Cyfoeth Naturiol Cymru Natural Resources Wales	**EPR Compliance Assessment Report**	Report ID: DP3832EF/0245732

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

Site	Distribution Way			Permit Ref	DP3832EF		
Operator/ Permit holder	Biotage GB Limited						
Date	12/08/2015			Time in	10:00	Out	12:45
What parts of the permit were assessed	Pre application discussions, monitoring, reporting and follow up inspection						
Assessment	Site Inspection	EPR Activity:	Installation X	Waste Op		Water Discharge	
Recipient's name/position	Paul Davies						
Officer's name	Andi Kemp			Date issued	12/08/2015		

Section 1 - Compliance Assessment Summary

This is based on the requirements of the permit under the Environmental Permitting Regulations. A detailed explanation and any action you may need to take are given in the "Detailed Assessment of Compliance" (section 3). 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				**Condition(s) breached**
a) Permitted activities	**1**. Specified by permit	A		
b) Infrastructure	**1.** Engineering for prevention & control of pollution	A		
	2. Closure & decommissioning	N		
	3. Site drainage engineering (clean & foul)	A		
	4. Containment of stored materials	A		
	5. Plant and equipment	N		
c) General management	**1**. Staff competency/ training	N		
	2. Management system & operating procedures	N		
	3. Materials acceptance	N		
	4. Storage handling, labelling, segregation	N		
d) Incident management	**1**. Site security	N		
	2. Accident, emergency & incident planning	N		
e) Emissions	**1.** Air	A		
	2. Land & Groundwater	N		
	3. Surface water	N		
	4. Sewer	N		
	5. Waste	N		
f) Amenity	**1**. Odour	A		
	2. Noise	A		
	3. Dust/fibres/particulates	A		
	4. Pests, birds & scavengers	A		
	5. Deposits on road	A		
g) Monitoring and records, maintenance and reporting	**1**. Monitoring of emissions & environment	A		
	2. Records of activity, site diary, journal & events	N		
	3. Maintenance records	N		
	4. Reporting & notification	A		
h) Resource efficiency	**1**. Efficient use of raw materials	N		
	2. Energy	N		

KEY: **C1, C2, C3, C4** = CCS breach category **(* suspended scores are marked with an asterisk),**
A = Assessed (no evidence of non-compliance), **N** = Not assessed, **NA** = Not Applicable, **O** = Ongoing non-compliance – not scored

Number of breaches recorded	0	**Total compliance score** (see section 5 for scoring scheme)	0

If the Total No Breaches is greater than zero, then please see Section 3 for details of 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 (e.g. 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 suspended or consolidated scores.
- details of advice given
- any other areas of concern
- all actions requested
- any examples of good practice.
- a reference to photos taken

This report should be clear, comprehensive, unambiguous and normally completed within 14 days of an assessment.

Purpose of Compliance Assessment

This was a follow up inspection from May 2014 and pre application discussions with respect to the annual air emissions monitoring performed and the inclusion of the sewer emission points covered by a DCWW TEC.

There were two recommendations and one action from May 2014 to follow up on.

A general brief visual inspection of the exterior of the site: boiler house, waste skips, oil and chemical stores and emission points and drainage system and interior of the solvent production lab.

Routine submissions are assessed.

Detailed comments and any actions and recommendations can be found below.

Permit Variation Pre-application Discussions

There are a number of reasons that these discussions took place: minor errors in the permit; identification of a release point to sewer; actual monitoring data that requires assessment which will lead to a permit variation.

The minor errors include: Table S4.1 refers to reporting monitoring data required by permit condition *3.5.1;* this should be condition 3.3.1. Table S2.1 appears to list the raw materials used in the processes and the amount in tonnes used per year – there is however no condition relating to this table and it is not clear if these substances and the amounts in the specification column are intended to be a permit control measure or limit of some kind. The reporting and associated tables and forms for performance parameters and annual production and treatment data need clarifying. Table S4.4 needs to make reference to separate forms for performance parameters (water and energy useage, raw materials used) and annual production and treatment (total product produced, total waste produced).

