

Notice of variation and consolidation with introductory note

The Environmental Permitting (England & Wales) Regulations 2010

Lonza Biologics Plc

Slough Biopharmaceuticals Plant
228 Bath Road
Slough
Berkshire
SL1 4DX

Variation application number

EPR/YP3437SP/V004

Permit number

EPR/YP3437SP

Slough Biopharmaceuticals Plant

Permit number EPR/YP3437SP

Introductory note

This introductory note does not form a part of the notice.

Under the Environmental Permitting (England & Wales) Regulations 2010 (schedule 5, part 1, paragraph 19) a variation may comprise a consolidated permit reflecting the variations and a notice specifying the variations included in that consolidated permit.

Schedule 1 of the notice specifies the conditions that have been varied and schedule 2 comprises a consolidated permit which reflects the variations being made. All the conditions of the permit have been varied and are subject to the right of appeal.

This variation is to extend the installation boundary to include new warehousing and storage areas incorporating laboratory facilities and storage for packaging, raw materials, finished materials and waste. Dispensing booths and a raw material sampling area will also be moved from the current permitted area to the new warehouse.

The installation manufactures active pharmaceutical ingredients by batch processing, to the requirements of current Good Manufacturing Practice (cGMP), and is located in an industrial area, with this site extending to an area of around 0.7Ha. The installation comprises the industrial unit known as 228 Bath Road and a pilot plant in the industrial unit known as 224 Bath Road, plus part of warehouse building 640 and some waste storage to the rear of the buildings.

To the north of the installation is a storage and distribution unit; to the south is an access road, beyond which lies a filling station, then light industrial units. Housing lies approximately 200m to the south of the site. East and west of the installation are industrial units used as offices and manufacturing sites.

The process operated in the installation is for the production of pharmaceutical materials for sale to other pharmaceutical companies. This includes a fermentation plant together with associated gas storage and supply facilities. Other activities at the installation include the operation of a gas-fired steam-raising boiler plant of thermal input <1MW, nitrogen refrigeration plant for provision of cooling medium, purification of town's water by ion-exchange and distillation, waste storage, prior to off site recycling or disposal and operation of stand-by diesel-fired generator

Within the installation are environmentally controlled areas where manufacturing takes place, with the process being split into three parts:

- Inoculum – cells are taken from frozen cell banks, thawed and incubated until the cell cultures are sufficient to inoculate the fermenters.
- Fermentation – after inoculation with the cell cultures, temperature and pH controlled fermentation takes place, with the cultures growing to produce the desired products. The product may be microbial, enzymes, proteins, cells or metabolites, as required to meet the requirements of the customer.
- Purification – after fermentation purification is undertaken to separate the product from growth media, cell debris etc, with the purification consisting of several steps. These steps, which depend on the product under manufacture, may include column chromatography, filtration and concentration. Following final purification the product is packaged into small containers for dispatch to the customer.

Total production on the site is around 150 kgs per annum, but the quantity of aqueous waste produced (>50m³/day), use of active abatement systems, presence of soakaways and energy consumption (>3MW) prevent the installation being classified as a Low Impact Installation.

Emissions to air occur from the production process, which takes place in rooms that are extracted to atmosphere through combined emission points. Other emissions to air occur from fume cupboards associated with the quality control aspects of the installation, and also from a small boiler. Emissions to

sewer take place through the use of floor drains within the installation, and also from surface drainage of outside areas. Cleaning of equipment, and product purification generate large quantities of effluent for release to sewer after treatment with disinfectant. Roof drains from the installation, along with some non-operational surface waters, drain to six soakaways located at the installation.

Water treatment takes place within the installation, and there are also supplies of cryogenic nitrogen and oxygen for use in the site. Bulk storage facilities of up to 2000 litres of sodium hydroxide are also provided, and wastes are stored in dedicated containers in various parts of the site.

The installation has no history of odour or noise complaints in the past, and there are no sensitive receptors close by. There are no SSSIs within 2 Km of the installation, but there are several SACs and SPAs within 10Km as listed below:

- Burnham Beeches SAC – 3.7Km from installation
- Windsor Forest & Great Park SAC – 5.2Km from installation
- South West London Waterbodies SPA – 6.9Km from installation
- South West London Waterbodies Ramsar site – 6.9Km from installation
- Wraysbury & Hythe End Gravel Pits SPA – 8.2Km from installation
- Wraysbury Reservoir SPA – 8.4Km from installation

The impact of the installation on these habitats sites has been assessed in an Appendix 11 assessment, which shows that there is no likely significant effect on these sites.

The site operates an EMS, which is not accredited to ISO14001 or EMAS, but is subject to external audit through a third party audit programme with a published methodology.

The schedules specify the changes made to the permit.

The status log of a permit sets out the permitting history, including any changes to the permit reference number.

