FUJIFILM Diosynth biotechnologies

Application Support Document

Substantial Permit Variation

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Application Support Document

Substantial Permit Variation

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NON-TECHNICAL SUMMARY

This document has been prepared on behalf of Fujifilm Diosynth Biotechnologies UK Ltd ('FDBK' or 'The Applicant' hereafter) by Sol Environment Ltd and provides supporting evidence as required by Environmental Permit Application Forms Part C2 and C3 issued by the Environment Agency (EA).

The subject site is located at Belasis Avenue, Billingham, TS23 1LH. The site is currently operated under Environmental Permit EPR/BJ8987IQ/V003.

Fujifilm Diosynth Biotechnologies UK Ltd previously traded under the name of MSD Biologics (UK) Ltd who are the named Operator on the current permit. Despite the change in company name, all other company information i.e. registered company number, address, etc. remains the same.

The existing Installation undertakes the manufacture of a range of pharmaceutical products based on chemical and biological manufacture. These products are sold for further onward processing by third parties to form finished pharmaceutical products or are included in third party pharmaceutical products and medicines.

Processing involves fermentation and biotransformation using a range of raw materials and varying process conditions. Manufacturing takes place in closed vessels, which are supplied with nutrients and air. Processing conditions such as pH, temperature and oxygen availability are kept under strict control. The main emissions from the process are water vapour and carbon dioxide.

Following completion of the fermentation process, the product may be pre-conditioned by adjusting the temperature or pH. This stage can be followed by purification by filtration or chromatography. The product is harvested using centrifugation and other filtration techniques. The product will be bottled and then held in chilled storage before dispatch. Due to the unique and commercially confident nature of the products and associated production processes, detailed manufacturing descriptions are not provided within this application document.

All processes are conducted under Good Manufacturing Practice (GMP) and are approved by the Food and Drug Administration (FDA) and the Medicines and Healthcare Products Regulatory Agency (MHRA).

The permitted activities currently meet the definition of an 'Installation' by virtue of Schedule 1:

- Section 4.5 'Pharmaceutical Production' Part A(1)(a) Producing pharmaceutical products.

Fujifilm is making this application to conduct a 'Substantial' Variation of their existing EPR permit under The Environmental Permitting (England and Wales) Regulations 2018 (as amended) to address the following:

- Borealis – The operation of a new 26,800m^2 (GIA) biotech manufacturing facility, comprising an array of production suites, warehouse and storage, buffer preparation and hold facilities, laboratories, and offices. Borealis includes a new liquid waste treatment plant, solid waste management building, and standby generator. This project introduces new process release points to air including an emission point from an emergency generator, new discharges to foul sewer and potential noise emissions (from a roof-mounted plant room). All foul discharges will be to the Northumbrian Water Limited (NWL) combined sewer. This will be regulated as a new Stationary Technical Unit Section 4.5 Part A(1)(a).
- BIC-UK (Bioprocessing Innovation Centre UK) – Development and construction of offices and laboratories purely for R&D purposes. Discharges from this facility are all discharged to foul sewer

via the Cowpen Road combined sewer. Although BIK-UK is for R&D purposes only, as per the Environment Agency *Note 4.3 of Regulatory Guidance Note No. 2 Understanding the meaning of regulated facility - Appendices 1 and 2,* the facility cannot be defined as pure R&D. It is therefore understood that the facility will be required to be permitted as a separate Section 4.5 Part A(1)(a) Activity.

- Minor operational changes – The inclusion of existing emission points previously missed or not included within previous permit variation applications.

The application includes the following changes to the Directly Associated Activities (DAA):

- Boiler plant upgrades – Upgrade of boiler plant from current >20 MWth to circa 10 MWth.
- Dewar Store and Nitrogen Tank – Installation of a bulk nitrogen storage tank, and small external store building for storing small dewars (nitrogen storage bottles). This is considered a Directly Associated Activity.

The inclusion of Borealis and BIC-UK requires additional land and therefore changes to the existing Installation Boundary.

Emissions to Air

The site currently has eight permitted emission points to air:

- A1 – 'T2' Boiler Plant;
- A2 – Spray Drier Plant;
- A3 and A4 – Fermenters;
- A5 – MF1 and MF2 Fermenters Stack;
- A6 – MF4 Fermenter Outlet;
- A7 – ABC 5000 Purification 1 Extract Vent; and
- A8 – 'T2' Boiler Plant.

Emission points A2, A3, A4 and A7 are being removed from the permit as part of this variation as no longer in use.

In addition, this application will introduce the following new emission points to the permit:

- A9 and A10 – MF3 Fermenter Outlet;
- A11 – L6 Dispensing Booths;
- A12 and A13 – New 'T2' Boiler Plant.

Emission points A9 – A11 are already existing and operational but have not previously been incorporated into the site permit.

As part of this permit variation a review has been undertaken on the existing boiler plant on site against the Medium Combustion Plant Directive. The existing boiler plant (Emission Point A1 and A8) is due to be upgraded to a new unit that provides much higher thermal efficiency and reliability. An Air Quality

Assessment has been conducted as part of this variation which re-baselines the potential air impacts from the site.

Please refer to *Annex F – Air Quality Assessment* for more information.

The report concludes that the predicted annual mean and hourly mean NO_2 concentrations are well below the relevant AQAL at all the nearby sensitive receptors and the impact of the proposed new boilers on annual mean concentrations is considered to be not significant, in accordance with the Environment Agency Risk Assessment Guidance.

The report concludes that the impact of emissions on habitats was assessed as not significant when compared with existing background conditions and relevant critical levels and critical loads.

The site has a number of small standby generator plants, two of which are above 1MWth input. Each generator is tested for 1 hour off-load every 2 weeks and 1 hour on-load every 3 months which equates to 30 hours per year. In 2025, the generators were used for approximately 30 hours. Although only operated for 30 hours a year, the two generators which are above 1MWth input (located at building L6 and Borealis) have been included within the updated Air Quality Assessment at the request of the EA.

Please refer to *Annex F – Air Quality Assessment* for more information.

An H1 screening assessment has been carried out on Emission Point A11 which is in relation to a chemical dispensing booth.

The principal VOC emissions from the dispensing booth include acetone, acetonitrile, ethanol, and methanol. The booth is generally only used for the dispensing of these chemicals (i.e. there is minimal mixing of chemicals) and there are no chemical reactions taking place and emissions would be from evaporation processes from these liquids. Therefore, it is expected that VOC emissions of acetone, acetonitrile, ethanol, and methanol would take place. The quantities dispensed vary but 2025 data indicate that the following quantities were dispensed:

- Acetonitrile – 2,560 litres/annum;
- Acetone – 66 litres/annum;
- Ethanol - 2,328 litres/annum; and
- Methanol – 56 litres/annum.

Based on 2025 operational data, the dispensing booth is estimated to operate for around 3,500 hour per annum (40% of the time).

The quantities utilised are very small and emission to air from the dispensing booth are likely to be low. The dispensing booth is fitted with a three-stage high efficiency filtration system that includes:

- Pre-pad filters located behind removable grilles;
- Fine dust filters (G4 and F8) which are 95% efficient also located behind removable exhaust grilles; and
- HEPA filters (H14) which are 99.995% efficient.

The report concludes that the H1 screening indicates that long-term impacts can be screened out as predicted concentrations (PC) are less than 1% of the EALs or the PECs are less than 70% of the EAL. The H1

screening indicates that short-term impacts can be screened out as predicted concentrations (PC) are less than 10% of the EALs or the PCs are less than 20% of the difference between the EAL and background concentrations.

Please refer to *Annex G – H1 Screening Assessment* for more information.

Emissions to Controlled Water

Detailed Site Drainage Plans are included within *Annex A – Site Plans*.

The site has an existing connection (Emission Point W1) which allows the discharge of process and cooling water and condensate to controlled waters (The Tees Estuary). This emission point runs to the south of the Billingham site and is shared with CF Fertilisers and a number of other permitted installations within the locality. Emissions to water from site are monitored at the discharge point into the Billingham drain as it enters the CF Fertilisers site.

There will be no amendments to Emission Point W1 as part of this permit application.

Emissions to Sewer

All process emissions from Borealis will be discharged to sewer which requires a new listed emission point to sewer (Emission Point S1).

The site has a trade effluent consent for the new discharge which is provided within *Annex K – Trade Effluent Discharge Consent*. The effluent undergoes treatment within the proposed Water Treatment Plant (pH neutralisation, temperature reduction, bio-inactivation, and segregation) prior to discharge.

This is assessed within a H1 Emission to Water assessment which is provided within *Annex D – H1 Assessment.*

The assessment has been conducted using the EA's current H1 assessment tool to assess the impact of Emission Point S1. The results of the screening assessment demonstrate that the indirect discharges (via the sewer) do not pose a significant risk of EQS exceedance in the receiving water body and therefore have passed the H1 assessment.

The discharge to sewer from BIC-UK is anticipated to be small and consists mostly of sanitary waste from the various R&D offices (Emission Point S2). It is anticipated that the volumes will be very low as this only relates to the R&D laboratories and not a production facility. Further information on this has been provided within the H1 Emission to Water assessment provided within *Annex D – H1 Assessment.*

In addition to this a Nutrient Neutrality Assessment has been completed which provides background information on the requirement for nutrient neutrality, a description of the proposed operations regarding discharges of nitrogen and an assessment of nutrient neutrality.

Please refer to *Annex E – Nutrient Neutrality Assessment* for more information.

Emissions to Land

There will be no emissions to land from the proposed activities on site.

All operations take place on good quality concrete hardstanding.

Odour

There are no odour emissions from the existing site or because of this permit application.

Noise

Borealis has the potential for noise emissions due to the proximity of nearby receptors and external plant. Due to this, a Noise Impact Assessment has been conducted which assesses the noise impacts in relation to the proposed Project Borealis.

The rest of the site is surrounded by other industrial processes and is not considered sensitive to noise.

A copy of the assessment is provided within *Annex H – Noise Impact Assessment.*

1. INTRODUCTION

Fujifilm Diosynth Biotechnologies UK Ltd ('FDBK' or 'The Applicant' hereafter) is making this application to conduct a 'Substantial' Variation of their existing EPR permit under The Environmental Permitting (England and Wales) Regulations 2018 (as amended) to address a number of changes on site.

The subject site is located at Belasis Avenue, Billingham, TS23 1LH. The site is currently operated under Environmental Permit EPR/BJ8987IQ/V003.

Fujifilm Diosynth Biotechnologies UK Ltd previously traded under the name of MSD Biologics (UK) Ltd who are the named Operator on the current permit. Despite the change in company names, all other company information i.e. registered company number, address etc remains the same.

The existing Installation undertakes the manufacture of a range of pharmaceutical products based on chemical and biological manufacture. These products are sold for further onward processing by third parties to form finished pharmaceutical products or are included in third party pharmaceutical products and medicines.

Processing involves fermentation and biotransformation using a range of raw materials and varying process conditions. Manufacturing takes place in closed vessels, which are supplied with nutrients and air. Processing conditions such as pH, temperature and oxygen availability are kept under control. The main emissions from the process are water vapour and carbon dioxide.

Following completion of the fermentation process, the product may be pre-conditioned by adjusting the temperature or pH. This stage can be followed by purification by filtration or chromatography. The product is harvested using centrifugation and other filtration techniques. The product will be bottled and then held in chilled storage before dispatch.

All processes are conducted under Good Manufacturing Practice (GMP) and are approved by the Food and Drug Administration (FDA) and the Medicines and Healthcare Products Regulatory Agency (MHRA).

The permitted activities currently meet the definition of an 'Installation' by virtue of Schedule 1:

- Section 4.5 'Pharmaceutical Production' Part A(1)(a) Producing pharmaceutical products.

Fujifilm is making this application to conduct a 'Substantial' Variation of their existing EPR permit under The Environmental Permitting (England and Wales) Regulations 2018 (as amended) to address the following:

- Borealis – The operation of a new 26,800m^2 (GIA) biotech manufacturing facility, comprising an array of production suites, warehouse and storage, buffer preparation and hold facilities, laboratories, and offices. Borealis includes a new liquid waste treatment plant, solid waste management building, and standby generator. This project introduces new process release points to air including an emission point from an emergency generator, new discharges to foul sewer and potential noise emissions (from a roof-mounted plant room). All foul discharges will be to the Northumbrian Water Limited (NWL) combined sewer. This will be regulated as a new Stationary Technical Unit Section 4.5 Part A(1)(a).
- BIC-UK (Bioprocessing Innovation Centre UK) – Development and construction of offices and laboratories purely for R&D purposes. Discharges from this facility are all discharged to foul sewer via the Cowpen Road combined sewer. Although BIK-UK is for R&D purposes only, as per the Environment Agency *Note 4.3 of Regulatory Guidance Note No. 2 Understanding the meaning of*

regulated facility - Appendices 1 and 2, the facility cannot be defined as pure R&D. It is therefore understood that the facility will be required to be permitted as a separate Section 4.5 Part A(1)(a) Activity.

- Minor operational changes – The inclusion of existing emission points previously missed or not included within previous permit variation applications.

The application includes the following changes to the Directly Associated Activities (DAA):

- Boiler plant upgrades – Upgrade of boiler plant from current >20 MWth to circa 10 MWth.
- Dewar Store and Nitrogen Tank – Installation of a bulk nitrogen storage tank, and small external store building for storing small dewars (nitrogen storage bottles). This is considered a Directly Associated Activity.

The inclusion of Borealis and BIC-UK requires additional land and therefore changes to the existing Installation Boundary.

The remainder of this application support document is structured accordingly:

- Section 2: Provides a detailed planning and permitting history of the site;
- Section 3: Provides specific nature of the proposed changes associated with the variation application;
- Section 4: Provides a detailed description of the existing and proposed emissions from the Installation;
- Section 5: Provides details of all monitoring associated with the Installation; and
- Section 6: Provides an Environmental Impact Assessment of the varied Installation.

All technical annexes associated with the Installation are included within the following:

- Annex A – Site Plans;
- Annex B – Technical Information;
- Annex C – Environmental Risk Assessment;
- Annex D – H1 Assessment;
- Annex E – Nutrient Neutrality Assessment;
- Annex F – Air Quality Assessment;
- Annex G – H1 Screening Assessment;
- Annex H – Noise Impact Assessment;
- Annex I – H5 Site Condition Report;
- Annex J – EMS Summary; and
- Annex K – Trade Effluent Discharge Consent.