On the 5th January 2015 Paul Davies (PD)(Biotage) sent an email to AK explaining that a BSI inspection (as part of Biotage working towards ISO14001 registration) revealed that the releases of effluent to sewer had not been authorised by DCWW under the terms of a Trade Effluent Consent. AK corresponded by return explaining that the environmental permit will also need to be varied to include this as an authorised emission point, with the possibility of an assessment leading to emission limit values (ELVs). Biotage submitted further information, enclosing the DCWW TEC which they had now been granted by DCWW; a sewer plan showing the release points was also enclosed. The TEC (dated 26th Nov 2014) issued by DCWW restricts the discharge to 1m3/d; flow rate no greater than 1l/s; the trace substances and pH range are also defined. Further information supplied by Dr Nick Jenkins (NJ)(Biotage) explained that the effluent enters the foul sewer via three points (SD1, SD2 & SD3), which are drainage pipes from internal

sinks in different process areas of building Unit C. On this basis of volume, concentrations of listed substances and the TEC in place, AK advised that the permit should be varied to include these as listed emission points to sewer; with no need for any further environmental assessment or permit limits – other than possibly including the volume per day limit from the TEC in the permit table for the emission points. The variation for the points above has been delayed in order to capture the changes likely to be required from data gathered in the recent monitoring exercise – see below.

In terms of air emissions monitoring, reporting and limits, reference should be made to permit conditions: 3.1.1, 3.1.2, 3.3.1. 3.3.2 (Table S3.1), 3.3.3, 4.2.2(a) and 4.2.3 (Table S4.1). For the year since the permit was issued (May 2014 – 31st Dec 2014) Biotage elected to submit a nil return, as they hadn't conducted any emissions monitoring at that point – they were taking up the option offered by AK of having a full 12 months (May 8th 2014 – May 7th 2015) to conduct their annual air emissions monitoring.

In an email to PD on 3rd Sep 2014 AK explained that going forward the option of conducting some form of emissions assessment by calculation (e.g. mass balance) instead of physical monitoring, would possibly be considered, but at least one round of physical emissions monitoring should be conducted to provide a basis for expected emissions under normal operating conditions and to validate assumptions made in the permit application. The operating conditions (peak emissions during the batch reactions) and stability of the process must be known and the methodology for any emissions releases calculations must be understood in order for this option to be considered.

To satisfy the annual air emissions monitoring permit conditions and to further the development of emissions quantification methodologies, Biotage contracted an MCerts accredited contractor to monitor the four emission points – this was conducted on 31st Mar and 1st Apr 2015 – report: P2251, No. R001. This data should be reported to NRW by 28th Jan 2016 as per the relevant permit condition. On 20th May 2015, NJ provided the report and informed NRW that some of the permit limits had been breached according to the results from the monitoring exercise.

AK has briefly looked at the report and has noted that in addition to uncertainties about the expected concentrations of substances and emissions profile over the course of a reaction period, the volumetric flow rates were larger than assumed and therefore this would lead to higher release rates on its own.

AK has recommended that as part of the permit variation, an H1 air emissions assessment would need to be conducted again, using the input parameters from the monitoring exercise. Using the measured concentrations and volumetric flow rate from the report to derive a g/s release rate and input this for each parameter into H1. The relevant figures need to be inputted for each permitted substance for each emission point that these substances are released from. Biotage should use the peak flow rate and highest (worst case) emission concentration. If, using worst case conditions, the emissions screen out, then this can give the regulator some confidence that Environmental Assessment Levels (EALs) won't be breached.