Status log of the permit		
Description	Date	Comments
Application	Duly made 25/04/06	
Additional information received	27/09/06	Confirmation of site boundary.
Permit determined EPR/YP3437SP	02/10/06	Original Permit issued to Lonza Biologics Plc
Part surrender application EPR/YP3437SP/S002	Duly made 17/08/11	Application to surrender the land behind Buildings 228 and 224
Additional information received	18/08/11	Revised site plan of reduced area with boundary in green
Part surrender determined EPR/YP3437SP/S002	19/09/11	Part surrender complete
Variation application EPR/YP3437SP/V003	Duly made 17/08/11	Application to vary permit to increase permitted area to include pilot plant.
Additional information received	18/08/11 19/08/11 02/09/11 12/09/11	Revised site plan
Variation determined EPR/YP3437SP/V003	20/09/11	Varied permit issued.
Variation application EPR/YP3437SP/V004	Duly made 01/02/17	Application to increase installation boundary to include warehousing and materials storage areas

Status log of the permit		
Description	Date	Comments
Additional information received	15/02/17	Revised site plan 228/1/0632 Rev7
Variation determined EPR/YP3437SP/V004 Billing Ref: NP3030DP	03/03/17	

End of introductory note

Notice of variation and consolidation

The Environmental Permitting (England and Wales) Regulations 2010

The Environment Agency in exercise of its powers under regulation 20 of the Environmental Permitting (England and Wales) Regulations 2010 varies and consolidates

Permit number

EPR/YP3437SP

Issued to

Lonza Biologics Plc (“the operator”)

whose registered office is

228 Bath Road

Slough

Berkshire

SL1 4DX

company registration number 2742471

to operate a regulated facility at

Slough Biopharmaceuticals Plant

228 Bath Road

Slough

Berkshire

SL1 4DX

to the extent set out in the schedules.

The notice shall take effect from 03/03/2107

Name	Date
Philip Lamb	03/03/2017

Authorised on behalf of the Environment Agency

Schedule 1

All conditions have been varied by the consolidated permit as a result of the application made by the operator.

Schedule 2 – consolidated permit

Consolidated permit issued as a separate document.

Permit

The Environmental Permitting (England and Wales) Regulations 2010

Permit number

EPR/YP3437SP

This is the consolidated permit referred to in the variation and consolidation notice for application EPR/YP3437SP/V004 authorising,

Lonza Biologics Plc (“the operator”),

whose registered office is

228 Bath Road

Slough

Berkshire

SL1 4DX

company registration number 2742471

to operate an installation at

Slough Biopharmaceuticals Plant

228 Bath Road

Slough

Berkshire

SL1 4DX

to the extent authorised by and subject to the conditions of this permit.

Name	Date
Philip Lamb	03/03/2017

Authorised on behalf of the Environment Agency

Conditions

1 Management

1.1 General management

- 1.1.1 The operator shall manage and operate the activities:
- (a) in accordance with a written management system that identifies and minimises risks of pollution, including those arising from operations, maintenance, accidents, incidents, non-conformances, closure and those drawn to the attention of the operator as a result of complaints; and
 - (b) using sufficient competent persons and resources.
- 1.1.2 Records demonstrating compliance with condition 1.1.1 shall be maintained.
- 1.1.3 Any person having duties that are or may be affected by the matters set out in this permit shall have convenient access to a copy of it kept at or near the place where those duties are carried out.

1.2 Energy efficiency

- 1.2.1 The operator shall:
- (a) take appropriate measures to ensure that energy is used efficiently in the activities;
 - (b) review and record at least every four years whether there are suitable opportunities to improve the energy efficiency of the activities; and
 - (c) take any further appropriate measures identified by a review.

1.3 Efficient use of raw materials

- 1.3.1 The operator shall:
- (a) take appropriate measures to ensure that raw materials and water are used efficiently in the activities;
 - (b) maintain records of raw materials and water used in the activities;
 - (c) review and record at least every four years whether there are suitable alternative materials that could reduce environmental impact or opportunities to improve the efficiency of raw material and water use; and
 - (d) take any further appropriate measures identified by a review.

1.4 Avoidance, recovery and disposal of wastes produced by the activities

- 1.4.1 The operator shall take appropriate measures to ensure that:
- (a) the waste hierarchy referred to in Article 4 of the Waste Framework Directive is applied to the generation of waste by the activities; and
 - (b) any waste generated by the activities is treated in accordance with the waste hierarchy referred to in Article 4 of the Waste Framework Directive; and
 - (c) where disposal is necessary, this is undertaken in a manner which minimises its impact on the environment.

- 1.4.2 The operator shall review and record at least every four years whether changes to those measures should be made and take any further appropriate measures identified by a review.

2 Operations

2.1 Permitted activities

- 2.1.1 The operator is only authorised to carry out the activities specified in schedule 1 table S1.1 (the “activities”).

