| Cyfoeth Naturiol Cymru / Natural Resources Wales | **EPR Compliance Assessment Report** | Report ID: DP3832EF/0211431 |
|---|---|---|

**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 | 30/05/2014 | | | Time in | 10:00 | Out | 12:30 |
| What parts of the permit were assessed | First Visit Since Permit Issue and Brief Visual Inspection | | | | | | |
| Assessment | Site Inspection | EPR Activity: | Installation | X | Waste Op | Water Discharge | |
| Recipient's name/position | Paul Davies, QHS Manager | | | | | | |
| Officer's name | Andi Kemp | | | Date issued | 13/06/2014 | | |

## 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 | N | | |
| | **5**. Plant and equipment | N | | |
| **c)** General management | **1**. Staff competency/ training | A | | |
| | **2**. Management system & operating procedures | N | | |
| | **3**. Materials acceptance | N | | |
| | **4**. Storage handling, labelling, segregation | N | | |
| **d)** Incident management | **1**. Site security | A | | |
| | **2**. Accident, emergency & incident planning | N | | |
| **e)** Emissions | **1.** Air | N | | |
| | **2**. Land & Groundwater | N | | |
| | **3.** Surface water | N | | |
| | **4**. Sewer | N | | |
| | **5**. Waste | N | | |
| **f)** Amenity | **1**. Odour | N | | |
| | **2**. Noise | N | | |
| | **3**. Dust/fibres/particulates | N | | |
| | **4**. Pests, birds & scavengers | N | | |
| | **5**. Deposits on road | N | | |
| **g)** Monitoring and records, maintenance and reporting | **1**. Monitoring of emissions & environment | N | | |
| | **2**. Records of activity, site diary, journal & events | N | | |
| | **3**. Maintenance records | N | | |
| | **4**. Reporting & notification | N | | |
| **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 Inspection**

Biotage at Distribution Way, Ystrad Mynach, have recently been issued with a permit after a protracted application process. The permit was issued on 8th May 2014. The purpose of this inspection was to visit the site for the first time and explain the main permit conditions to the site team. This was a chance to exchange regulatory contact details.

AK was introduced to Chris Williams (UK Managing Director), Dr Nick Jenkins (Chemical Production Manager) and Paul Davies (Quality, Health, Saftey and Environment Manager). The format of the visit comprised a discussion about the permit, monitoring and reporting, OPRA, drainage, waste and raw materials, EMS, accident management plan, guidance and a brief visual inspection of the external aspects of the site and location.

**Permit Conditions**

The main conditions were discussed. The scope of the permit in terms of how the permit conditions cover and control: what it is you do; where you do it; how you do it; and what data and reporting / notifications are required. The permit includes schedules referring to reporting forms, permitted activities, monitoring; operating techniques.

A written management system is required (permit condition 1.1.1) and must be documented; this is supposed to cover planned preventative maintenance, training, staff competency, accident management, environmental policy, internal audits, periodic management reviews, environmental objectives for continual improvement etc. The written environmental management system may incorporate or at least make reference to other operational documents (work instructions, maintenance processes etc.). Things need not be duplicated, but the main body of the EMS must make reference to the location and version of relevant documents.

Condition 2.1.1 (Table S1.1) limits the site operations to specific activities from the Environmental Permitting Regulations as described in Part 2 of Schedule 1 of the regulations. Table S1.1 describes four entries for production of organic and inorganic chemicals, from the receipt of raw materials to product dispatch. Alterations to these activities will need a permit variation. Variations are not automatically granted and an application process must be carried out.

Condition 2.2.1 refers to a plan in Schedule 7 of the permit - this limits the above activities to the areas in the site boundary as indicated in the drawing. Comments above about variations to go beyond this boundary apply.

Condition 2.3.1 refers to table S1.2 and legally incorporates into the permit the specific techniques used on site to carry out the process. These documents would have been drawn up by Biotage to answer questions in the permit application. They are sometimes supplemented by requests for further information or points to clarify by NRW. Together they comprise how you will operate the plant; with the emphasis on pollution prevention, waste minimisation, management control, prevention or control of emissions and an evaluation of whether the proposed techniques and emissions are considered to be in line with Best Available Technology. BAT is a concept that underpins how permitted activities are carried out. You may need a permit variation to alter the operating techniques. Any changes need to be assessed and sometimes written confirmation is all that is required.

Section 3 of the permit describes your authorised emission points - see table S3.1 - it includes details of any emission limits and methods and frequency of monitoring these emissions. The emission limit values (ELVs) are based on data you supplied and assessed by NRW to be indicative of BAT for your process and to be protective of the environment they are released into.

Section 4 requires certain information to be reported to NRW, using prescribed forms (included when the permit was sent to you). See Schedule 4. The three main elements are:

- reporting the monitoring required by condition 3.3.1 (not 3.5.1 as the permit incorrectly states); condition 4.2.3

- reporting the annual performance data; condition 4.2.2
- notifying NRW of listed events / occurrences such as incidents, accidents, emission exceedances or any permit breach, and malfunctions / breakdowns that have the potential to harm the environment; condition 4.3.1

There are various other conditions relating to waste, noise, odour, energy efficiency etc.