H1 takes the release rate (g/s) and applying a Dispersion Factor (DF, which is based on effective stack height and some factors for wind speed and mixing – see H1 guidance) provides a release concentration, called the Process Contribution (PC) – the PC assumes the release is immediately dispersed to a limited degree as a function of the DF and gives a ground level concentration adjacent to the release point. It is the PC that is used to compare to the EAL. If the releases on a long and short term basis are not screened out, H1 proceeds and adds estimated background concentrations to the PC to derive the Predicted Environmental Concentration (PEC). The PEC is compared to EALs on a LT and ST basis. H1 guidance indicates what options there if PECs are a certain percentage of, or exceed the EAL. The higher the % of the EAL the PEC takes up the more likely, either:

i) detailed modelling would be required to get a more accurate result,

ii) reduction of emissions production at source and or emissions abatement may be required,
iii) the emission is prohibited

Biotage were also advised to provide the basis on which the worst case emissions are measured to ensure the peak concentrations are captured during the batch. The operator can also put forward details that describe what processes are operating and when. This could form part of the justification put forward by the operator in terms of deriving permit limits – so it is possible for NRW to take on board, that while the PECs may take up considerable headroom of the EAL based on immediate concentrations at a point in time, the overall environmental loading may be significantly less based on limited operating hours and / or process batch runs. NRW could consider using annual mass limits or mass releases (g/hr) as permit limits instead of concentrations as this is sometimes more applicable in batch processes as it avoids under reporting as the whole batch release is captured. Limiting the raw material inputs or quantifying the amount of a substance in the raw materials is also an option. Further, limiting operating hours may also be something Biotage could have put in the permit in place of routine monitoring – this is all to be considered as part of the permit variation application. A combination of these may be required.

The variation, based on the outputs of the second H1 assessment, could include a number of the options above. These may be used to control estimated emissions and replace actual physical monitoring, if, based on the variation information submitted, an accurate concentration calculation methodology can be developed. The outcome of the variation would be to have some form of limits set and confirm what methods of emissions assessment will be required. The variation may include improvement items, that require further work on emissions quantification, the output of which may then be a set limit. AK also requested that Biotage include all emission points on a plan (there are additional points on top of A1 – A4) and justify why some points do not need detailed assessment or limits set, e.g. LEVs. All production areas need to be considered, e.g. the resins building.

Action 1 Biotage 120815: *NJ to rerun H1 for air emissions from A1 – A4 and discuss results with AK*. **Due:** 30th September 2015.

AK discussed the potential non compliance situation for the releases to air and has decided that as long as a permit variation application is submitted and the results from Mar / Apr 2015 are submitted as the annual results for 2015, then a non compliance may not be raised for these breaches. This position is supported by the fact that the application emissions information wasn't accurate (this was not the intention of the operator), that the first round of monitoring only revealed the elevated concentrations, and that the limits therefore set by NRW were incorrect. Based on data supplied it is anticipated that there is no detriment to human health or the environment from these releases.

Previous CAR1 Form Actions / Recommendations

The CAR1 from May 2014 was discussed. There was one recommendation to colour code the surface water and foul drains – this has been done and was verified on the inspection on 12th Aug 2015.

A second recommendation was to put the oil tank and other critical environmental protection / pollution prevention kit on a planned preventative maintenance inspection regime. AK has not verified if the site has done this.

The action from May 2014 was to ensure the waste solvent store is locked to prevent unauthorised access. This was not specifically checked on the 12th Aug – see inspection section below.

Inspection: 12TH August 2015

Unit C Solvent Production lab was inspected and these revealed that the glass reactors are all separate in sealed extracted cupboards, self bunded and with a pressure powder fire deluge system controlled by a pressurised fire tracer - if there is a fire, the tracer line is breached and the resultant pressure loss triggers the powder deluge. The rest of the buildings contain variously washing rooms, storage, R&D labs and a resins production room. There is also the admin section.

There are no materials stored in sufficient quantity to lead to significant environmental risk. The biggest risks are materials going into the surface water system (they have blue colour coding), unauthorised entry into sewer or from a fire. The site know what they are holding and where, what the properties of the substances are and it is highly unlikely that there would be breaches of enough containers simultaneously to cause significant pollution.

