

Compliance Assessment Report

Report ID:
CAR_NRW0033594

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	29/06/2018	Time in	10:00	Out	12:00
Assessment type	Report/Data Review				
Parts of the permit assessed	Emissions data and IC				
Lead officer's name	Kemp, Andi				
Accompanied by					
Recipient's name/position	Dr Nick Jenkins/ Chemistry Production Manager	Date issued	09/07/2018		

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
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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	0	Total compliance score (see section 5 for scoring scheme)	0
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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

Biotage Compliance Assessment: Friday 29th June 2018

Purpose of Compliance Assessment

In November 2017 a CAR1 form was raised that included an action on Biotage to be completed by 31st March 2018. This action concerned reviewing the data from the 2016 monitoring exercise with a view to confirming actual batch emission timings, working out average data, assess impact through H1 or direct to modelling, propose new ELVs or a new averaging basis and / or propose production alterations – all to set appropriate ELVs and maintain compliance with them.

This action builds upon what was required from Improvement Condition 2 – essentially investigate exceedances from the batch monitoring (IC1) and propose new ELVs, new ELV basis and / or production and abatement options to reduce emissions.

The improvement item was extended in April 2018 until 31st July 2018. On 29th June 2018 AK (NRW) met Dr Nick Jenkins at the Biotage site to confirm what progress the site had made.

It became apparent, after the monitoring report was received (refer to November 2017 CAR1), that anomalies were revealed and to that end the “process” of dealing with and completing IC2 was embellished by Action 1 Biotage 24th November 2017 (CAR1 November 2017).

So on top of the advice given in the November CAR1, additional advice was emailed from AK on 30th April 2018 (3 emails) and discussions held on site on 29th June 2018, so now NRW believes the operator is absolutely clear on how they should proceed. AK needs to set a revised timeline for this impact assessment and options proposal, in order to complete IC2.

AK did stress that there must be real tangible progress to close out IC2, as the item cannot be extended indefinitely and then the only option to secure compliance and environmental protection, would be to raise an enforcement notice.

Progress to Date

Based on the previous advice and meeting and based on the content of the emissions monitoring report, this is what is still required:

- H1 files for the worst case and average emissions (see Action 1 Nov 2017, items (i)).
- For the above to be carried out and based on the continuous monitoring (FID and FTIR) that was conducted alongside the extractive sampling, define the batch times for each process.
- The operator must propose a sensible batch timeline, from the time reaction starts to when emissions stop or become insignificant, after drying for example.
- The average emissions per hour can then be worked out, based on a more accurate (probably longer) average batch time.
- Work out average emissions and worst case peak emissions.
- It's the culmination of the above that will go into H1 for average and worst case comparison of process contributions (PCs) to Environmental Assessment Levels (EALs) – see H1.
- It was discussed on the 29th June 2018, when the maximum and average releases and accurate batch timings are worked out, factoring in how many batches for each process the site has CAPACITY to produce, that transient exceedances may be acceptable – based on duration, concentration and how many times per year that may happen.

Extension of Improvement Condition 2 and Action 1 24th November 2017

The revised H1 to be submitted by 31st August 2018 – this will include the revised worst case and average (based on revised average batch time) emissions screened. Depending on the results, this may be sufficient to amend the basis of ELVs in the permit by virtue of a different batch period. **Due: 31st August 2018**

If the H1 results, based on these refined emission levels and batch durations, cannot be screened out, then Action 1 24th November 2018, part (ii), must be embarked upon, with a timeline for delivery of proposals to be submitted by **31st October 2018**.

END

EPR Compliance Assessment Report

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Operator/Permit holder	Biotage GB Limited	Date	29/06/2018

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.

Other than the provision of advice and guidance, at present we do not intend to take further enforcement action in respect of the non-compliance identified above. This does not preclude us from taking enforcement action if further relevant information comes to light or advice isn't followed.

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			

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.