The site location and installation boundary are provided overleaf in Figures 1.1 and 1.2. Further facility layouts are provided within *Annex B – Technical Information.*

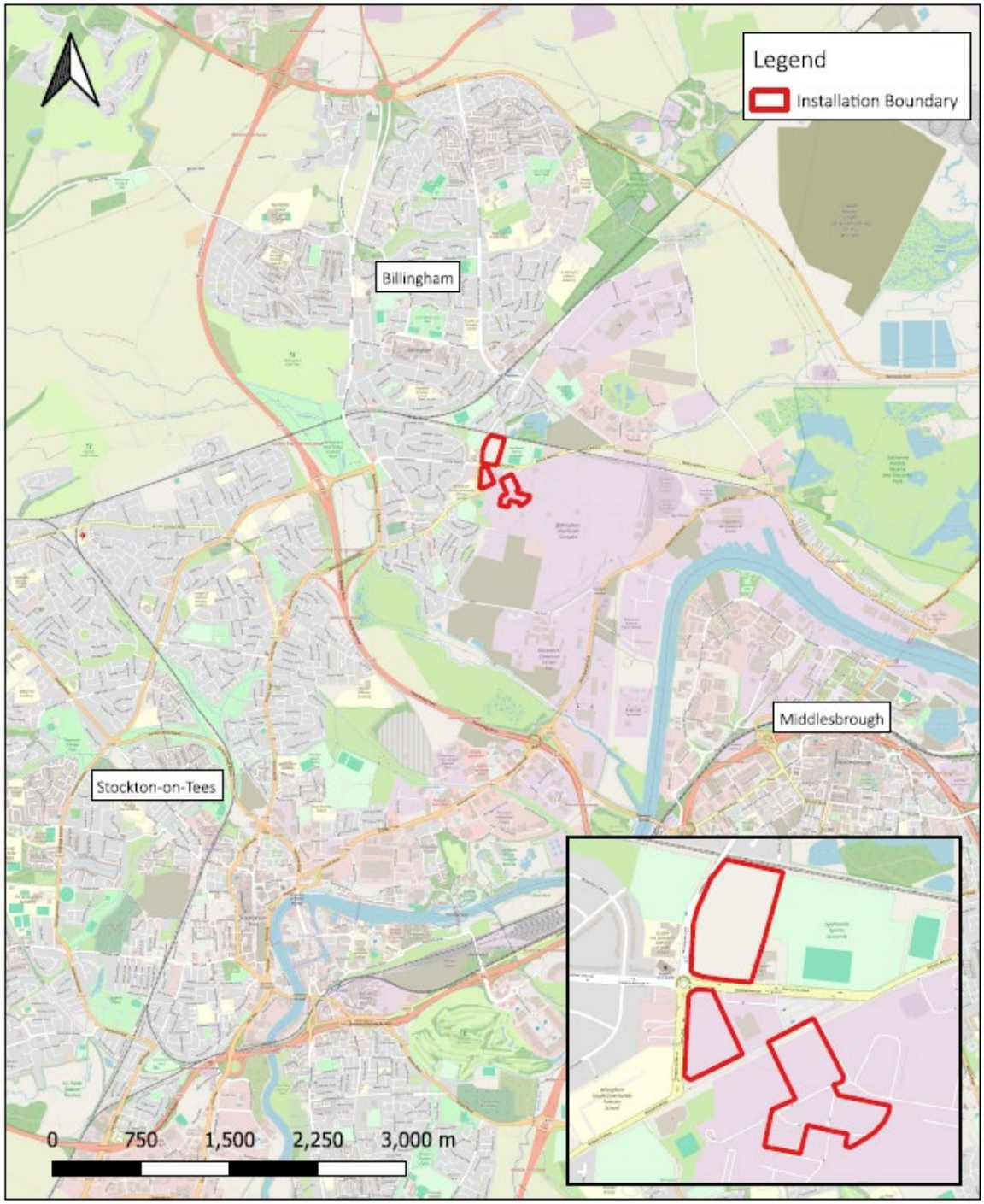

Figure 1.1 – Site Location

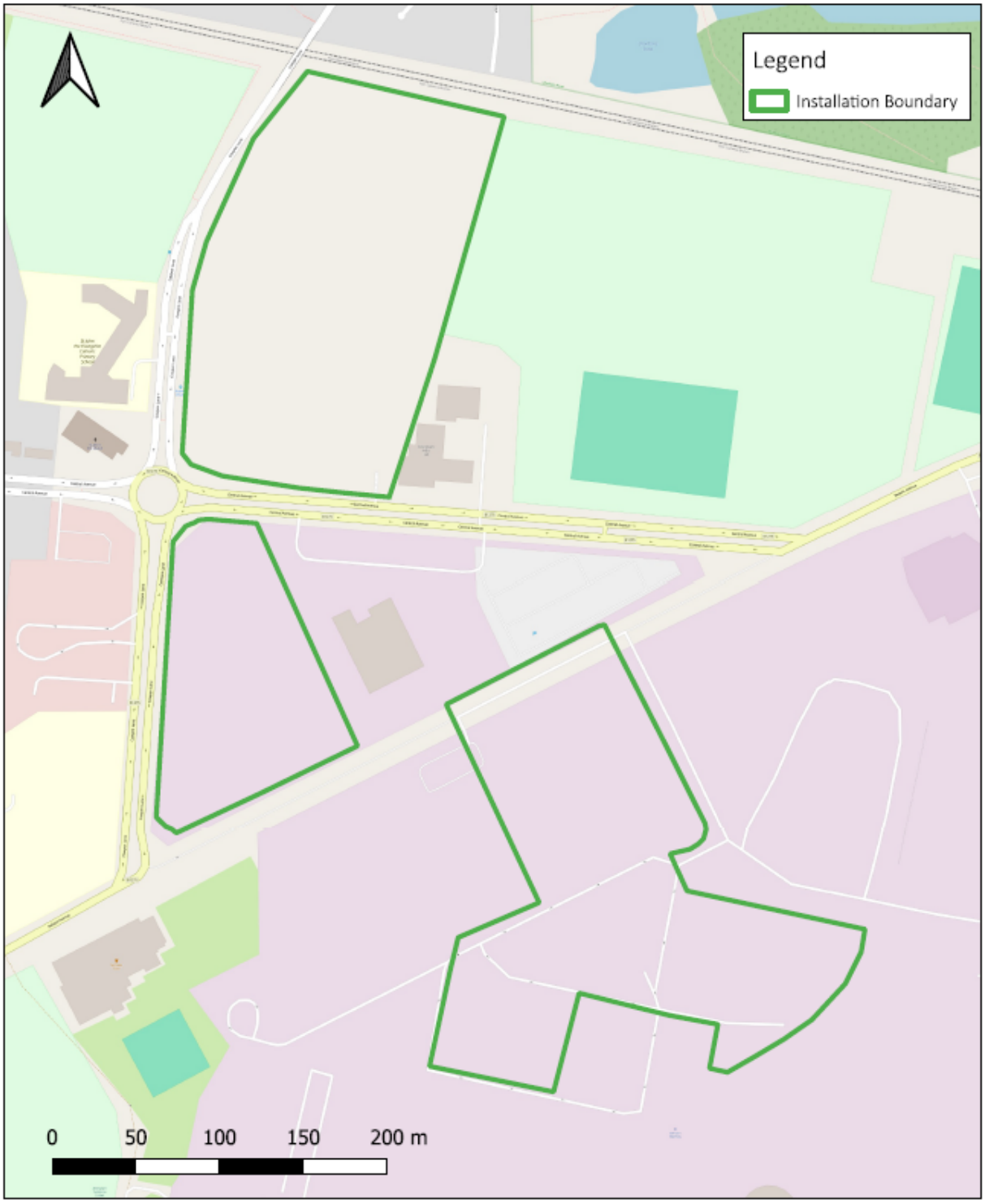

Figure 1.2 – Proposed Installation Boundary

2. PLANNING AND PERMITTING HISTORY

The sites permitting and planning history is provided within Table 2.1.

Table 2.1 – Permitting and Planning History

Permitting History			
Reference	Description	Status	Date
EPR/BJ8987IQ/V004	This permit application	-	-
EPR/BJ8987IQ/V003	Administrative Variation	Granted	29/03/10
EPR/BJ8987IQ/V002	Permit Variation	Granted	10/09/09
EPR/BJ8987IQ	Original permit application	Granted	29/03/07
Planning History			
Reference	Description	Status	Date
22/2291/FUL	Erection of a manufacturing facility (Use Class B2/B8)	Granted	22/12/2022
22/2014/REM	Reserved matters application for the appearance, landscaping, layout, and scale for the erection of buildings for office, research and development, manufacturing, and storage (Use classes B1, B2 and B8) with associated boundary enclosure and the closure of part of Belasis Avenue.	Granted	22/12/2022
22/1669/FUL	Industrial development comprising of the erection of a manufacturing facility within Use Class B2/B8 (industrial, storage and distribution) with ancillary office space, gatehouse, liquid waste treatment plant, solid waste management building, landscaping, parking, service areas, and associated works.	Granted	07/12/2022
21/3018/VARY	Section 73 application to vary condition no.2 (Approved Plans) of planning approval 20/1659/FUL - Extensions to building ABC5000 to accommodate expanded pharmaceutical production and purification facilities. Extension to warehouse building L6 to house additional high capacity, vertical storage equipment.	Granted	02/03/2022

20/1659/FUL	Extensions to building ABC5000 to accommodate expanded pharmaceutical production and purification facilities. Extension to warehouse building L6 to house additional high capacity, vertical storage equipment.	Granted	14/10/2020
20/0074/FUL	Erection of Dewar Store building and bulk liquid nitrogen storage tank at Fujifilm Diosynth Biotechnologies, Belasis Avenue, Billingham	Granted	02/03/2020

3. DESCRIPTION OF PROPOSED VARIATION

3.1 Description of the Proposed Changes

Fujifilm Diosynth Biotechnologies UK Ltd ('Fujifilm' or 'The Applicant' hereafter) is making this application to conduct a 'Substantial' Variation of their existing EPR permit under The Environmental Permitting (England and Wales) Regulations 2018 (as amended) to address a number of changes on site which will introduce additional permitted Activities.

The existing Installation is a long-established facility that undertakes the manufacture of a range of pharmaceutical products based on chemical and biological manufacture. These products are sold for further onward processing by third parties to form finished products or are included in pharmaceutical products such as tablets. The permitted activities currently meet the definition of 'Pharmaceutical Manufacturing' and meets the definition of an 'Installation' by virtue of Schedule 1:

- **Section 4.5 'Pharmaceutical Production' Part A(1)(a)** Producing pharmaceutical products.

In summary, the following new permitted Activities will be added to the existing permit because of this permit variation:

- Borealis – a new biotech manufacturing facility comprising 5 processing lines. The facility will meet the definition of a new Stationary Technical Unit as defined by Section 4.5 Part A(1)(a).
- BIC-UK (Bioprocessing Innovation Centre UK) – an R&D facility previously known as Project Kibou. Although the facility will be used for R&D purposes only, as per the Environment Agency *Note 4.3 of Regulatory Guidance Note No. 2 Understanding the meaning of regulated facility - Appendices 1 and 2*, the facility cannot be defined as pure R&D. It is therefore understood that the facility will be required to be permitted as a separate Section 4.5 Part A(1)(a) Activity.
- Boiler plant upgrades which will require an amendment to the existing DAA on site for a new Medium Combustion Plant Activity.
- Dewar Store and Nitrogen Tank which will meet the definition of a DAA.

Any proposed changes to the Listed Activities are depicted in Table 3.1 in RED.

Table 3.1 – Permitted Activities

Activity Reference	Activity Listed in Schedule 1 of the PPC Regulations	Description of Specified Activity	Limits of Specified Activity
A1 – Current activities	Section 4.5 Part A(1)(a)	Producing pharmaceutical products using a chemical or biological process	From receipt of raw materials to despatch of finished product including the handling and storage of waste
A2 – Borealis (5 lines)	Section 4.5 Part A(1)(a)	Producing pharmaceutical products using a chemical or biological process	From receipt of raw materials to despatch of finished product including the handling and storage of waste

A3 – BIC-UK	Section 4.5 Part A(1)(a)	Producing pharmaceutical products using a chemical or biological process for R&D purposes only.	This is for R&D purposes only.
Directly Associated Activities			
DAA	Boiler Plant	Combustion of gas to generate heat for processing via hot oil systems	Combustion of gas in a combustion plant with a total thermal input of 21.8MW originating from 2 natural gas fired boilers.
DAA	New Boiler Plant (Medium Combustion Plant Activity)	Combustion of gas to generate heat for processing	Combustion of gas in a combustion plant with a total thermal input of 10MWth originating from 2 natural gas fired boilers.
DAA	Dewar Store and Nitrogen Tank	Bult storage tank and small external store for nitrogen storage bottles.	-

The existing site and proposed operations ensure compliance with the relevant sections of the following guidance:

- Environment Agency (2009) Speciality Organic Chemicals Sector (EPR 4.02), March 2009. (Environment Agency, 2009).
- European Union (2016). Best Available Techniques (BAT) Reference Document for Common Wastewater and Waste Gas Treatment/Management Systems in the Chemical Sector (CWW). (European Union, 2016).
- European Union (2016). Commission Implementing Decision (EU) 2016/902 of 30 May 2016 establishing best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for common wastewater and waste gas treatment/management systems in the chemical sector (notified under document C(2016) 3127). (European Union, 2016).

3.2 Details of the Installation

3.2.1 Installation Boundary

Additional land is being added to the Installation Boundary because of this permit variation application. A figure showing the existing and proposed Installation Boundary is provided in Section 1, Figure 1.1, and *Annex A – Site Plans.*

Due to this, a H5 Site Condition Report has been completed as part of the application, reestablishing the baseline of the site.

Please refer to *Annex I – Site Condition Report* for more information.

3.2.2 Site Drainage

The site has an existing connection (Emission Point W1) which allows the discharge of process and cooling water and condensate to controlled waters (The Tees Estuary). This emissions point runs to the south of the Billingham site and is shared with CF Fertilisers and a number of other permitted installations within the locality. Emissions to water from site are monitored at the discharge point into the Billingham drain as it enters the CF fertilisers site.

There will be no amendments to Emission Point W1 as part of this application.

Project Borealis requires a new authorised release point to sewer (Emission Point S1).

The Borealis site has a new trade effluent consent to sewer for the new discharge which is provided within *Annex K – Trade Effluent Discharge Consent*. The effluent undergoes treatment with the proposed Water Treatment Plant. (pH neutralisation, temperature reduction, bio-inactivation, and segregation) prior to discharge.

The proposed emission point is assessed within a H1 Emission to Water assessment which is provided within *Annex D – H1 Assessment.*

The discharge to sewer from BIC-UK is anticipated to be small and consists mostly of sanitary waste from the various R&D offices (Emission Point S2). It is anticipated that the volumes will be very low as this only relates to the R&D laboratories and not a production facility. Further information on this has been provided within the H1 Emission to Water assessment provided within *Annex D – H1 Assessment.*

Site Drainage Plans have been included within *Annex A – Site Plans*.

3.2.3 Raw Materials

FDBK has documented procedures for the management of raw materials and materials handling. This is to ensure that all materials received, transported, stored, used, processed, and exported are managed in such a way that they do not pose a risk to safety, health, and the environment.

The installation manufacturers a range of products using similar technologies. Although the raw materials differ slightly between processes, the production technique is essentially similar for all products.

