11th March 2026

Environment Agency

By Email

Our Ref: RMA/LC2919_2 - Fujifilm Stockton on Tees S1 NNA

Dear Sir/Madam,

RE: FUJIFILM DIOSYNTH BIOTECHNOLOGIES UK LIMITED, CHILTON LIFESCIENCES EA/EPR/BJ8987IQ, BELASIS AVENUE, CLEVELAND, TS23 1LH - NUTRIENT NEUTRALITY ASSESSMENT FOR PROJECT BOREALIS

RMA Environmental were commissioned to assess the potential effects of a proposed variation to the existing Environmental Permit at the Fuljifilm site in Stockton-on-Tees with specific regard to nutrient neutrality in response to a request by the Environment Agency (EA).

This Nutrient Neutrality Assessment provides background information on the requirement for nutrient neutrality, a description of the proposed operations with regard to discharges of nitrogen and an assessment of nutrient neutrality for the permit variation.

This report should be read in conjunction with the Surface Water Risk Assessment report prepared by Sol Environment which provides a more detailed description of the operations and the existing and proposed discharge arrangements for the site.

Background

The requirement for nutrient neutrality within the River Tees catchment arises from statutory advice issued by Natural England, following evidence that the Teesmouth and Cleveland Coast Special Protection Area (SPA) is in an unfavourable condition due to nutrient enrichment, particularly from excess nitrogen entering the river system. This nutrient pollution poses a risk to sensitive habitats and protected species, placing a legal duty on planning authorities to ensure that new development does not worsen nitrogen levels in the catchment.

While much of the national focus on nutrient neutrality has been on residential development, industrial activities also fall within the scope where they involve processes that discharge nitrogen or otherwise contribute to nutrient loads. Local authorities have clarified that while most industrial development is ordinarily out of scope, industrial proposals that involve specific nitrogen-releasing processes must demonstrate nutrient neutrality before consents can be granted.

Nutrient neutrality means ensuring that the amount of nitrogen discharged after industrial development is no greater than the baseline level before development occurs. This is to prevent further deterioration of the River Tees and associated protected coastal habitats. Where industrial discharges would increase nutrient inputs, mitigation must be secured, either onsite, offsite or through participation in Natural England's Nutrient Mitigation Scheme (or similar), which enables operators to purchase credits that offset their nutrient impact. The scheme is designed to ensure that development can proceed without compromising ecological protection objectives.

Existing Process Description

Fujifilm Diosynth Biotechnologies UK Limited operates a manufacturing site at the northern boundary of the Billingham site grid reference NZ 466 226. The Billingham site comprises several installations within a site boundary, each operated by a different company.

The site comprises manufacturing, office and laboratory areas (not included within the installation) and is within a predominantly industrial area on the north bank of the River Tees.

The 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 products or are included in pharmaceutical products (such as tablets).

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 preconditioned 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. Once harvested, the product is further purified in some cases by washing and then spray dried before packaging. Products are held in chilled storage before dispatch.

Proposed Variation

Project Borealis involves the construction and operation of a new 26,800 m^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 generators. This project introduces new discharges to foul sewer (referred to as S1; discussed further below). All foul discharges are to combined sewer.

Discussion of S1 Discharge

In line with the other permitted activities, the wastewater generated within the facility will follow one of two paths:

- Washings – subject to pH neutralisation and then discharge to drain and sewer (S1); and

- Aqueous effluent - this can be high in ammonia, have a high COD and/or require a kill cycle (where necessary). In all cases, the effluent stream is subject to on-site treatment, storage and disposal.

Nutrient Neutrality Assessment

Project Borealis will comprise of five lines which would discharge a maximum of 350.25 g/week of NH_4-N as set out in the data provided by the client in Appendix A.

The calculations in Table 1 (below) convert this to an annual loading of NH_4-N in the discharge to Bran Sands wastewater treatment works (WwTW) and then applies a treatment reduction factor (taken from the EA's Sewage Treatment Reduction Factor (STRF) data for Total Nitrogen) to estimate the nitrogen budget from the S1 process at the point of discharge from the WwTW.

The Teesmouth & Cleveland Coast Special Protection Area/Ramsar nutrient budget calculator cannot be run for industrial discharges. The calculations below are therefore bespoke to the proposed process variation but have adopted the 20% precautionary buffer used in the calculator to account for uncertainties in the input data.

Table 1: Nutrient Budget Calculations for S1

Item	Value	Units
NH_4-N budget per S1 line	350.25	g/week
	18.213	kg/year
NH_4-N budget for 5 lines	91.065	kg/year
NH_4-N at discharge into WwTW	91.065	kg/year
Sewage Treatment Reduction Factor	52%	
NH_4-N budget after WwTW	43.711	kg/year
Precautionary buffer (20%)	8.742	kg/year
Total NH_4-N Budget	**52.453**	**kg/year**

The calculations in Table 1 show that the NH_4-N budget for the five S1 lines is 91.065 kg/year of which 52% would be removed in the Bran Sands WwTW in accordance with the EA's sewage treatment reduction factor of 52% for total nitrogen. Therefore, after treatment, the S1 discharge would give rise to an NH_4-N budget of 43.711 kg/year and a final budget (after application of the 20% precautionary buffer) of **52.453 kg/year**.

