number of batches and average releases*
- ii. *With the data gathered from (i) propose:*
 - a. *new ELVs – taking on board the impact assessment and balancing exceedances of ELVs or EALs against duration and number of batches and mass released per year*
 - b. *confirm if the averaging batch period is to be extended – thus the calculation of average concentration would be based on a longer averaging period*
 - c. *based on the full assessment, propose if relevant, alterations to production timings, chemistry, raw materials or active emission abatement options, to ensure emissions are within either current ELVs or proposed ELVs (if accepted by NRW) from (ii) b.*
 - d. *Provide the regulator with a timed action plan to implement agreed proposals as a result of this action. This action plan should include proposals and justification for a monitoring programme (annual) going forward or alternative to actual monitoring in terms of assessing emissions against all ELVs, including the parameters that have not exceeded during the 2016 monitoring exercise.*

Due: 31st March 2018

Non compliance: *A CCS3 minor non-compliance has been given for an exceedance of permit emission limit values and permit condition 3.1.2. This is an offence under the Environmental Permitting Regulations (as amended) 2010. Failure to address this issue (see Action 1 above) can lead to an escalation of the severity of non-compliance and other enforcement responses.*

END

EPR Compliance Assessment Report

**Report ID:
CAR_NRW0032498**

This form will report compliance with your permit as determined by an NRW officer

Site	Distribution Way EPR/DP3832EF	Permit Ref	DP3832EF
Operator/Permit holder	Biotage GB Limited	Date	24/11/2017

Section 3 – Enforcement Response

You must take immediate action to rectify any non-compliance and prevent repetition. Non-compliance with your permit conditions constitutes an offence and can result in criminal prosecutions and/or suspension or revocation of a permit. Please read the detailed assessment in Section 2 and the steps you need to take in Section 4 below.

In respect of the above non-compliance you have been issued with a warning. At present we do not intend to take further enforcement action. This does not preclude us from taking additional enforcement action if further relevant information comes to light or offences continue.

Section 4 – Action(s)

This section summarises the actions identified during the assessment along with the timescales for when they will need to be completed.

Criteria Ref.	CCS Category	Action required/advised	Due Date
See Section 1 above			
E1	C3	Action see CAR1 - impact assessment, proposed ELVs or abatement and action plan	31/03/2018

Section 5 – Compliance notes for the Operator

To ensure you correct actual or potential non-compliance we may

- Advise on corrective actions verbally or in writing
- Require you to take specific actions verbally or in writing
- Issue a notice
- Require you to review your procedures or management system
- Change some of the conditions of your permit
- Decide to undertake a full review of your permit

Any breach of a permit condition is an offence and we may take legal action against you

- We will normally provide advice and guidance to assist you to come back into compliance either after an offence is committed or where we consider that an offence is likely to be committed. This is without prejudice to any other enforcement response that we consider may be required.
- Enforcement action can include the issue of a formal caution, prosecution, the service of a notice and/or suspension or revocation of the permit.

See our Enforcement and Civil Sanctions guidance for further information

This report does not relieve the site operator of the responsibility to

- Ensure you comply with the conditions of the permit at all times and prevent pollution of the environment
- Ensure you comply with other legislative provisions which may apply

Non-compliance scores and categories

CCS category	Description	Score
C1	A non-compliance that could have a major environmental effect	60
C2	A non-compliance which could have a significant environmental effect	31
C3	A non-compliance which could have a minor environmental effect	4
C4	A non-compliance which has no potential environmental effect	0.1

Operational Risk Appraisal (Opra) - Compliance assessment findings may affect your Opra score and/or your charges. This score influences the resource we use to assess permit compliance.

Section 6 – General information

Data protection notice

The information on this form will be processed by the Natural Resources Wales (NRW) to fulfil its regulatory and monitoring functions and to maintain the relevant public register(s). The NRW may also use and/or disclose it in connection with:

- Offering/providing you with its literature/services relating to environmental matters
- Consulting with the public, public bodies and other organisations (eg. Health and Safety Executive, local authorities) on environmental issues
- Carrying out statistical analysis, research and development on environmental issues
- Providing public register information to enquirers
- Investigating possible breaches of environmental law
- Assessing customer service satisfaction and improving its service
- Freedom of Information Act/Environmental Regulations request

The NRW may pass it on to its agents/representatives to do these things on its behalf. You should ensure that any persons named on this form are informed of the contents of this data protection notice.

Disclosure of information

The NRW will provide a copy of this report to the public register(s). However, if you consider that any information contained in this report should not be released to the public register(s) on the grounds of commercial confidentiality, you must write to your local area office within fifteen working days of receipt of this form indicating which information it concerns and why it should not be released, giving your reasons in full.

Customer charter

What can I do if I disagree with this compliance assessment report?

If you are unable to resolve the issue with your site officer, you should firstly discuss the matter with officer's line managers using the informal appeals procedure. If you wish to raise your dispute further through our official Complaints and Commendations procedure, phone our general enquiry number 0300 065 3000 (Mon to Fri 08.00 – 18.00) and ask for the Customer Contact team or send an email to enquiries@naturalresourceswales.gov.uk. If you are still dissatisfied you can make a complaint to the Public Services Ombudsman for Wales. For advice on how to complain to the Ombudsman phone their helpline on 0845 607 0987.

Welsh Language

If you would like this form in Welsh please contact your Regulatory Officer.