All raw materials and products for use at site are stored in contained areas such as materials stores, tank farms or drum parks which have been designed in accordance with recognised BAT and to ensure that the pollution risks are minimised.

Raw materials are strictly controlled as part of Good Manufacture Practice (GMP).

Materials are dispensed upon request from manufacturing as per the project bill of materials (BOM) after which they are transported in secure containment to the required plant.

A substance inventory is provided within *Annex B – Technical Information* which details a full list of the raw materials that are stored on site and dispensing quantities from 2023.

As part of this permit variation, Fujifilm are also including a dedicated dewar and nitrogen tank storage area. The location of this area will be within Building H4 which is shown on the Site Master Layout provided within *Annex A – Site Plans.*

All storage locations are labelled, and the inventory of materials location and movement are recorded and tracked as part of the sites management system.

Storage areas are clearly marked and signposted, and containers are clearly labelled. All storage areas a regularly inspected and spillage procedures are in place to identify any damaged or leaking containers.

All surfaces within the existing and proposed production plant and yards are constructed of hardstanding. All storage tanks are installed with secondary containment and designed to comply with the necessary standards and pollution prevention guidance.

Surfacing and bunds are regularly inspected and maintained in accordance with Fujifilm's inspection and maintenance programme.

The storage areas on site include:

- Building O1 – used for the storage of final product stability samples. The product is stored frozen at temperatures down to -70^{o}C.
- Building L4 – used for the storage of final product before shipping off site.
- L6 Warehouse – the L6 warehouse is used for the storage of liquid chemicals in small quantities (in bunds), raw materials in solid form (on pallets) and consumables. Materials for manufacturing are dispensed in this area under controlled conditions within dispensing booths. There is also a bunded drum and IBC park located outside of the warehouse.
- 04 Equipment Storage Building – this building stores the MCC09 manufacturing equipment.
- 08 Engineering Spares Storage Building – this building stored small parts i.e. seals, gaskets etc.
- External Storage – there is also external storage of materials in drum parks within bunded containment units.

The site also consists of the following laboratories:

- R Building Research Laboratory – currently this building consists of project development work however this will be transferred to the BIC-UK building once operational.
- L5 Research Laboratory – larger scale research work takes place here using small scale fermenters.
- R3 Training Laboratory – this is a training laboratory where staff are trained for instrument / equipment use.
- R4 Raw Materials Testing Laboratory – this laboratory is where quality control testing of all incoming raw materials takes place.
- QC Laboratories (housed within building MF1 and MF2) – these laboratories are used for in process control testing of materials as well as environmental monitoring of the manufacturing areas across site.

Containment

The containment and bunding for the effluent storage before treatment / disposal at all the proposed sites and for the reactors and chemical storage tanks meet the capacity requirements of CIRIA C736, specifically:

- 110% of the largest tank the bund is protecting; and
- 25% of the combined volume of all the tanks the bund is protecting.

3.2.4 Description of Existing Site

The manufacturing and support facilities operated by Fujifilm currently consist of the following buildings / facilities:

- MF1 and MF2 – microbial fermentation production scale facility for the manufacture of Active Pharmaceutical Ingredients for clinical and commercial products;
- MF3 – microbial fermentation small scale facility for the manufacture of Active Pharmaceutical Ingredients for clinical and commercial trials;
- MF4 – microbial fermentation process development;
- MCC – mammalian cell culture and downstream processing and Insect cell culture and downstream processing;
- L6 – raw materials store and drum and IBC park;
- R4 – raw materials quality control laboratory;
- L4 – final product store;
- O8 – engineering spares store;
- O1, O4 and O6 – support the activities of the manufacturing facilities where equipment testing, closed processing and other storage-based activities can be conducted;
- O3 – office space; and
- T2 – boiler house providing steam to the site.

The existing manufacturing processes take place within MF1, MF2, MF3, MF4 and MCC. The processes consist of microbial fermentation for the manufacture of Active Pharmaceutical Ingredients for clinical and commercial products.

The production processes produce Active Pharmaceutical Ingredients that are proteins often called biopharmaceuticals. The products and manufacturing processes are complex and tightly regulated. Compliance with the principles and guidelines of GMP (Good Manufacturing Practice) is a statutory requirement. In the United Kingdom, these regulations are set out in Commission Directive 2003/94/EC.

MF3 and MF4 was constructed in 1998 by the modification of an existing building. It has subsequently been extended to allow two-stream operation. MF3 consists of a 100-litre fermenter with another identical fermenter located within MF4. MF3 and MF4 comprise dedicated facilities for the provision of services, inoculum grow-up, media make-up and effluent collection. Separation and purification suites have been designed to allow a range of unit operations to be easily installed. Products are manufactured under GMP

conditions and are produced as demonstration runs prior to larger scale operation in MF1 and MF2, or for production of small quantities for clinical trial purposes.

MF3 and MF4 has the following three emission to air points:

- Emission Point A6 – a release point from the MF4 fermenter outlet which only releases CO_2 and water vapour. There are no emission limit values in relation to this emission point; and
- Emission Point A9 and A10 – two release points from the MF3 fermenter outlets which only release CO_2 and water vapour. There are no emission limit values in relation to this emission point.

The MF1 and MF2 facility became operational in 2003 and is a scaled-up version of MF3 and MF4. The facility houses two 5,000 litre fermenters, each with support fermenters (500 litres and 50 litres). The sets of fermenters are in separate clean rooms / suites. There is also two separation and purification suites. Depending on the processes, the facility can operate in one or two stream mode. The processes mirror those conducted in MF3 and MF4, only on a larger scale, and are of a size to allow production of not only clinical trial quantities but also launched product.

Due to the use of ammonia sulphate in the MF1 and MF2 facility, an abatement system is present to prevent the release of ammonia gas. To mitigate the release of ammonia gas to atmosphere, this liquid waste stream is transferred to a disposable IBC, and the exit gas line is fed through two water lutes to absorb the ammonia gas producing ammonia hydroxide. All ammonia hydroxide solutions are sent for offsite disposal via a specialist waste contractor. There are no emission points from this abatement system.

There is no emission point after the lutes due to the ammonia gas being dispersed in the water lute. This was confirmed during a recent inspection where the last lute was checked with a drager tube and no ammonia was detected.

MF1 and MF2 have the following emission to air point:

- Emission Point A5 – a release point from the fermenters which only releases CO_2 and water vapour. There are no emission limit values in relation to this emission point.

All upstream effluent produced by the manufacturing facilities is tankered off site for treatment within a third-party wastewater treatment plant.

The downstream process consists of filtration processes where the final product starts to develop and is eventually transferred into 5 litre bottles which are stored in secure freezers. The effluent from the downstream filtration is either segregated for treatment offsite or is suitable for discharge to Emission Point W1. Any segregated waste will be tankered or collected in IBCs for offsite treatment. The process cooling water and condensate has very low COD levels and can therefore be pH adjusted and discharged via Emission Point W1 once treated.

Figure 3.1 below shows a schematic of microbial fermentation:

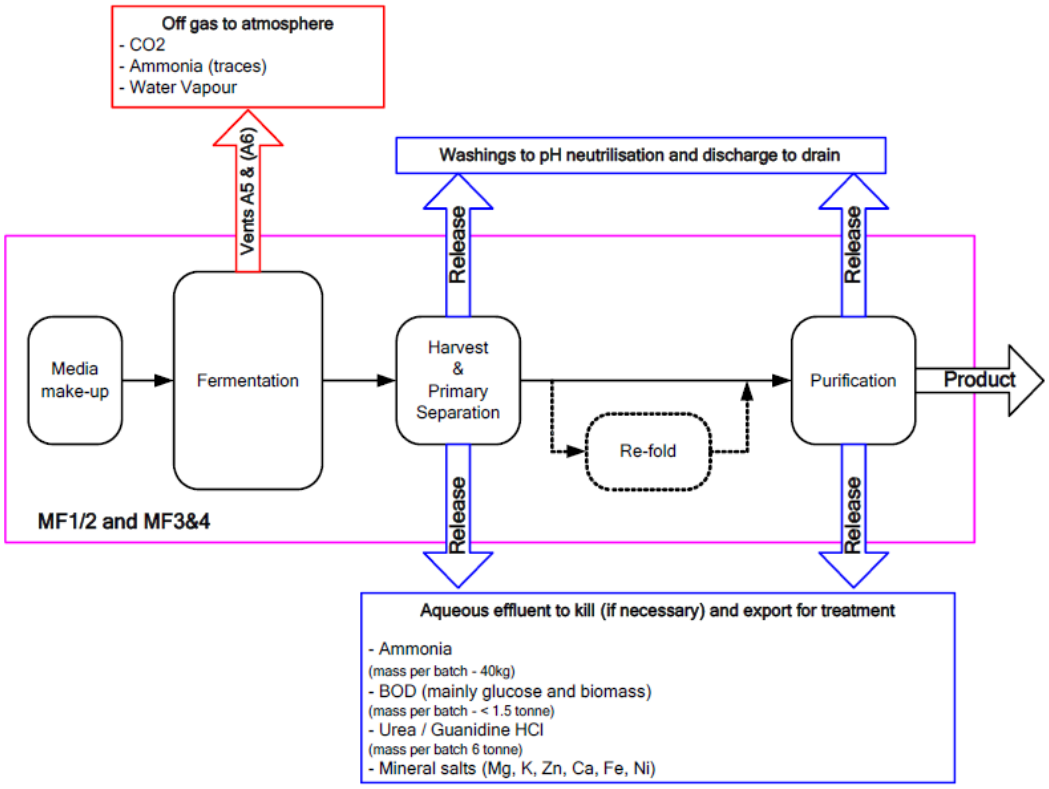

Figure 3.1 – Microbial Fermentation Schematic

The site also has an existing Mammalian Cell Culture (MCC) facility which is also used for the manufacture of Active Pharmaceutical Ingredients. The MCC processes are slower than the other facilities however the facility has dual stream capability and still operates to GMP. There are no emission to air points from this facility. Figure 3.2 below shows a schematic of the MCC process:

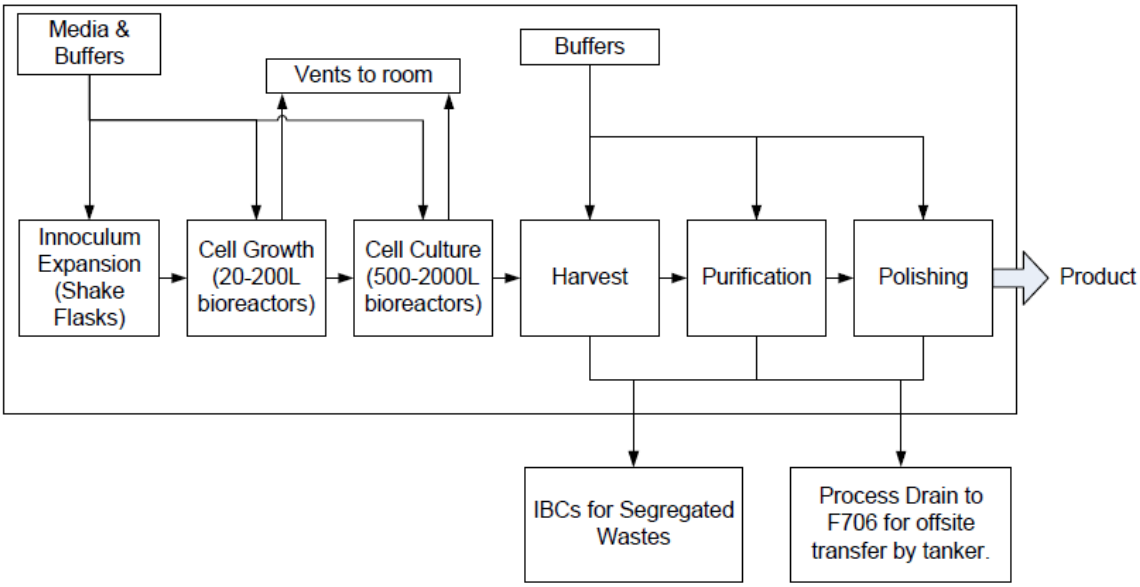

Figure 3.2 – MCC Process Schematic

3.2.5 Description of Proposed Amendments

This permit application is being applied to address the following amendments:

- Borealis – a new biotech manufacturing facility comprising 5 process lines;
- Replacement of the boiler house; and
- BIC-UK – a new laboratory purely for R&D purposes.

Borealis

Borealis will consist of a new biotech manufacturing facility, comprising of production suites, a warehouse for storage, buffer preparation and hold facilities, laboratories, and offices. The facility will have an integrated materials warehouse, complete with central raw materials dispensing and solution preparation and storage.

The Borealis facility will conduct similar work to the existing manufacturing facilities on site, however, will expand capacity by having 2 medium scale lines (5,000 litres each) and 3 small scale lines (2,000 litres each) totalling 16,000 litres capacity. The facility will improve safety through closed-process operations using single-use technology. Although Fujifilm do not plan to operate all lines initially, production at the site will be progressively phased depending on commercial demand.

The first stage of the proposed process is cell expansion. Product-producing cells will be thawed and cultivated in 250 / 500 ml shaker flasks. Over a period of around 2 days, the cell concentration is gradually increased. Once the cells reach the capacity of the flask, they are transferred into larger flasks or bioreactors, processing through 20 litre rocking bioreactors and then 50 litre and 500 litre single use bioreactors. This systematic increase allows the efficient build-up of cell biomass, preparing for the final production stage.

The cells are then transferred into a 5,000-litre bioreactor, where the final stage of cell growth occurs. Over 14 days, cell concentration peaks and product synthesis occurs. Post growth, cells are separated from the product using centrifugation and filtration, with the filtered product stored in a harvest tank, ready for downstream processing.

The first stage of downstream processing consists of initial purification. Protein A chromatography uses affinity chromatography to selectively purify the target product. Viral inactivation then deactivates potential viral contaminants in the product solution, followed by depth filtration to eliminate any precipitants. Cation exchange chromatography further purifies the product by separating molecules based on their positive charge characteristics.

The second stage of downstream processing then continues the purification process. Anion exchange chromatography enhances purity by separating molecules with negative charges. Viral filtration employs a membrane filter to remove any remaining viral particles ensuring a safe product.

The final purification and packaging stages include ultrafiltration / diafiltration to concentrate and stabilise the product by removing small impurities and integrating buffer changes. The final product is then prepared for packaging into final fill bags.

All wastewater from the process will be treated via a wastewater treatment plant and discharged to sewer (Emission Point S1). The wastewater treatment plant will be restricted to treat less than 50 tonnes per day of effluent, which is non-hazardous. This is conducted via the Siemens S7 Control System which can

physically restrict the capacity of the plant. It ensures that the plant operates to a defined fixed and set range of parameters.

Fujifilm request that the permit includes an Improvement Condition stating that this be revisited should the plant result in the need for more than 50 tonnes of effluent to be treated within the effluent treatment plant.