The oil tank for the boiler near the resin area (the main boiler is located adjacent to Unit C and runs off mains gas) is a double skinned tank stored on a concrete plinth. There is a level gauge inside the building and the volume is around 2000lts. PD advised that the tank is inspected annually when the boiler is serviced.

Any spills can be responded to with spill kits, trained staff and an accurate drainage plan.

From May 2014 the drains have now been colour coded to aid staff in prevention of discharge of chemicals to the surface water system. The site were also recommended to create a list of critical environmental kit and then this equipment should be put on a planned preventative maintenance regime. Such items would be: tanks, bunds, shut off valves, abatement equipment, drainage routes, level alarms etc. The solvent store was noted in May 2014 as being unlocked – AK will leave it to the site to ensure it is locked when not being used by staff.

The action and recommendations from May 2014 are now replaced by the following:

Action 2 Biotage 120815: *Site to define and draw up a list of critical environmental kit. This is any equipment that is used to prevent or contain pollution and includes tanks, alarms, impermeable surfaces, drainage routes, spill kits, double skinned tanks. These pieces of kit should then have a planned preventative inspection and maintenance regime created, implemented and recorded. For example drainage survey every 5 – 10 years (dependant on condition), visual inspection of tanks weekly, annual internal inspection, leak detection etc.* **Due:** 30th November 2015.

The oil tank and waste solvents store area is in the adjacent haulage yard area, which benefits from a sliding gate out of hours. The site only operate Mon – Fri 9 – 5, so security during those times is not an issue. However, there is a public path alongside the river adjacent to Unit C and at the bottom of Unit C, near the bridge over a ditch and there is no fence between the site and the paths. The only risk here is access to the waste bins and possible vandalism, leading to entry of substances into the surface water drains. The site are considering fencing.

Recommendation 1 Biotage 120815: *Biotage to consider fencing their site to prevent any unauthorised access.*

Routine Reporting

The site submitted a nil return for annual air monitoring for 2014 – permit condition: 4.2.3. They don't have to submit 2015 data until 28th Jan 2016.

The site also have to report, under condition 4.2.2(a) a review of results from routine monitoring – this is not applicable for 2014, but for 2015 data the site must supply some commentary on their results in addition to the actual data. Such commentary could be explaining why there was a breach or that emissions were as expected or that increased production lead to a breach or near miss etc. etc.

Under condition 4.2.2(b)(c) annual production and treatment data and performance parameters (Tables S4.2 and S4.3 respectively) needs to be reported by 31st Jan every year. For 2014 the site submitted total amount of product produced, total amount of raw material used, total water and energy usage. The site did not submit the total hazardous and non hazardous waste produced and sent off site for 2015.

Action 3 Biotage 120815: *Please provide waste data as per Table S4.2. You will have some information on this from duty of care waste transfer notes, hazardous waste consignment notes and from entry of the Pollution Inventory.* **Due:** 30th September 2015.

END

Cyfoeth Naturiol Cymru Natural Resources Wales	**EPR Compliance Assessment Report**	Report ID: DP3832EF/0245732

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

Site	Distribution Way	Permit	DP3832EF
Operator/ Permit	Biotage GB Limited	Date	12/08/2015

Section 3- Enforcement Response **Only one of the boxes below should be ticked**

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.	
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.	
We will now consider what enforcement action is appropriate and notify you, referencing this form.	

Section 4- Action(s)

Where non-compliance has been detected and an enforcement response has been selected above, this section summarises the steps you need to take to return to compliance and also provides timescales for this to be done.

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 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 which 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 fulfill 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 (e.g. 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 and taking any resulting action
- preventing breaches of environmental law
- assessing customer service satisfaction and improving its service
- Freedom of Information Act/Environmental Information 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 twenty 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 the officer's line managers. 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.