**Monitoring and Reporting**

The site is required, as described above and in the permit, to monitor certain listed air emission points annually. Table S4.1 gives the reporting period as 1st January. This means that one round of sampling must be taken every 12 months from 1st January to 31st December and reported (condition 4.2.3) within 28 days of the end of the reporting period, i.e. by 28th January, using the form listed in Table S4.4. The sampling can be conducted any time from now until 31st December 2014 and reported for the first time by 28th January 2015. NRW may accept that you may not arrange for sampling and monitoring until 2015 as long as this is done before the 12 month permit issue anniversary date of 8th May 2015. In this case the 28th January 2015 monitoring submission should be made explaining this; i.e. a nil return. If you did indeed conduct monitoring between January and May 7th 2015, this round needs to be reported by 28th January 2016.

Also required are the annual performance parameters contained in Tables S4.2 and S4.3, using the forms in Table S4.4; these include total raw materials used in tonnes, total product produced in tonnes, total hazardous and non hazardous waste produced, water, gas and electricity used.

**OPRA**

OPRA is the EA / NRW risk assessment tool used by operators for their application and reviewed annually to form a base score (used for variation and surrender applications), that along with any compliance adjustment, provides the annual subsistence fee.

OPRA looks at what you do, where, how and what emissions or waste you produce. Each calendar year the previous year's compliance scores are totalled to adjust the base profile score and produce a subsistence fee for the forthcoming financial year. Your profile will be attached with this CAR1 for you to check with your copy – this is the definitive version and discard any other you may have.

I have double checked the profile and there are one or two minor changes to be made. These changes, for example to the location tab, are not big enough to alter the overall lettered banding given for each attribute (complexity, emissions, location, operator performance) and so I propose that we will look again at this in line with the usual annual review period of October – December, ready for billing the following year.

**Drainage**

It is critical that all drainage routes to surface water and to foul sewer are identified and put on an accurate scale drawing. This is useful in the event of a spill or fire where the FRS and NRW will want to know where fire fighting run off may go; e.g. via a surface water outfall into the river Rumney.

We have drawing: Main Site Drainage Layout, ver 1 Sept 2012. The site advised that they have a Trade Effluent Consent for discharge of waste water to DCWW public foul sewer. It appeared from the visual inspection that most surface water routes are from roof downpipes.

**Recommendation 1 Biotage 30th May 2014:** Ensure any open drain grids or gullies leading to surface water sewer or direct to river are colour coded or otherwise visually identified so that staff do not use these for emptying of washings, oil or contaminated water, or chemicals.

**Waste & Raw Materials**

Only low amounts of waste and raw materials are stored in the site yards or warehouses. Most of the raw materials are in small containers and there is a dedicated sealed chemical store. Waste comprises of a solvents store and the usual commercial bins for cardboard and office waste etc.

Waste must be assessed as either hazardous or non hazardous and reported in terms of tonnes produced annually. Waste classification and management is often an area of NRW compliance work.

**Action 1 Biotage 30th May 2014:** Ensure the waste solvent store is locked to prevent unauthorised access.

**EMS**
It is understood that Biotage are considering applying for registration to ISO14001. As far as the permit is concerned, to be compliant with condition 1.1.1, a written EMS is required. Our guidance sign posts you to the main elements of an EMS, which do not differ fundamentally to the requirements of 14001 – see opening section re. condition 1.1.1.

**Accident Management**
This is part of condition 1.1.1 and guidance is contained in our overarching How To Comply With Your Environmental Permit document. This is an area that is frequently assessed for compliance. Essentially operators must identify all possible foreseeable accidents; risk assess and provide control measures to eliminate or reduce; and then provide actual response and contingency measures to deal with an accident should it happen.

Key to this is good site plans for drainage and chemical stores; communication routes; equipment to deal with spills. Sites should consider accidents arising from shutdown, breakdown, malfunction, normal and abnormal operation, vandalism, staff error. Consideration should be given to what activities take place on site and what substances are used. Measures such as pollution prevention kit, tankers, pumps, containers, training and the use of less hazardous substances, should play a part in accident management.

**Guidance**
Your main guidance is the How To Comply.... document mentioned and attached – use the EA website to keep to the up to date version.

This guidance lists various other higher level guidance from Defra and the EA on Environmental Permitting; EA Regulatory Guidance Notes on definitions of operator, installation, technical competence, surrender tests, substantial change (variations); EA Sector Guidance notes e.g. for the chemical industry; EU BAT Reference Documents (technology used and typical or achievable emissions); EA horizontal guidance on monitoring, noise, odour, environmental impact assessment / risk assessment (H1).

**Inspection**
Only a brief visual inspection of the outside of the main buildings; proximity to the river; drainage; raw material and waste storage; and emission points to air; took place. A double skinned oil tank was seen and this appeared in good order. An item like this should be on the planned preventative maintenance programme – see below.

See recommendations and action about drainage, solvents store above and maintenance below.

The site appeared to be a secure site, although access could be gained along the river path. Site are looking into this, but with lockable chemical and waste solvents stores, this shouldn't present any real problems with pollution.

**Recommendation 2 Biotage 30th May 2014:** Site should design a planned preventative maintenance schedule for items that are defined as *critical environmental kit,* e.g. oil tanks, level alarms, emission abatement, bunds, concrete floor / kerbs; drainage etc.

# END

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| Site | Distribution Way | Permit | DP3832EF |
| Operator/ Permit | Biotage GB Limited | Date | 30/05/2014 |

| **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.<br>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.