Except for the emergency generator there are no emissions to air relating to this activity.

Replacement Boiler House

The site currently uses two derated steam generating boilers for heat generation with a total stated thermal input of 21.8MW[1]. The boilers are fired using natural gas and are used for generating steam required to heat the fermenters.

It is planned that in in Q4 of 2025, the existing boiler house will be replaced with more efficient boiler plant. The boilers will be replaced with 2 x Clayton Steam Generators (DS-GEN-19069). Please refer to *Annex B – Technical Information* for more information on the generator sets.

An Air Quality Assessment has been completed and provided within *Annex F – Air Quality Assessment* which assesses the impact of the existing and proposed boilers.

The site has a number of additional existing emergency generators on site, details of which are shown in Table 3.2 below.

Each generator is tested for 1 hour off-load every 2 weeks and 1 hour on-load every 3 months which equates to 30 hours per year. In 2025, the generators were used for approximately 30 hours.

Table 3.2 – Standby Generator Information

Number	Location	Thermal Input	Fuel Type	Installation Date	Hours Used 2025	Hours of Testing
J35	L5	76.358 kW	Diesel	19/02/2011	30	1 hour off-load every 2 weeks and 1 hour on-load every 3 months
42-J-124	R01	248.5kW	Diesel	21/04/2020	30	
56-M-2	R09	248.5kW	Diesel	06/05/2020	30	
XBBJ191	R09	288.26kW	Diesel	06/09/2013	30	
J629	L6	288.26kW	Diesel	23/05/2024	30	
J100	L4	447.3kW	Diesel	23/05/2024	30	
J632	L6	1061.592kW	Diesel	19/09/2024	30	
J9019	Rear R09	303.17kW	Diesel	21/12/2021	30	
R-J555	R Building	136.178kW	Diesel	2025	30	
TBC	BIC-UK	955kW	Diesel	2024	30	
TBC	Borealis	6397kW	Diesel	2025	30	

[1] Noting that the actual thermal capacity is significantly below the quoted thermal capacity and <20MWth

Although only operated for 30 hours a year, the two generators (located at building L6 and Borealis) which are above 1MWth input (located at building L6 and Borealis) have been included within the updated Air Quality Assessment at the request of the EA.

A BAT Assessment for the standby generators is provided within Table 3.3 below. The assessment is in line with the Defra Guidance *Emergency Backup Diesel Engines on Installations: Best Available Techniques (BAT)* published 21st August 2023.

Table 3.3 – Stand-by Generator BAT Assessment (L6 and Borealis)

BAT	Compliance
Regulatory Requirements	
Where appropriate, as a minimum you must meet the requirements of: • Schedule 25A of the medium combustion plant directive; • Schedule 25B of the specified generators regulation.	Both diesel standby generators will meet the requirements of the relevant directives.
Build Standards	
Engines must be optimised to reduce emissions ('emissions optimised'). Engines that are optimised to reduce fuel ('fuel optimised') have greater emissions and will not meet BAT unless they have secondary abatement.	The standby generator at L6 is 'emissions optimised' and not 'fuel optimised'. The evidence of this is provided within *Annex B – Technical Information*. The standby generator at Borealis is currently 'fuel optimised' however Fujifilm are arranging this to be amended to 'fuel optimised'. The evidence of this is provided within *Annex B – Technical Information*.
Combustion plant specification sheets that keep to one or more of the former 2g TA Luft and United States Environment Protection Agency (EPA) Tier 2 (or equivalent) standards are acceptable proof of BAT plant. These do not need on-site exhaust emission monitoring.	The standby generator at L6 is 'emissions optimised' and not 'fuel optimised'. The evidence of this is provided within *Annex B – Technical Information*. The standby generator at Borealis is currently 'fuel optimised' however Fujifilm are arranging this to be amended to 'fuel optimised'. The evidence of this is provided within *Annex B – Technical Information*.
If you can show your engine achieves the following guidance level (which is not an ELV compliance requirement), it can be considered emissions optimised. Approximately 750mg per m^3 NOx (as NO_2) at 15% O_2 standard temperature and pressure, dry, 273K and 101.3kPa (equivalent to 2,000mg per m^3 at 5% O_2 – commonly termed '2g') at a typical emergency load (usually greater than 67% of standby power rating).	Both stand-by generators will be 'emissions optimised' and not 'fuel optimised' and will meet 2,000mg per m^3 at 5% O_2.
Your stack design should ensure good flue gas dispersion. Stacks should be vertical and emissions should not be obstructed by caps or cowls.	The stacks have been designed to ensure good flue has dispersion. More information on the stacks is

	provided within the Air Quality Assessment provided within *Annex F – Air Quality Assessment.*
Operational Controls	
Minimise how much you test diesel engines. You must test for less than 50 hours a year.	This BAT will be met.
Avoid testing engines when the air quality is poor.	This BAT will be met.
Do not test more than one engine at a time.	The engines will not be tested at the same time.

BIC-UK

BIC-UK is a purpose-built R&D (Process Development) and Quality Control building for the development and analytical testing of biological pharmaceutical products. It will comprise of labs, office space, and meeting rooms. The processes that will be carried out within the laboratories are:

- Speculative technique and process development;
- Transfer of processes from customers / other Fujifilm sites;
- Development of processes from customers / other Fujifilm sites;
- Development of processes involved in manufacturing of biologics at laboratory scale in order to transfer into a manufacturing facility for clinical purposes; and
- Analytical activities associated within clinical manufacture.

The laboratories are predominantly small scale, operating up to 20 litre upstream processes and subsequent downstream purification.

There are 2 labs in the building which have the capacity to operate up to 500 litre upstream processes and subsequent downstream purification. Biologics in use can be microbial, mammalian and viral gene therapy components.

A site drainage plan for the facility is provided within *Annex A – Site Plans*. Discharges from this facility are extremely low volume and are all discharged to foul sewer via the Cowpen Road combined sewer (Emission Point S2).

The facility will release the following two effluent streams to Emission Point S2:

1. Water that goes straight to drain (e.g. tap water); and
2. Any effluent that can be pH corrected and discharged via Emission Point S2. The nature of the lab-based activities is such that effluent is not generated continuously, however it is estimated that approximately 500 litre per day of effluent will be generated.

Any effluent that cannot go to Emission Point S2 will be segregated and tankered off site.

Further information on this has been provided within the H1 Emission to Water assessment provided within *Annex D – H1 Assessment.*

There will be an emission point to air from this facility that is in relation to a lab fume hood. When working in the fume hood, bottles will be open for a very short period of time and therefore it is not possible to

identify the emissions from this part of the process. It is understood from pre-application advice that assessment is not required for emissions from onsite laboratory processes and therefore this emission point is not considered further.

3.2.6 Energy Efficiency

Fujifilm have an existing Energy and Resource Management Policy that outlines how the site will control and manage energy and utility consumption.

Energy is supplied as electricity from the national grid via CF Fertilisers main substation and gas from the British Gas network directly to site.

The site has a number of measures to improve energy efficiency which will also apply to the new areas on site:

- The existing T2 boiler house is being replaced with a new, more efficient boiler system;
- The continuous sterilisers feeding fermenters have interchangers in order to maximum heat recovery;
- Heating, ventilation, and air conditioning systems within MF1, MF2 and MCC recirculate 90% of the air. The air circulation rates in the manufacturing facilities are controlled by frequency inverters;
- Inverters are used to adjust the cooling water circulation pumps in MF1 and MF2 to control the differential pressure between supply and return;
- MF1, MF2, MF3 and MF4 have two variable speed units;
- MCC has two standalone compressor packages with redundancy built into each unit;
- During vessel sterilisation, once air has been purged from the vessel, steam traps are used to maintain pressure in the system and minimise steam usage;
- Pipe work insulation is applied wherever appropriate, and maintained in serviceable condition; and
- The steam distribution system on site has undergone many alterations over the years to improve efficiency.

Fujifilm have the following servicing arrangements in place to ensure all plant operation is optimised:

- All air compressors are serviced on a quarterly basis under service agreements. Filters and drying modules are checked and replaced as required.
- Service agreements are in place for all heating, ventilation, and air conditioning systems requiring routine inspections and the systems associated with GMP controlled areas are requalified annually.
- Fujifilm operate a TLV Trapman computerised system for steam trap management, and combined with routine regular visual inspection, steam leaks are kept to a minimum.

- All refrigeration systems on site that are used to provide cooling or environmental control are subjected to service contracts. All receivers and condensers associated with refrigeration units are registered pressure vessels and are subject to regular inspection by the vessel inspector.
- The fridges and freezers which are used extensively in the biological processes are required as part of GMP to be qualified when installed to confirm they meet the required specification as well as annually to ensure their performance still meets the specification. They are serviced on a 6 monthly basis.
- Replacement of lighting is an ongoing site-wide project, with a large number of buildings now lit with high efficiency lighting and fitted with movement sensors where appropriate.
- The heat exchangers most prone to fouling undergo chemical cleaning regimes as required by the plant procedures. The fermenter cooling performance is monitored and chemical cleaning carried out as required. Chemical cleaning of cooling systems in MF1/2 is carried out annually.

3.2.7 Environmental Management System

Fujifilm's existing management system is documented in a series of SHESOPs which are controlled documents detailed within the site's electronic document management system.

The principals of the company's Environmental Management System are:

- All environmental aspects in relation to Fujifilm's operations (routine, intermittent and abnormal) are identified and their impact on the receiving environment is assessed;
- Environmental aspects are considered as part of the design of plant or process modifications and in the development of maintenance schedules;
- Where impacts are shown to be unacceptable, improvement plans are prepared;
- Environmental improvement plans are developed and monitored following a documented procedure;
- Appropriate objectives and targets are established for relevant functions, and these are reviewed at appropriate intervals. Actual performance, which includes environmental incidents and near misses and emissions, are monitored and included in the review process;
- Compliance and system audits are carried out at defined intervals. Non-conformances lead to improvement actions;
- Training and information on environmental legislation and impact is provided where such training has been identified in a training needs analysis to assure competency. Contractor induction includes reference to environmental issues;
- Emergency preparedness and response procedures are documented. Methods for and records of communications (internal and external) are documented;
- Any public complaints will be responded to formally in line with the sites complains procedure.

Any environmental, health or safety incident, or potential incident, is recorded through an electronic Accident, Incident Management System (AIMS).

The Fujifilm Emergency Planning and Response Plan and supporting documentation forms a comprehensive Accident Management Plan, which covers all types of potential emergency including chemical spillage, toxic gas emission, fire, loss of services and external emergency.

The plan outlines the requirements and procedures that must be followed by all personnel, including communication within the company and with the emergency services, and the procedure for establishing additional (e.g. management) support outside normal working hours.

A summary of the sites existing EMS is provided within *Annex J – EMS Summary*.

4. EMISSIONS AND THEIR ABATEMENT

4.1 Emissions to Air

The sites existing permit allows the emission to air detailed within Table 4.1 below.

Table 4.1 – Existing Emissions to Air

Emission Point Reference	Parameter	Source	Limit
A1	Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	Boiler 1 (Danks)	200 mg/m^3
A2	Particulate Matter	Spray Drier Plant	5 mg/m^3
A3	No parameters	Fermenter	No limit set
A4	No parameters	Fermenter	No limit set
A5	No parameters	Fermenter	No limit set
A6	No parameters	Fermenter	No limit set
A7	No parameters	ABC 5000 Purification 1 extract vent	No limit set
A8	Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	Boiler 2 (Babcock)	200 mg/m^3

As part of this permit variation, additional emission to air points will be included as well as an amendment to the existing boilers now being required to meet the 'existing' Medium Combustion Plant Directive Emission Limit Values (ELVs).

Emission points A2, A3, A4 and A7 are being removed from the permit as no longer in use. Emission points A9 – A11 are already operational but previously have not been included within the permitted installation.

Please refer to Table 4.2 below which shows the proposed emissions to air from the varied facility.

Table 4.2 – Proposed Emissions to Air

Emission Point Reference	Parameter	Source	Limit
A1	Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	Boiler 1 (Danks)	190 mg/m^3
A5	No parameters	Fermenter	No limit set
A6	No parameters	Fermenter	No limit set
A8	Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	Boiler 2 (Babcock)	200 mg/m^3
A9	No parameters	Fermenter (MF3)	No limit set
A10	No parameters	Fermenter (MF3)	No limit set
A11	VOCs (abated by a filter)	Dispensing Booths	No limit set
A12	Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	Clayton Boiler 1	100 mg/m^3
A13	Oxides of Nitrogen (NO and NO_2 expressed as NO_2)	Clayton Boiler 2	100 mg/m^3

Detailed emission modelling has been carried out as part of this application, considering the existing boilers and the proposed boilers once installed. This can be found in *Annex F – Air Quality Assessment.*

In addition to this, an H1 screening assessment has been carried out to assess the emissions from Emission Point A11. This can be found in *Annex G – H1 Screening Assessment.*

4.2 Emissions to Controlled Water

Emissions to water from the installation include the discharge of process, cooling waters and condensate which drain via Emission Point W1 into a shared drainage system that runs through the Billingham site (operated by C F Fertilisers UK Ltd). The discharge terminates in an outflow directly into the River Tees. Emission Point W1 is monitored for flow, pH, suspended solids, COD and Ammoniacal N.

The sites existing permit allows the emissions to water detailed within Table 4.3 below.

Table 4.3 – Existing Emissions to Water

Emission Point Reference	Parameter	Source	Limit	Reference Period
W1	Flow	Process cooling water and condensate	No limit set	Continuous

W1	pH	Process cooling water and condensate	5 – 12	Hourly average
W1	Chemical Oxygen Demand (COD)	Process cooling water and condensate	700 mg/l	Weekly time proportional sample
W1	Ammoniacal nitrogen as N	Process cooling water and condensate	No limit set	Weekly time proportional sample

There will be no amendments to Emission Point W1 and therefore it is not considered further within this application.

It is recognised that in the event of a fire, the site does not have the necessary drainage infrastructure to ensure that all contaminated fire water will be contained on site. Therefore, Fujifilm will be carrying out a full review of the sites drainage infrastructure and assess the options to ensure that containment can be achieved in the future.

The site drainage system is shown in *Annex A – Site Plans.*

4.3 Emissions to Sewer

The sites existing permit currently allows no emissions to sewer.

As part of this permit variation, the operation of Borealis will result in a new emission point to sewer (Emission Point S1) and the operation of BIC-UK will result in an additional emission point to sewer (Emission Point S2).

The washings produced as part of the processes carried out within Borealis will be pH corrected and then discharged to sewer via Emission Point S1. Fujifilm have applied to Northumbrian Water for a discharge consent (Ref: T1955) which is provided within *Annex K – Effluent Discharge Consent*.