It should be noted that a precautionary approach has been adopted in the above calculations and the estimated NH_4-N budget is therefore considered to be a maximum value.

Nutrient Mitigation

Nutrient offsetting for Project Borealis will be achieved by the purchase of 52.453 kg/year of nitrogen credit from an approved nutrient credit scheme in the River Tees SPA/Ramsar catchment either via the Natural England or a private credit provider. Nutrient credits would need to be purchased prior to operation of the Project Borealis process.

Summary & Conclusions

The NH_4-N budget for Project Borealis, including the 20% precautionary buffer, is estimated as **52.453 kg/year**. Therefore, the proposed process would give rise to a nitrogen surplus and mitigation is required to achieve nutrient neutrality.

It is proposed that the operator will purchase 52.453 kg/year of nitrogen credits from a registered credit supplier to ensure that the development achieves nutrient neutrality. Nutrient credits would be purchased from a Natural England approved nutrient credit scheme prior to operation of the Project Borealis process.

With the above mitigation in place, the nitrogen budget arising from the proposed process would be offset and therefore there would be no adverse effects on the River Tees SPA/Ramsar site.

Please do not hesitate to contact me if you have any questions or need any additional information.

Yours sincerely

Rob Murdock
Director

Encs: Appendix A: NH_4-N Data for the S1 Discharge (Source: Fujifilm)

Appendix A:
NH_4-N Data for the S1 Discharge

Assumptions:

No inorganic nitrate and nitrite supplied and only very low amout can be produced as a byproduct in the bioproceesing operation. Detremental to cell viability.
Ammonia content less than 5mM average in the bioreactor over 14 days. Detremental to cell viability.
Total Organic Nitrogen in the process is aminoacid and protein, including producuct and cell component.

Total NH4-N	mM	mg/L	5K SUB (g /week)
	5mM	70	350

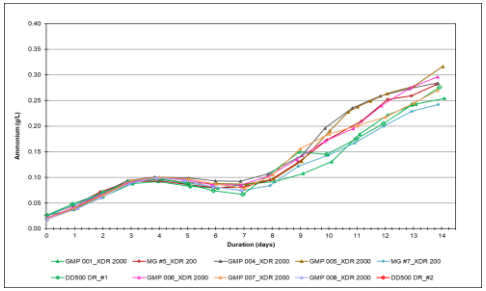

Table 1 Media composition

	Total amino acid conc (mM)	Note
Basal	52.3	
FeedA	698	Typical feeding amount: 2%
FeedB	461	Typical feeding amount: 0.2%l

At the end of the bioreactor run we are at ~ 24% Feed A, ~2.4% Feed B and ~73.6% basal

Table 2 Nitrogen calculation

Media	Total AA (mM)	End of 14 days composition (%)	1L AA composition (mM)	N (mM)	N (g/L)	5K (N kg)
Basal	52.3	73.6	38.5	57.7	0.81	4.04
Feed A	698	24	167.5	251.3	3.52	17.59
Feed B	461	2.4	11.1	16.6	0.23	1.16
		Sum	217.1	325.6	**4.56**	22.79

L	kg	
5000	22.79	N/5000L

Table 3 mAb N content
5K SUB 5g/L

mAb (M)	kg	N (kg)
1	150	18.2
0.17	25	3.03

Table 4

Sk Bioreactor	kg	kg (75% DSP yield)			
All N (basal + feed)	22.79				
N in the product (5g/L)	3.03	0.8	25% waste in DSP unitops		
N in the media (basal)	4.04		ProA waste		
N in biomass (CHO)	15.72		Solid waste Depth filtration		

Table 5 Total N kg waste successful 5k SUB

	N (kg)
Solid:	15.72
Liquid:	4.80
Sum	20.52

Table 6 Total N kg waste unssuccessful 5000L SUB end of 14 days

	N (kg)
Solid + liquid	22.79

Table 7 N/AA ratio in media

	Nirogen
Arg	4
His	3
Lys	2
Asp	1
Glu	1
ser	1
Thr	1
Asn	3
Gln	2
Cys	1
Gly	1
Pro	1
Ala	1
Ile	1
Leu	1
Met	1
Phe	1
Trp	2
Tyr	1
Val	1
Avarage	**1.5**

Table 8 N / AA ratio in mAb

	mab 1	N
Arg	14	56
His	13	39
Lys	49	98
Asp	23	23
Glu	31	31
ser	88	88
Thr	55	55
Asn	26	78
Gln	30	60
Cys	16	16
Gly	44	44
Pro	48	48
Ala	40	40
Ile	14	14
Leu	45	45
Met	6	6
Phe	20	20
Trp	13	26
Tyr	31	31
Val	58	58
Sum	**664**	**876**
	average	**1.3**

5g/L

1M mAb = 150kg

2000/

ammonia content:

mM	g NH3	max 5mM NH3-N (g)	MW 17.03 (NH4+) 5000L sum
1000	17.03	14.01	70050
5	0.085	0.070	350.25
15	0.25545		