Emission Point S1 will be managed as per the consent. The consent provides the following compliance points:

- Maximum volume – 12.5m^3 (over 24 hours);
- Maximum rate – 10 litres/second;
- pH – 6 to 10;
- Non-volatile matter (oil and grease) – 100 mg/l;
- COD – 20,000 mg/l;
- Suspended Solids – 500 mg/l;
- Chloride – 400 mg/l;
- Iron – 10 mg/l;
- Copper – 1 mg/l;
- Zinc – 10 mg/l;

- Manganese – 1 mg/l;
- Nitrogen Ammoniacal – 25 mg/l;
- Phosphorus – 5000 mg/l;
- Sulphide – 0.2 mg/l;
- Sulphate – 600 mg/l;
- Cobalt thiocyanate Active Substances – 75 mg/l; and
- Anionic Detergents – 75 mg/l.

Waste water discharges from BIC-UK will be discharged to foul sewer via the Cowpen Road combined sewer (Emission Point S2). This discharge is anticipated to be small and consists mostly of sanitary waste from the various R&D offices. It is anticipated that the volumes will be very low and as this only relates to the R&D laboratories and not a production facility.

Further information on Emission Point S1 and S2 has been provided within the H1 Emission to Water assessment provided within *Annex D – H1 Assessment.*

4.4 Emission to Land

There will be no emissions to land from the proposed variation.

4.5 Odour

Due to the design of the site, the fully enclosed processing activities and the nature of the operations carried out on site, there is very little potential for offsite odour emissions and impacts to arise from the site. In addition, the site is located in an industrial area and has no history of any odour complaints.

Therefore, there will be no impact in terms of odour from the proposed operations on site.

4.6 Noise Impacts

The design of the installation has considered the potential impacts on the environment and neighbouring receptors with regards to noise. All processing activities take place within fully enclosed buildings and are inherently quiet in their operation. The site is located in an industrial area and has no history of any noise complaints.

Project Borealis does have the potential for noise emissions due to a roof-mounted plant room. Therefore, a Noise Impact Assessment has been produced considering the operational impact of the manufacturing facility.

The assessment includes a baseline noise survey, undertaken at positions representative of the nearest noise sensitive receptors to determine the typical background noise levels during both daytime and night-time periods.

This report describes the assessment methodology and the baseline conditions currently prevailing across the development site to evaluate the potential noise impact of the development.

Please refer to *Annex H – Noise Impact Assessment* for more information.

During the validation of the previously submitted permit application, the following points were raised with regards to the noise assessment. This was raised as something that would not prevent duly making, but something that was required during permit determination.

Kindly provide the following information regarding scope of the NIA:

a) Confirm whether the background sound measurements made at UL1 and UL2 were affected by the existing permitted site operations. If yes, then you would need to provide an updated background sound survey which is not affected.

b) Confirm whether the Project Borealis project has progressed to detailed design stage. If the Project Borealis project has progressed to detailed design stage, the NIA and noise modelling must be updated and resubmitted.

Kindly provide the following data:

c) Background sound data - Please provide data for sound levels measured at UL1 and UL2 in a spreadsheet format (LAeq & LA90 sound levels in 15-minute periods).

For point a), during enhanced pre-application advice it was explained that the consultant in attendance during the survey in 2023 confirmed that the acoustic environment was predominantly road traffic from Cowpen Lane, railway traffic to the north and noise from the school playground / field. The actual Borealis site was not active, and no operations from the other Fujifilm buildings to the south of Central Ave were observed. The EA agreed with this explanation and confirmed that the 2023 survey remains valid for the purposes of the variation application.

For point b), due to onsite noise measurements being the only way to get an accurate updated noise assessment, this is currently being undertaken with the assessment being updated ASAP. This will be forwarded to the EA when complete.

For point c), this has been provided within *Annex H – Noise Impact Assessment.*

4.7 Fugitive Emissions

There are no fugitive emissions for the existing and proposed activities on site.

4.8 Waste Generation and Management

Fujifilm Diosynth Biotechnologies UK Ltd has a documented waste management system. The basis of the waste management system is that:

- All wastes are fully contained until they are transferred off site;
- All wastes are characterised and classified, using the Environment Agency Technical Guidance WM3;
- Wastes are only transferred to licensed waste management contractors;
- Duty of Care audits are carried out on all waste management facilities before disposal contracts are signed;
- Only authorised persons may sign waste transfer notes;
- Hazardous wastes are transferred off site as soon as practicable; and

- Copies of all waste carriers licences are kept on file.

In developing routes for waste management, the hierarchy of waste is always considered.

Waste is generally subdivided by site management into a number of categories:

- Packaging waste;
- Process waste (routine);
- Process waste (shut-down and non-routine);
- Laboratory waste;
- Engineering waste; and
- Office and amenity waste.

Waste streams from site are shown in Table 4.4 below.

Table 4.4 – Waste Streams from Site

Waste Type	Description	Source	Recovery / Disposal Route
Packaging Waste	Bottles, boxes, kegs, paper sacks, and other packaging	Process operations	Mostly recycled but certain glass bottles (for ethanol etc) are returned to suppliers for reuse.
	220 litre drums	NaOH for plant cleaning	Returned to supplier for re-use.
	IBCs	Ethanol, methanol, sulphuric and phosphoric acid supply	Returned to supplier for re-use.
	Pallets	Transport operations	Returned to supplier for re-use.
Process Waste (routine)	Aqueous effluent	Manufacturing processes	Either transferred off site for wastewater treatment or if possible, sent to Emission Point W1.
	Active GMOs and Single Use Consumables from MCC	Manufacturing processes	Transferred off site for incineration at Stericycle, Leeds.
	Resins and ethanol	Manufacturing processes	Transferred off site for incineration or solvent recovery.

	Fermentation solids	Manufacturing process after product has been extracted	Transferred off site for incineration or contract treatment.
	Other chemicals	Manufacturing operations	Disposal by specialist waste management contractors.
	General maintenance waste e.g. gaskets, sweepings etc	Maintenance work in support of process operations	Stored in a designated location before disposal in landfill.
Process waste (non-routine)	Aqueous effluent and / or fermentation solids	A failed or contaminated fermentation batch	Heat treated and/or pH adjusted before collection in tank for contract wastewater treatment.
	Time expired raw materials	Manufacturing processes	Disposal by specialist waste management contractors.
Laboratory waste	Lab glassware	Process analysis	Recycled off site.
	Active GMOs	Process analysis	Transferred off site for incineration at facility notified to the HSE.
Engineering Waste	Waste oil	Compressors, drive gear boxes, forklift trucks, and other maintenance equipment	Recycled off site.
	Scrap metal – engineering waste	Engineering operations on site	Recycled off site.
Office waste	General domestic	Canteen and offices	Recycled off site. Canteen waste is sent for energy recovery.
	Sharps and medical / clinical waste	First aid room	Transferred off site for incineration.
	Ladies hygiene	Toilets	Transferred off site for incineration.

5. ENVIRONMENTAL MONITORING

5.1 Emissions to Air

The monitoring of the existing and new boiler plant will be carried out in accordance with the Medium Combustion Plant Directive. The proposed monitoring frequencies and standard are detailed within Table 5.1 below.

All monitoring and sampling will be carried out by a suitably MCERTS qualified specialist contractor.

The sampling port at the facility will be designed in accordance with the Environment Agency's Technical Guidance Note (Monitoring) M1 *"Sampling Requirements for Stack Emissions Monitoring"*.

There are no monitoring requirements for the fermenter emission points or emergency exhausts.

Table 5.1 – Air Emissions Monitoring

Emission Point	Parameter	Monitoring Frequency	Monitoring Standard
A1	Oxides of Nitrogen	Annual	MCERTS BS EN 14792
A8	Oxides of Nitrogen	Annual	MCERTS BS EN 14792
A12	Oxides of Nitrogen	Every 3 years	MCERTS BS EN 14792
A13	Oxides of Nitrogen	Every 3 years	MCERTS BS EN 14792

5.2 Emissions to Controlled Water

In line with the sites existing permit, Emission Point W1 is monitored for flow, pH, suspended solids, COD and Ammoniacal N. Please refer to Table 5.2 below for more information.

There will be no amendment to Emission Point W1 and therefore monitoring will remain as currently permitted.

Table 5.2 – Existing Permit Water Emission Monitoring

Emission Point Reference	Parameter	Monitoring Frequency	Monitoring Standard or Method
W1	Flow	Continuous	SCA estimation of flow and load
W1	pH	Continuous	SCA measurement of electronic conductivity and determination of pH
W1	Chemical Oxygen Demand (COD)	Weekly	BS 6068-2.34:1988

W1	Ammoniacal nitrogen as N	Weekly	BS6068: Section 2.11 1987

5.3 Emissions to Sewer

The monitoring required at Emission Point S1 will take place as per the sites trade effluent consent provided within *Annex K – Trade Effluent Discharge Consent.*

Due to Emission Point S2 relating mostly to sanitary waste from the various R&D offices, no monitoring at this point is proposed.

5.4 Emissions to Land

There are no point source emissions to land arising from the process.

Therefore, no monitoring is required.

6. BAT ASSESSMENT

All plant and equipment has been designed in accordance with BAT and will comply with the relevant standard and guidance requirements.

The following BAT demonstration is based on the *Common Wastewater and Waste Gas Treatment / Management Systems in the Chemical Sector* BAT conclusions published in 2016. Table 6.1 below summarises the indicative BAT requirements that apply to the proposed process.

Table 6.1 – BAT Review: Common Wastewater and Waste Gas Treatment / Management Systems in the Chemical Sector

BAT Reference	BAT Conclusion	Justification
General BAT Conclusions		
BAT 1	In order to improve the overall environmental performance, BAT is to implement and adhere to an environ mental management system (EMS) that incorporates all of the features detailed within the BAT Conclusions.	Fujifilm's existing management system is documented in a series of SHESOPs which are controlled documents detailed within the site's electronic document management system.
BAT 2	In order to facilitate the reduction of emissions to water and air and the reduction of water usage, BAT is to establish and to maintain an inventory of wastewater and waste gas streams, as part of the EMS that incorporates all of the features detailed within the BAT Conclusions.	Fujifilm maintain an inventory of all emissions to water and air as part of the site EMS. This is reviewed regularly and updated in the event of any variations on site.
BAT 3	For relevant emissions to water as identified by the inventory of wastewater streams (see BAT 2), BAT is to monitor key process parameters (including continuous monitoring of wastewater flow, pH, and temperature) at key locations (e.g. influent to pretreatment and influent to final treatment).	All monitoring at Emission Point W1 is carried out in line with the sites environmental permit.
BAT 4	BAT is to monitor emissions to water in accordance with EN standards with at least the minimum frequency given in the BAT Conclusions. If EN standards are not available, BAT is to use ISO,	All monitoring at Emission Point W1 is carried out in line with the sites environmental permit.

	national or other international standards that ensure the provision of data of an equivalent scientific quality.	
BAT 5	BAT is to periodically monitor diffuse VOC emissions to air from relevant sources by using an appropriate combination of the techniques I-III or, where large amounts of VOC are handled, all of the techniques I-III.	N/A – the only potential for VOC emissions is from the dispensing booths which are treated by a filter. Diffuse VOC emissions to air are not expected from the site. The activities carried out on site do not have potential for odorous emissions.
BAT 6	BAT is to periodically monitor odour emissions from relevant sources in accordance with EN standards.	N/A – due to the design of the site, the fully enclosed processing activities and the nature of the operations carried out on site, there is very little potential for offsite odour emissions and impacts to arise from the site. In addition, the site is located in an industrial area and has no history of any odour complaints. Therefore, there will be no impact in terms of odour from the proposed operations on site.
BAT 7	In order to reduce the usage of water and the generation of wastewater, BAT is to reduce the volume and/or pollutant load of wastewater streams, to enhance the reuse of wastewater within the production process and to recover and reuse raw materials.	Water reuse is generally not applicable to the site, due to the processes being regulated to only use known raw materials that are tested and certified. However, water usage is optimised where possible.
BAT 8	In order to prevent the contamination of uncontaminated water and to reduce emissions to water, BAT is to segregate uncontaminated wastewater streams from wastewater streams that require treatment.	Uncontaminated wastewater streams are segregated from wastewater streams that require treatment.
BAT 9	In order to prevent uncontrolled emissions to water, BAT is to provide an appropriate buffer storage capacity for waste water incurred during other than normal operating conditions based on a risk assessment (taking into account e.g. the nature of the pollutant, the effects on further treatment, and the receiving	Fujifilm have appropriate storage capacity on site to store wastewater that may be produced during an abnormal operation event.

	environment), and to take appropriate further measures (e.g. control, treat, reuse).	
BAT 10	In order to reduce emissions to water, BAT is to use an integrated wastewater management and treatment strategy that includes an appropriate combination of the techniques in the priority order given within the BAT Conclusions.	The site does not currently have a wastewater treatment plant. Any effluent that can be discharged via Emission Point W1 will be pH corrected and discharged accordingly. Any wastewater that cannot be meet the discharge conditions will be collected and then tankered off site for treatment. A wastewater treatment plant is proposed as part of Project Borealis. This plant has been designed to meet BAT.
BAT 11	In order to reduce emissions to water, BAT is to pretreat wastewater that contains pollutants that cannot be dealt with adequately during final wastewater treatment by using appropriate techniques.	The site does not currently have a wastewater treatment plant. Any effluent that can be discharged via Emission Point W1 will be pH corrected and discharged accordingly. Any wastewater that cannot be meet the discharge conditions will be collected and then tankered off site for treatment. A wastewater treatment plant is proposed as part of Project Borealis. This plant will be designed in accordance with BAT.
BAT 12	In order to reduce emissions to water, BAT is to use an appropriate combination of final wastewater treatment techniques.	The site does not currently have a wastewater treatment plant. Any effluent that can be discharged via Emission Point W1 will be pH corrected and discharged accordingly. Any wastewater that cannot be meet the discharge conditions will be collected and then tankered off site for treatment. A wastewater treatment plant is proposed as part of Project Borealis. This plant will be designed in accordance with BAT.
BAT 13	In order to prevent or, where this is not practicable, to reduce the quantity of waste being sent for disposal, BAT is to set up and implement a waste management plan as part of the environmental management system (see BAT 1) that, in order of	Fujifilm reduce the quantity of waste sent for disposal as far as practicably possible and have a dedicated waste management system. In developing routes for waste management, the hierarchy of waste is always considered.

	priority, ensures that waste is prevented, prepared for reuse, recycled or otherwise recovered.	
BAT 14	In order to reduce the volume of wastewater sludge requiring further treatment or disposal, and to reduce its potential environmental impact, BAT is to use one or a combination of the techniques given within the BAT Conclusions.	N/A – wastewater sludge is not produced on site.
BAT 15	In order to facilitate the recovery of compounds and the reduction of emissions to air, BAT is to enclose the emission sources and to treat the emissions, where possible.	Where required, enclosure and treatment of emission is ensured.
BAT 16	In order to reduce emissions to air, BAT is to use an integrated waste gas management and treatment strategy that includes process-integrated and waste gas treatment techniques.	The only emission to air point that requires treatment is A11 – dispensing booth filter. This emission has the necessary abatement to ensure emissions to air are reduced.
BAT 17	In order to prevent emissions to air from flares, BAT is to use flaring only for safety reasons or non-routine operational conditions (e.g. start-ups, shutdowns) by using one or both of the techniques given in the BAT Conclusions.	N/A – there are no flares on site.
BAT 18	In order to reduce emissions to air from flares when flaring is unavoidable, BAT is to use one or both of the techniques given in the BAT Conclusions.	N/A – there are no flares on site.
BAT 19	In order to prevent or, where that is not practicable, to reduce diffuse VOC emissions to air, BAT is to use a combination of the techniques given in the BAT Conclusions.	N/A – the only potential for VOC emissions is from the dispensing booths which are treated by a filter. Diffuse VOC emissions to air are not expected from the site. The activities carried out on site do not have potential for odorous emissions.
BAT 20	In order to prevent or, where that is not practicable, to reduce odour emissions, BAT is to set up, implement and regularly review an odour management plan, as part of the environmental	N/A – due to the low risk of odorous emissions from site, an odour management plan is not considered appropriate.

	management system (see BAT 1), that includes all of the elements detailed within the BAT Conclusions.	
BAT 21	In order to prevent or, where that is not practicable, to reduce odour emissions from wastewater collection and treatment and from sludge treatment, BAT is to use one or a combination of the techniques detailed within the BAT Conclusions.	N/A – there is no risk of odorous emissions from wastewater collection. There is no sludge treatment carried out on site.
BAT 22	In order to prevent or, where that is not practicable, to reduce noise emissions, BAT is to set up and implement a noise management plan, as part of the environmental management system (see BAT 1), that includes all of the following elements within the BAT Conclusions.	N/A – due to the low risk of noise emissions on site, a noise management plan is not considered appropriate.
BAT 23	In order to prevent or, where that is not practicable, to reduce noise emissions, BAT is to use one or a combination of the techniques given in the BAT Conclusions.	Operational measures such as the inspection and maintenance of equipment, closing doors and windows where possible, all equipment being operated by experienced staff and avoidance of noisy activities at night are prioritised where practicably possible. Low-noise equipment is selected where possible.

As discussed during pre-application advice with the EA, it is understood that the draft C*ommon Waste Gas Management and Treatment Systems in the Chemical Sector (WGC)* BREF Guidance has not yet been adopted but will be during the application determination process. It is understood that any requirements detailed within the WGC that are relevant to the Fujifilm site will become legally required when the permit is issued.

A review of the site against the BAT Conclusions has been undertaken. There is only one existing waste treatment gas system at the Fujifilm site. This relates to the following:

- Emission point A11 – dispensing booth emission point abated via a filter.

Therefore, the following BAT demonstration provided within Table 6.2 has been based on the above emission point.

Table 6.2 – BAT Review: Common Waste and Gas Management and Treatment Systems in the Chemical Sector

BAT Reference	BAT Conclusion	Justification
General BAT Conclusions		
BAT 1	In order to improve the overall environmental performance, BAT is to elaborate and implement an environmental management system that incorporates all of the features detailed within the BAT Conclusions.	Fujifilm have an Environmental Management System (EMS) in place that is accredited to ISO 14001 standard. Fujifilm's existing management system is documented in a series of SHESOPs which are controlled documents detailed within the site's electronic document management system.
BAT 2	In order to facilitate the reduction of emissions to air, BAT is to establish, maintain and regularly review (including when a substantial change occurs) an inventory of channelled and diffuse emissions to air, as part of the environmental management system that incorporates all of the features detailed within the BAT Conclusions.	Fujifilm maintain an inventory of all emissions to air as part of the site EMS. This is reviewed regularly and updated in the event of any variations on site.
BAT 3	In order to reduce the frequency of the occurrence of OTNOC and to reduce emissions to air during OTNOC, BAT is to set up and implement a risk-based OTNOC management plan as part of the environmental management system (see BAT 1) that includes all of the features within the BAT Conclusions.	Due to the nature of the site and the minimal waste gas treatment systems on site, an OTNOC management plan is not considered necessary for the site.
BAT 4	In order to reduce channelled emissions to air, BAT is to use an integrated waste gas management and treatment strategy that includes, in order of priority, process-integrated recovery and abatement techniques.	Fujifilm will operate in accordance with BAT utilising an integrated waste gas management and treatment strategy in order to reduce channelled emissions to air.
BAT 5	In order to facilitate the recovery of materials and the reduction of channelled emissions to air, as well as to increase energy	The only emission to air point that requires treatment is A11 – dispensing booth filter. This emission point has the necessary abatement to ensure emissions to air are reduced.

	efficiency, BAT is to combine waste gas streams with similar characteristics, thus minimising the number of emission points.	
BAT 6	In order to reduce channelled emissions to air, BAT is to ensure that the waste gas treatment systems are appropriately designed (e.g. considering the maximum flow rate and pollutant concentrations), operated within their design ranges, and maintained (through preventive, corrective, regular and unplanned maintenance) so as to ensure optimal availability, effectiveness and efficiency of the equipment.	The gas treatment systems are appropriately designed in accordance with the BAT requirements to reduce channelled emissions to air. All process equipment and machinery will be subject to a planned preventative maintenance schedule to ensure optimal availability, effectiveness, and efficiency of the equipment.
BAT 7	BAT is to continuously monitor key process parameters (e.g. waste gas flow and temperature) of waste gas streams being sent to pretreatment and/or final treatment.	Due to the treatment systems on site, continuous monitoring is not considered appropriate. However, Fujifilm will carry out periodic monitoring to ensure that the systems are operating correctly.
BAT 8	BAT is to monitor channelled emissions to air with at least the frequency given within the BAT Conclusions and in accordance with EN standards. If EN standards are not available, BAT is to use ISO, national or other international standards that ensure the provision of data of an equivalent scientific quality.	VOCs will be monitored from Emission Point A12 once every 6 months in accordance with BS EN 12619 if considered necessary by the EA.
BAT 9	In order to increase resource efficiency and to reduce the mass flow of organic compounds sent to the final waste gas treatment, BAT is to recover organic compounds from process off-gases by using one or a combination of the techniques given within the BAT conclusions and to reuse them.	N/A – the only potential release of organic compounds is VOCs is from the dispensing booth filter.
BAT 10	In order to increase energy efficiency and to reduce the mass flow of organic compounds sent to the final waste gas treatment, BAT is to send process off-gases with a sufficient calorific value to a combustion unit that is, if technically possible, combined	N/A – the only potential release of organic compounds is VOCs is from the dispensing booth filter.

	with heat recovery. BAT 9 has priority over sending process off-gases to a combustion unit.	
BAT 11	In order to reduce channelled emissions to air of organic compounds, BAT is to use one or a combination of the techniques given within the BAT Conclusions.	N/A – the only potential release of organic compounds is VOCs is from the dispensing booth filter.
BAT 12	In order to reduce channelled emissions to air of PCDD/F from thermal treatment of waste gases containing chlorine and/or chlorinated compounds, BAT is to use techniques a. and b., and one or a combination of techniques c. to e., given within the BAT Conclusions.	N/A – there is no thermal treatment of waste gases on site.
BAT 13	In order to increase resource efficiency and to reduce the mass flow of dust and particulate-bound metals sent to the final waste gas treatment, BAT is to recover materials from process off-gases by using one or a combination of the techniques given within the BAT Conclusions and to reuse them.	N/A – there are no releases of dust and particulate-bound metals on site.
BAT 14	In order to reduce channelled emissions to air of dust and particulate-bound metals, BAT is to use one or a combination of the techniques given within the BAT Conclusion.	N/A – there are no releases of dust and particulate-bound metals on site.
BAT 15	In order to increase resource efficiency and to reduce the mass flow of inorganic compounds sent to the final waste gas treatment, BAT is to recover inorganic compounds from process off-gases by using absorption and to reuse them	N/A – there are no releases of dust and particulate-bound metals on site.
BAT 16	In order to reduce channelled emissions to air of CO, NOX and SOX from thermal treatment, BAT is to use technique c. and one or a combination of the other techniques given within the BAT Conclusions.	N/A – there is no thermal treatment of waste gases on site.

BAT 17	In order to reduce channelled emissions to air of ammonia from the use of selective catalytic reduction (SCR) or selective non-catalytic reduction (SNCR) for the abatement of NOX emissions (ammonia slip), BAT is to optimise the design and/or operation of SCR or SNCR (e.g. optimised reagent to NOX ratio, homogeneous reagent distribution and optimum size of the reagent drops).	N/A – there is no SCR or SNCR on site.
BAT 18	In order to reduce channelled emissions to air of inorganic compounds other than channelled emissions to air of ammonia from the use of selective catalytic reduction (SCR) or selective non-catalytic reduction (SNCR) for the abatement of NOX emissions), channelled emissions to air of CO, NOX and SOX from the use of thermal treatment, and channelled emissions to air of NOX from process furnaces/heaters, BAT is to use one or a combination of the techniques given within the BAT Conclusions.	N/A – there is no SCR or SNCR on site.
BAT 19	In order to prevent or, where that is not practicable, to reduce diffuse VOC emissions to air, BAT is to elaborate and implement a management system for diffuse VOC emissions, as part of the environmental management system (see BAT 1), that all the aspects detailed within the BAT Conclusions	The only potential release of organic compounds is VOCs is from the dispensing booth filter; therefore, a VOC management system is not appropriate for the site.
BAT 20	BAT is to estimate fugitive and non-fugitive VOC emissions to air separately at least once every year by using one or a combination of the techniques given within the BAT Conclusion, as well as to determine the uncertainty of this estimation. The estimation distinguishes between VOCs classified as CMR 1A or 1B and VOCs that are not classified as CMR 1A or 1B.	Fugitive and non-fugitive VOC emissions are not expected from the site, apart from potential release from the dispensing booth filter. Therefore, this conclusion is not considered appropriate for the site.

BAT 21	BAT is to monitor diffuse VOC emissions from the use of solvents by compiling, at least once every year, a solvent mass balance of the solvent inputs and outputs of the plant, as defined in Part 7 of Annex VII to Directive 2010/75/EU and to minimise the uncertainty of the solvent mass balance data by using all of the techniques given within the BAT Conclusion.	Some fermentation processes do use small quantities of solvent as feedstock. A solvent mass balance can be compiled if considered necessary by the EA.
BAT 22	BAT is to monitor diffuse VOC emissions to air with at least the frequency given below and in accordance with EN standards. If EN standards are not available, BAT is to use ISO, national or other international standards that ensure the provision of data of an equivalent scientific quality.	N/A – diffuse VOC emissions are not expected from the site.
BAT 23	In order to prevent or, where that is not practicable, to reduce diffuse VOC emissions to air, BAT is to use a combination of the techniques given within the BAT conclusion with order of priority.	N/A – diffuse VOC emissions are not expected from the site.
BAT 24	To prevent or, where that is not practicable, to reduce channelled emissions to air of CO, dust, NOX and SOX, BAT is to use technique c. and one or a combination of the other techniques given in the BAT conclusions	N/A – there are no process furnaces / heaters on site.
BAT 25 – 26	Polymers and synthetic rubbers	N/A
BAT 27 – 31	Production of polyvinyl chloride (PVC)	N/A
BAT 32 – 33	Production of synthetic rubbers	N/A
BAT 34 – 36	Production of viscose using carbon disulphide	N/A

A BAT Assessment has also been carried out against '*How to Comply with your Environment Permit – Speciality Organic Chemicals EPR 4.02'* which was published in March 2009.

Table 6.3 below summarises the indicative BAT requirements that apply to the proposed process.

Table 6.3 – EPR 4.02 Indicative BAT Requirements

Reference	Indicative BAT Requirement	Justification
1.0 General Requirements		
1	Monitor and benchmark your environmental performance and review this at least once a year. Your plans for minimising environmental impacts should be incorporated into on-going Improvement programmes. Indicators can be derived using the Horizontal Guidance Note H1 Environmental Risk Assessment (see GTBR Annex 1). It is suggested that indicators are based on tonnes of organics produced (tOP) as they provide a good basis for measuring performance within an installation or a single company year on year.	The operator is committed to monitoring environmental performance, and the wider environmental management of the site. This will be done as part of an annual review of its environmental systems in place to protect the environment from potential impacts. On-going improvement programmes will be directed by the outcomes of these annual reviews. Additional reviews will be undertaken if required in response to environmental harm caused by failure of the site's systems.
2	Assess the environmental impact of each process and choose the one with the lowest environmental impact. (We recognise that your choice may be constrained, for example, by the integration of processes on a complex site).	Before each project is undertaken, a detailed Environmental Impact Assessment is carried out. This is carried out for every product that is manufactured on site and provides details on all raw materials used and any waste produced.
3	Maximise heat transfer between process streams where water is needed for cooling. Use a recirculating system with indirect heat exchangers and a cooling tower in preference to a once-through cooling system.	HVAC cooling is closed loop, so water is recycled. Process cooling water is similarly recycled on a return system. Asset monitoring is carried out for any leaks as well as 'independent' Service Technician monitoring, to minimise waste.
4	Where water is used in direct contact with process materials, recirculate the water after stripping out the absorbed substances.	Water is not used in direct contact with process materials. Water is treated to 'Water for Injection' quality standard and then used to create buffers for the

		process, so there is no direct water contact with the process materials that could be recovered / reused.
5	Demonstrate that the chosen routes for recovery or disposal represent the best environmental option. Consider avenues for recycling back into the process or reworking for another process wherever possible.	Where possible, recovery is the primary route for waste generated on site. Disposal is only used as a last resort where recovery is not possible or viable. This is applicable to all waste listed in Table 4.4 of the Application Support Document.
6	Provide a detailed assessment identifying the best environmental options for waste disposal where you cannot avoid disposing of waste.	Fujifilm Diosynth Biotechnologies UK Ltd has a documented waste management system which ensures that when developing routes for waste management, the hierarchy of waste is always considered. For some process wastes, disposal is the only viable option.
2.0 Operations		
2.1 Design of a New Plant		
7	No Indicative BAT Listed	N/A
2.2 Storage and handling of raw materials, products, and wastes		
8	Consider all potential environmental impacts from the outset in any new project for manufacturing chemicals.	All potential impacts of the site's pharmaceutical processes have been considered and reviewed from the outset.
9	Undertake the appropriate stages of a formal HAZOP study as the project progresses through the process design and plant design phases. The HAZOP studies should consider amongst other things the points noted above.	The appropriate stages of a formal HAZOP study have been undertaken throughout the process design and plant design phases, and all potential environmental impacts have been considered.
10	Store reactive chemicals in such a way that they remain stable, such as under a steady gas stream, for example. If chemical additions are necessary, then tests should be carried out to ensure the required chemical composition is maintained. Inhibitors may also be added to prevent reactions.	All raw materials and products for use at site are stored in contained areas such as material stores, tank farms, and drum parks which have been designed in accordance with recognised BAT to prevent pollution risk from storage. Storage of materials have been designed to ensure any reactive chemicals remain stable.
11	Vent storage tanks to a safe location.	Storage tanks are vented, where necessary, to a safe location at all times.

12	Use measures to reduce the risk of contamination from large storage tanks. In addition to sealed bunds, use double-walled tanks and leak detection channels.	All storage tanks are installed with secondary containment and designed to comply with CIRIA C736. Larger tanks are double walled and have leak detection measures.
13	Use HAZOP studies to identify risks to the environment for all operations involving the storage and handling of chemicals and wastes. Where the risks are identified as significant, plans and timetables for improvements should be in place.	HAZOP studies have been undertaken to identify risks to the environment for all operations including storage and handling of chemicals and wastes.
2.3 Plant Systems and Equipment		
14	Formally consider potential emissions from plant systems and equipment and have plans and timetables for improvements, where the potential for substance or noise pollution from plant systems and equipment has been identified.	Emissions from plant and equipment have been identified and parameters and monitoring schedules have been put in place. All emissions from site have been identified within this permit application. Substance or noise pollution from the site is not considered likely and therefore an improvement plan is not required.
15	Carry out systematic HAZOP studies on all plant systems and equipment to identify and quantify risks to the environment.	HAZOP studies on all plant and equipment have been carried out to identify and quantify risks to the environment.
16	Choose vacuum systems that are designed for the load and keep them well maintained. Install sufficient instrumentation to detect reduced performance and to warn that remedial action should be taken.	Appropriate vacuum systems designed for the load have been selected and will be well-maintained throughout their lifespan. Appropriate instruments to detect reduced performance have been selected to warn of remedial action to be undertaken.
Over-pressure protection systems		
17	Carry out a systematic HAZOP study for all relief systems, to identify and quantify significant risks to the environment from the technique chosen.	A systematic HAZOP study for all relief system has been completed to identify and quantify significant risks to the environment.
18	Identify procedures to protect against overpressure of equipment. This requires the identification of all conceivable over-pressure situations, calculation of relief rates, selection of relief method, design of the vent system, discharge and disposal considerations, and dispersion calculations.	Fujifilm use 3rd party guidance (TUV Rhineland) to set relief valves / airbrakes / air gaps in systems. The procedure is governed through guidance documentation (SHESOP 6.2 series): • 6.2 Pressure Systems Management;

	In some cases, careful design can provide intrinsic protection against all conceivable over-pressure scenarios, so relief systems and their consequential emissions can be avoided.	• 6.2.1 Purchase, Installation & Commissioning of Pressure Equipment; • 6.2.2 Operation & Maintenance of Pressure Systems; • 6.2.3 Assessment & Registration of Pressure Systems; • 6.2.4 Registration & Testing of Instrumented Protection Devices; and • 6.2.5 Glossary of Terms for Pressure Systems Procedures. The site's over-pressure protection system has been designed to prevent overpressure of equipment. Suitably trained staff will be available throughout operations to monitor pressure within equipment. The design of the overpressure protection systems reduces the risk of over pressurisation and prevent emissions arising as a result of over-pressurisation.
19	Maintain in a state of readiness all equipment installed in the venting system even though the system is rarely used.	All equipment installed in the venting system will remain in a state of readiness
Heat exchangers and cooling systems		
20	Consider leak detection, corrosion monitoring, and materials of construction, preferably in a formal HAZOP study. Plans and timetables for improved procedures or replacement by higher integrity designs should be in place where the risks are identified as significant.	Leak-detection and corrosion monitoring are in place on site. This is to prevent damage to the site or harm towards the environment.
21	If corrosion is likely, ensure methods for rapid detection of leaks are in place and a regime of corrosion monitoring in operation at critical points. Alternatively, use materials of construction that are inert to the process and heating/cooling fluids under the conditions of operation.	Although corrosion is not considered likely on site, leak-detection and corrosion monitoring are in place.
22	For cooling water systems, use techniques that compare favourably with relevant techniques described in the Industrial Cooling Systems BREF.	Fujifilm have 11 chillers that do glycol and water chilling in the same unit, most of which have been upgraded to modern efficiencies in the past couple of years.
Purging facilities		

23	Assess the potential for the release to air of VOCs and other pollutants along with discharged purge gas and use abatement where necessary.	The only VOC emissions released on site arise from the dispensing booth and these are treated by use of a filter (Emission Point A11). The extent of VOC release on site is minimal.
2.4 Reaction Stage		
24	With a clear understanding of the physical chemistry, evaluate options for suitable reactor types using chemical engineering principles.	Suitable reactor systems have been selected on site following an evaluation using recognised chemical engineering principles.
25	Select the reactor system from a number of potentially suitable reactor designs - conventional STR, process-intensive or novel-technology - by formal comparison of costs and business risks against the assessment of raw material efficiencies and environmental impacts for each of the options.	Suitable reactor systems have been selected from potentially suitable designs following a comparison of costs and business risks against the assessment of raw material efficiencies and environmental impacts.
26	Undertake studies to review reactor design options based on process-optimisation where the activity is an existing activity and achieved raw material efficiencies and waste generation suggest there is significant potential for improvement. The studies should formally compare the costs and business risks, and raw material efficiencies and environmental impacts of the alternative systems with those of the existing system. The scope and depth of the studies should be in proportion to the potential for environmental improvement over the existing reaction system.	Studies have been undertaken to review reactor design options based on process optimisation. Studies have been undertaken in line with the requirements listed in this BAT measure.
27	Maximise process yields from the selected reactor design, and minimise losses and emissions, by the formalised use of optimised process control and management procedures (both manual and computerised where appropriate).	Optimised process control and management procedures are in place to maximise process yields and minimise losses and emissions.
28	Minimise the potential for the release of vapours to air from pressure relief systems and the potential for emissions of organic solvents into air or water, by formal consideration at the design stage - or formal review of the existing arrangements if that stage has passed.	Design stage reviews and reviews of existing arrangements will ensure that the potential for the release of vapours to air from pressure relief systems is minimised.

Minimisation of liquid losses from reaction systems

29	Use the following features that contribute to a reduction in waste arisings from clean-outs: • low-inventory continuous throughput reactors with minimum surface area for cleaning. • minimum internals such as baffles and coils in the reactor. • smooth reactor walls, no crevices. • flush bottom outlet on reaction vessels. • all associated piping to slope back to the reactor or to a drain point • sufficient headroom under the reactor for collection of all concentrated drainage in drums or other suitable vessel, if necessary. • minimal pipework, designed to eliminate hold-up and to assist drainage. • pipework designed to allow air or nitrogen blowing. • system kept warm during emptying to facilitate draining. • HAZOP studies used to assess the potential for the choking of lines by high-melting point material. • campaigns sequenced so that cleaning between batches is minimised. • campaigns made as long as possible to reduce the number of products changeovers. • where a complete clean is necessary, use cleaning methods that minimise the use of cleaning agents, (e.g. steam-cleaning, rotating spray jets or high-pressure cleaning) or use a solvent which can be re-used. • carry out HAZOP studies to minimise the generation of wastes and to examine their treatment/disposal.	The listed features described in this BAT requirement will be implemented where possible to help reduce waste arising from clean-outs.

	• consider use of disposable plastic pipe-liners. • eliminate or minimise locations for solids to settle-out. • consider duplicate or dedicated equipment where it can reduce the need for cleaning that is difficult.	
Minimisation of vapour losses		
30	Review your operating practices and review vent flows to see if improvements need to be made.	N/A – there are no unwanted vapour losses occurring as part of the process. Undesired off gases produced in the fermentation phase are released to atmosphere and include CO_2 and water vapour.
31	Consider opportunities to enhance the performance of abatement systems.	
2.5 Separation Stages		
Liquid-vapour separations		
32	Choose your separation technique following a detailed process design and HAZOP study. Follow formal operating instructions to ensure effective separation and minimisation of losses. Adhere to design conditions such as heat input, reflux flows, and ratios, etc.	N/A – there is no liquid-vapour separation carried out.
33	Install instrumentation to warn of faults in the system, such as a temperature, pressure, or low coolant-flow alarms.	
Liquid-liquid separation		
34	Use techniques which maximise physical separation of the phases (and also aim to minimise mutual solubility) where practicable.	N/A – there is no liquid-liquid separation carried out.
35	When the phases are separated, use techniques which prevent (or minimise the probability and size of) breakthrough of the organics phase into a waste-water stream. This is particularly important where the environmental consequences of subsequent releases of organics to air or into controlled waters may be significant (e.g. where the effluent is treated in a DAF unit or some of the organic components are resistant to biological treatment).	

36	When a separation is done by hand, use a "dead man's handle", backed up by good management, to improve the chance of the flow being properly controlled as the phase boundary approaches	
37	Consider if automatic detection of the interface is practicable.	
38	Where you are discharging to drain, consider whether there should be an intermediate holding or "guard" tank to protect against accidental losses from the organics phase.	
Solid-liquid separation		
39	Use techniques to minimise, re-use and/or recycle rinse water, and to prevent breakthrough of solids.	N/A – there is no solid-liquid separation undertaken.
40	Install instrumentation or other means of detecting malfunction as all of the techniques are vulnerable to solids breakthrough.	
41	Consider installing "guard" filters of smaller capacity downstream which, in the event of breakthrough, rapidly 'clog' and prevent further losses.	
42	Have good management procedures to minimise loss of solids, escape of volatiles to air and excessive production of wastewater.	
2.6 Purification Stage		
43	No Indicative BAT Measures Listed	N/A
2.7 Chemical Process Controls		
44	Monitor the relevant process controls and set with alarms to ensure they do not go out of the required range.	Relevant process controls will be monitored to ensure the processes are optimised.
2.8 Analysis		
45	Analyse the components and concentrations of by products and waste streams to ensure correct decisions are made regarding onward treatment	Fujifilm Diosynth Biotechnologies UK Ltd has a documented waste management system which ensures that when developing routes for waste management, the hierarchy of waste is always considered. For some process

	or disposal. Keep detailed records of decisions based on this analysis in accordance with management systems.	wastes, disposal is the only viable option. All waste streams are analysed to ensure the correct recycling / disposal route is achieved.
3.0 Emissions and Monitoring		
3.1 Point Source Emissions		
Emissions to Air		
46	Formally consider the information and recommendations in the BREF on Common Wastewater and Waste Gas Treatment/ Management Systems in the Chemical Sector (see Reference 1) as part of the assessment of BAT for point-source releases to air, in addition to the information in this note.	A BAT assessment against the *Common Wastewater and Waste Gas Treatment/ Management Systems in the Chemical Sector* BREF has been provided within Table 6.1 / 6.2.
47	Identify the main chemical constituents of the emissions, including VOC speciation where practicable.	Potential emissions have been identified as part of this permit variation application. The only VOC emissions released on site arise from the dispensing booth and these are treated by use of a filter (Emission Point A11). The extent of VOC release on site is minimal.
48	Assess vent and chimney heights for dispersion capability and assess the fate of the substances emitted to the environment.	Potential emissions have been identified as part of this permit variation application. An Air Quality Assessment has been carried out in relation to the replacement of the boiler plant on site.
49	Use the following measures to minimise emissions to air: • recover emissions rich in organics by fractionation and then recycle; • recover and reuse solvents; • continuously monitor off-gas concentration from reaction vessels, dryers, condensers, evaporators, and scrubbers where off-gases are shown to be environmentally significant.	N/A – the site does not release emissions rich in organics.
Emissions to Water		

50	Control all emissions to avoid a breach of water quality standards as a minimum. Where another technique can deliver better results at reasonable cost it will be considered BAT and should be used.	All emissions to water are controlled on site to avoid a breach of water quality standards. Emissions to water from the installation include the discharge of process, cooling waters and condensate which drain via Emission Point W1 into a shared drainage system that runs through the Billingham site (operated by C F Fertilisers UK Ltd). The discharge terminates in an outflow directly into the River Tees. Emission Point W1 is monitored for flow, pH, suspended solids, COD and Ammoniacal N.
51	Use the following measures to minimise water use and emissions to water: where water is needed for cooling, minimize its use by maximising heat transfer between process streams: • use water in recirculating systems with indirect heat exchangers and a cooling tower rather than a once through system. (A water make-up treatment plant and a concentrated purge stream from the system to avoid the build-up of contaminants are likely to be necessary.); • leaks of process fluids into cooling water in heat exchangers are a frequent source of contamination. Monitoring of the cooling water at relevant points should be appropriate to the nature of the process fluids. In a recirculatory cooling system, leaks can be identified before significant emission to the environment has occurred. The potential for environmental impact is likely to be greater from a once through system. Planned maintenance can help to avoid such occurrences; • water used for cleaning can be reduced by a number of techniques, e.g. by spray cleaning rather than whole vessel filling, strip process liquor and treat, if necessary, then recycle/reuse;	The measures described in this BAT requirement will be ensured where possible to minimise water use and emissions to water from the site and its processes.

	• use wet air oxidation for low volumes of aqueous effluent with high levels of organic content, such as waste streams from condensers and scrubbers; • neutralise waste streams containing acids or alkalis to achieve the required pH for the receiving water; • strip chlorinated hydrocarbons in waste streams with air or steam and recycle by returning to process where possible; • recover co-products for re-use or sale; • periodically regenerate ion exchange columns; • pass wastewater containing solids through settling tanks, prior to disposal; • treat waste waters containing chlorinated hydrocarbons separately where possible to ensure proper control and treatment of the chlorinated compounds. Contain released volatile chlorinated hydrocarbons and vent to suitably designed incineration equipment; • non-biodegradable organic material can be treated by thermal incineration. However, the thermal destruction of mixed liquids can be highly inefficient, and the waste should be dewatered prior to incineration.	
52	Use the following measures to minimise emissions to land: • use settling ponds to separate out sludge (Note: Sludge can be disposed of to an incinerator, encapsulation, land, or lagoon depending upon its make up.); • chlorinated residues should be incinerated and not released to land. (Chlorinated hydrocarbons are not to be released to the environment due to their high global warming and ozone depletion potentials.);	N/A – no emissions to land are proposed as part of this permit variation

	• either recycle off spec product into the process or blend to make lower grade products where possible; • many catalysts are based on precious metals, and these should be recovered, usually by return to the supplier.	
3.2 Fugitive Emissions		
53	Identify all potential sources and develop and maintain procedures for monitoring and eliminating or minimising leaks and releases of VOCs from all non-process stream sources.	N/A - there are no fugitive emissions for the existing and proposed activities on site. The only VOC emissions released on site arise from the dispensing booth and these are treated by use of a filter (Emission Point A11). The extent of VOC release on site is minimal.
54	Choose vent systems to minimise breathing emissions (for example pressure/ vacuum valves) and, where relevant, should be fitted with knock-out pots and appropriate abatement equipment.	N/A - there are no fugitive emissions for the existing and proposed activities on site.
55	Use the following techniques (together or in any combination) to reduce losses from storage tanks at atmospheric pressure: • maintenance of bulk storage temperatures as low as practicable, considering changes due to solar heating etc.; • tank paint with low solar absorbency; • temperature control; • tank insulation; • inventory management; • floating roof tanks; • bladder roof tanks; • pressure/vacuum valves, where tanks are designed to withstand pressure fluctuations; • specific release treatment (such as adsorption condensation).	Tanks are designed appropriately to reduce losses from storage tanks at atmospheric pressure. This includes effective inventory management.

Fugitive emissions to surface water, sewer, and groundwater

56	Provide hard surfacing in areas where accidental spillage or leakage may occur, e.g. beneath prime movers, pumps, in storage areas, and in handling, loading, and unloading areas. The surfacing should be impermeable to process liquors.	All surfaces within the existing and proposed production plant and yards are constructed of impermeable hardstanding to prevent pollution to ground or water in the event of accidental spills or leakages. The hardstanding on site is well maintained and free of holes or cracks that may allow the accidental release of chemicals offsite. The hardstanding will be repaired if damage is sustained as to prevent any accidental release offsite.
57	Drain hard surfacing of areas subject to potential contamination so that potentially contaminated surface run-off does not discharge to ground. pollution. Poorly maintained drainage systems are known to be the main cause of groundwater contamination and surface/above-ground drains are preferred to facilitate leak detection (and to reduce explosion risks).	Where potential contamination exists on hardstanding surfaces, the area will be cleaned appropriately using spill kits or pumps if necessary, and the resultant waste material or contaminated substances will be disposed of appropriately offsite. Large scale contamination of hard standing areas is not expected to be a concern during normal operation.
58	Hold stocks of suitable absorbents at appropriate locations for use in mopping up minor leaks and spills and dispose of to leak-proof containers.	Stocks of appropriate absorbents will be held at strategic locations across the site to effectively manage the clean-up of minor leaks and spills. All spent absorbent material will be disposed of in a suitable manner and stored in leak-proof containers whilst on site.
59	Take particular care in areas of inherent sensitivity to groundwater pollution. Poorly maintained drainage systems are known to be the main cause of groundwater contamination and surface/above-ground drains are preferred to facilitate leak detection (and to reduce explosion risks).	The drainage systems are maintained carefully to ensure there is no groundwater contamination on site.
60	Additional measures could be justified in locations of particular environmental sensitivity. Decisions on the measures to be taken should take account of the risk to groundwater, taking into consideration the factors outlined in the Agency document, Policy and Practice for the Protection of Groundwater, including groundwater vulnerability and the presence of groundwater protection zones.	No additional measures, other than those described in this assessment, have currently been proposed given the minimal risk to groundwater from onsite activities due to the site protection measures.

61	Surveys of plant that may continue to contribute to leakage should also be considered, as part of an overall environmental management system. In particular, you should consider undertaking leakage tests and/or integrity surveys to confirm the containment of underground drains and tanks.	Surveys will be undertaken of plant and equipment that may contribute to leakages, including the onsite drainage system, periodically.
3.3 Odour		
62	Manage the operations to always prevent release of odour.	Operations have been designed to always manage odour. The fully enclosed processing activities and the nature of the activities on site means there is little potential for offsite odour emissions.
63	Where odour releases are expected to be acknowledged in the permit, (i.e. contained and treated prior to discharge or discharged for atmospheric dispersion): • for existing installations, the releases should be modelled to demonstrate the odour impact at sensitive receptors. The target should be to minimise the frequency of exposure to ground level concentrations that are likely to cause annoyance; • for new installations, or for significant changes, the releases should be modelled, and it is expected that you will achieve the highest level of protection that is achievable with BAT from the outset; • where there is no history of odour problems then modelling may not be required although it should be remembered that there can still be an underlying level of annoyance without complaints being made; • where, despite all reasonable steps in the design of the plant, extreme weather or other incidents are liable, in our view, to increase the odour impact at receptors, you should take appropriate and timely action, as agreed with us, to prevent further annoyance (these agreed actions will be defined either in the permit or in an odour management statement).	N/A – there are no odour released from site.

64	Where odour generating activities take place in the open, or potentially odorous materials are stored outside, a high level of management control and use of best practice will be expected.	No odour generating activities take place in the open. The site has been designed to fully enclose its processing activities to prevent any odour impacts offsite.
65	Where an installation releases odours but has a low environmental impact by virtue of its remoteness from sensitive receptors, it is expected that you will work towards achieving the standards described in this guidance note, but the timescales allowed to achieve this might be adjusted according to the perceived risk.	N/A – due to the design of the site, the fully enclosed processing activities and the nature of the operations carried out on site, there is very little potential for offsite odour emissions and impacts to arise from the site. In addition, the site is in an industrial area and has no history of any odour complaints.
66	Where further guidance is needed to meet local needs, refer to Horizontal Guidance Note H4 Odour (see GTBR).	Horizontal Guidance Note H4 will be referred to if further guidance is required to meet local needs, however this is considered unlikely.
3.4 Noise and Vibration		
67	Install particularly noisy machines such as compactors and pelletisers in a noise control booth or encapsulate the noise source.	All processing activities take place within fully enclosed buildings and are inherently quiet in their operation. The site is in an industrial area and has no history of any noise complaints. The site does not operate particularly noisy equipment such as compactors or pelletisers.
68	Where possible without compromising safety, fit suitable silencers on safety valves	Given the low-noise equipment used on site, the use of silencers of safety valves is not deemed necessary.
69	Minimise the blow-off from boilers and air compressors, for example during start up, and provide silencers.	The existing boiler plant is being replaced by newer plant, which is designed to be low in noise emissions.
3.5 Monitoring and Reporting of Emissions to Air and Water		
70	Carry out an analysis covering a broad spectrum of substances to establish that all relevant substances have been considered when setting the release limits. The need to repeat such a test will depend upon the potential variability in the process and, for example, the potential for contamination of raw materials. Where there is such potential, tests may be appropriate.	All releases, monitoring and reporting will be carried out in line with environmental permit. Any additional monitoring required will be carried out if requested by the Environment Agency.

71	Monitor more regularly any substances found to be of concern, or any other individual substances to which the local environment may be susceptible and upon which the operations may impact. This would particularly apply to the common pesticides and heavy metals. Using composite samples is the technique most likely to be appropriate where the concentration does not vary excessively.	At present, the proposed monitoring of substances is as follows: • Monitoring of the existing and new boiler plant will be carried out in accordance with the Medium Combustion Plant Directive. This will involve monitoring for oxides of nitrogen from A1 and A8 annually, and from A12 and A13 every 3 years. • Monitoring of emissions to water will be carried out as per the existing permit, where W1 is monitored for flow, pH, suspended solids, cod, and ammoniacal nitrogen. If the EA deem that more frequent monitoring of any substance found to be of concern, the site will increase monitoring frequency of those substances until such a time where it is no longer required.
72	If there are releases of substances that are more difficult to measure and whose capacity for harm is uncertain, particularly when combined with other substances, then "whole effluent toxicity" monitoring techniques can be appropriate to provide direct measurements of harm, for example, direct toxicity assessment.	N/A – all substances identified are easy to measure and will be done so in line with the permit.
Monitoring and reporting of waste emissions		
73	Monitor and record: • the physical and chemical composition of the waste; • its hazard characteristics; and • handling precautions and substances with which it cannot be mixed.	All details described in this requirement will be monitored and recorded.
Environmental monitoring (beyond installation)		
74	Consider the following in drawing up proposals: • determinants to be monitored, standard reference methods, sampling protocols.	All environmental monitoring will be carried out in line with the Environment Agency requirements.

	• monitoring strategy, selection of monitoring points, optimisation of monitoring approach. • determination of background levels contributed by other sources. • uncertainty for the employed methodologies and the resultant overall uncertainty of measurement. • quality assurance (QA) and quality control (QC) protocols, equipment calibration and maintenance, sample storage, and chain of custody/audit trail. • reporting procedures, data storage, interpretation, and review of results, reporting format for the provision of information.		

7. IMPACT TO THE ENVIRONMENT

7.1 Impacts to Air – Boiler Plant

An assessment has been carried out to determine the air quality impacts associated with the sites existing boiling plant and the new upgraded boiler plant.

The scope of the assessment has been determined in the following way:

- review of air quality data for the area surrounding the site, including data from the Defra Air Quality Information Resource (UK-AIR);
- desk study to confirm the location of nearby areas that may be sensitive to changes in local air quality; and
- review and modelling of emissions data which has been used as an input to the UK Atmospheric Dispersion Modelling System (ADMS).

The assessment comprises a review of emission parameters for the existing and new boiler plant and dispersion modelling to predict ground-level concentrations of pollutants at sensitive human and habitat receptor locations. Predicted concentrations are compared with relevant air quality assessment levels for the protection of health and critical levels/ loads for the protection of sensitive ecosystems and vegetation.

The modelling is provided in *Annex F – Air Quality Assessment.*

Sensitive Human Health Receptors

Specific receptors have been identified where people are likely to be regularly exposed for prolonged periods of time (e.g. residential areas). The location of the discrete sensitive receptors is presented in Table 7.1 below.

Table 7.1 – Sensitive Human Health Receptors

Ref.	Receptor	Type	Easting	Northing
R1	School	Education	450968	433368
R2	Central Avenue	Residential	450994	433215
R3	School	Education	452100	432936
R4	Weardale Crescent	Residential	452248	433619
R5	Cricket Pavilion	Leisure	453045	433465
R6	Monksfield	Residential	452867	433730
R7	Rawlinson Avenue	Residential	451650	433678
R8	Bowling Club	Leisure	450971	433718
R9	Sports Ground	Leisure	450803	433713
R10	Greenwood Road	Residential	450458	433717
R11	Cafe Technology Park	Commercial	450423	433514
R12	Hereford Terrace	Residential	450415	433409

The report concludes that the predicted annual mean and hourly mean NO_2 concentrations are well below the relevant AQAL at all the nearby sensitive receptors and the impact of the proposed new boilers on annual mean concentrations is considered to be not significant, in accordance with the Environment Agency Risk Assessment Guidance.

Please refer to *Annex F – Air Quality Assessment* for more information.

Impacts on Sensitive Habitat Sites

The Environment Agency's risk assessment guidance [2] states that the impact of emissions to air on vegetation and ecosystems should be assessed for the following habitat sites within 10 km of the source:

- Special Areas of Conservation (SACs) and candidate SACs (cSACs) designated under the EC Habitats Directive[3];
- Special Protection Areas (SPAs) and potential SPAs designated under the EC Birds Directive[4]; and
- Ramsar Sites designated under the Convention on Wetlands of International Importance[5].

Within 2 km of the source:

- Sites of Special Scientific Interest (SSSI) established by the 1981 Wildlife and Countryside Act;
- National Nature Reserves (NNR);
- Local Nature Reserves (LNR);
- local wildlife sites (Sites of Interest for Nature Conservation, SINC and Sites of Local Interest for Nature Conservation, SLINC); and
- Ancient woodland.

The location of the local habitat sites is presented in Table 7.2 below.

Table 7.2 – Habitat Sites

Receptor	Sensitive Habitat
H1. Teesmouth & Cleveland Coast SPA and SSSI	Coastal dune grasslands (grey dunes) and calcareous grassland
H2. Teesmouth & Cleveland Coast SPA, SSSI and proposed Ramsar site	Coastal dune grasslands (grey dunes) and calcareous grassland

The report concludes that the impact of emissions on habitats was assessed as not significant when compared with existing background conditions and relevant critical levels and critical loads.

Please refer to *Annex F – Air Quality Assessment* for more information.

2 https://www.gov.uk/guidance/air-emissions-risk-assessment-for-your-environmental-permit

3 Council Directive 92/43/EEC on the conservation of natural habitats and of wild fauna and flora.

4 Council Directive 79/409/EEC on the conservation of wild birds

5 Ramsar (1971), The Convention of Wetlands of International Importance especially as Waterfowl Habitat.

7.2 Impacts to Air – Emission Point A11

An H1 screening assessment has been carried out on Emission Point A11 which is in relation to a chemical dispensing booth.

The principal VOC emissions from the dispensing booth include acetone, acetonitrile, ethanol, and methanol. The booth is generally only used for the dispensing of these chemicals (i.e. there is minimal mixing of chemicals) and there are no chemical reactions taking place and emissions would be from evaporation processes from these liquids. Therefore, it is expected that VOC emissions of acetone, acetonitrile, ethanol, and methanol would take place. The quantities dispensed vary but 2025 data indicate that the following quantities were dispensed:

- Acetonitrile – 2,560 litres/annum;
- Acetone – 66 litres/annum;
- Ethanol - 2,328 litres/annum; and
- Methanol – 56 litres/annum.

Based on 2025 operational data, the dispensing booth is estimated to operate for around 3,500 hour per annum (40% of the time).

The quantities utilised are very small and emission to air from the dispensing booth are likely to be low. The dispensing booth is fitted with a three-stage high efficiency filtration system that includes:

- Pre-pad filters located behind removable grilles;
- Fine dust filters (G4 and F8) which are 95% efficient also located behind removable exhaust grilles; and
- HEPA filters (H14) which are 99.995% efficient.

The report concludes that the H1 screening indicates that long-term impacts can be screened out as predicted concentrations (PC) are less than 1% of the EALs or the PECs are less than 70% of the EAL. The H1 screening indicates that short-term impacts can be screened out as predicted concentrations (PC) are less than 10% of the EALs or the PCs are less than 20% of the difference between the EAL and background concentrations.

Please refer to *Annex G – H1 Screening Assessment* for more information.

7.3 Impacts to Controlled Water

There will be no impacts to controlled water because of this permit variation.

Emission Point W1 will remain as currently permitted.

7.4 Impacts to Sewer

As part of this permit variation, there will be two new discharges to sewer (Emission Point S1 and S2). Due to this, an H1 Emissions to Water assessment has been carried out as part of this variation.

An applicant is required to evaluate and assess any hazardous chemicals and elements that are to be released into surface water. Screening tests must then be carried out on the pollutants to assess if they are

a risk to the environment. This is called a specific substances assessment. There are three stages to the screening:

- Identify Pollutants;
- Gather data on the pollutants; and
- Carry out a screening test.

The assessment has been undertaken using the current H1 assessment tool (Version 2.7.8 – January 2017). The updated H1 Assessment Tool v9.2 has been issued but the water impact assessment modules remain under maintenance.

The results of the screening assessment demonstrate that the indirect discharges (via the sewer) do not pose a significant risk of EQS exceedance in the receiving water body and therefore have passed the H1 assessment.

Please refer to *Annex D – H1 Assessment* for more information and a copy of the full assessment.

In addition to this a Nutrient Neutrality Assessment has been completed which provides background information on the requirement for nutrient neutrality, a description of the proposed operations regarding discharges of nitrogen and an assessment of nutrient neutrality.

Please refer to *Annex E – Nutrient Neutrality Assessment* for more information.

7.5 Impacts to Land

There are no impacts to land relating to the Installation.