2.2 The site

- 2.2.1 The activities shall not extend beyond the site, being the land shown edged in green on the site plan at schedule 7 to this permit.

2.3 Operating techniques

- 2.3.1 The activities shall, subject to the conditions of this permit, be operated using the techniques and in the manner described in the documentation specified in schedule 1, table S1.2, unless otherwise agreed in writing by the Environment Agency.
- 2.3.2 If notified by the Environment Agency that the activities are giving rise to pollution, the operator shall submit to the Environment Agency for approval within the period specified, a revision of any plan or other documentation (“plan”) specified in schedule 1, table S1.2 or otherwise required under this permit which identifies and minimises the risks of pollution relevant to that plan, and shall implement the approved revised plan in place of the original from the date of approval, unless otherwise agreed in writing by the Environment Agency.
- 2.3.3 Any raw materials or fuels listed in schedule 2 table S2.1 shall conform to the specifications set out in that table.
- 2.3.4 The operator shall ensure that where waste produced by the activities is sent to a relevant waste operation, that operation is provided with the following information, prior to the receipt of the waste:
- (a) the nature of the process producing the waste;
 - (b) the composition of the waste;
 - (c) the handling requirements of the waste;
 - (d) the hazardous property associated with the waste, if applicable; and
 - (e) the waste code of the waste.

2.4 Improvement programme

- 2.4.1 The operator shall complete the improvements specified in schedule 1 table S1.3 by the date specified in that table unless otherwise agreed in writing by the Environment Agency.
- 2.4.2 Except in the case of an improvement which consists only of a submission to the Environment Agency, the operator shall notify the Environment Agency within 14 days of completion of each improvement.

3 Emissions and monitoring

3.1 Emissions to water, air or land

- 3.1.1 There shall be no point source emissions to water, air or land except from the sources and emission points listed in schedule 3 tables S3.1 and S3.2.
- 3.1.2 The limits given in schedule 3 shall not be exceeded.
- 3.1.3 Periodic monitoring shall be carried out at least once every 5 years for groundwater and 10 years for soil, unless such monitoring is based on a systematic appraisal of the risk of contamination.

3.2 Emissions of substances not controlled by emission limits

- 3.2.1 Emissions of substances not controlled by emission limits (excluding odour) shall not cause pollution. The operator shall not be taken to have breached this condition if appropriate measures, including, but not limited to, those specified in any approved emissions management plan, have been taken to prevent or where that is not practicable, to minimise, those emissions.
- 3.2.2 All liquids in containers, whose emission to water or land could cause pollution, shall be provided with secondary containment, unless the operator has used other appropriate measures to prevent or where that is not practicable, to minimise, leakage and spillage from the primary container.

3.3 Odour

- 3.3.1 Emissions from the activities shall be free from odour at levels likely to cause pollution outside the site, as perceived by an authorised officer of the Environment Agency, unless the operator has used appropriate measures, including, but not limited to, those specified in any approved odour management plan, to prevent or where that is not practicable to minimise the odour.
- 3.3.2 The operator shall:
 - (a) if notified by the Environment Agency that the activities are giving rise to pollution outside the site due to odour, submit to the Environment Agency for approval within the period specified, an odour management plan which identifies and minimises the risks of pollution from odour;
 - (b) implement the approved odour management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.

3.4 Noise and vibration

- 3.4.1 Emissions from the activities shall be free from noise and vibration at levels likely to cause pollution outside the site, as perceived by an authorised officer of the Environment Agency, unless the operator has used appropriate measures, including, but not limited to, those specified in any approved noise and vibration management plan to prevent or where that is not practicable to minimise the noise and vibration.
- 3.4.2 The operator shall:
 - (a) if notified by the Environment Agency that the activities are giving rise to pollution outside the site due to noise and vibration, submit to the Environment Agency for approval within the period specified, a noise and vibration management plan which identifies and minimises the risks of pollution from noise and vibration;
 - (b) implement the approved noise and vibration management plan, from the date of approval, unless otherwise agreed in writing by the Environment Agency.

3.5 Monitoring

- 3.5.1 The operator shall, unless otherwise agreed in writing by the Environment Agency, undertake the monitoring specified in the following tables in schedule 3 to this permit:
- (a) point source emissions specified in table S3.2
- 3.5.2 The operator shall maintain records of all monitoring required by this permit including records of the taking and analysis of samples, instrument measurements (periodic and continual), calibrations, examinations, tests and surveys and any assessment or evaluation made on the basis of such data.
- 3.5.3 Monitoring equipment, techniques, personnel and organisations employed for the emissions monitoring programme and the environmental or other monitoring specified in condition 3.5.1 shall have either MCERTS certification or MCERTS accreditation (as appropriate), where available, unless otherwise agreed in writing by the Environment Agency.
- 3.5.4 Permanent means of access shall be provided to enable sampling/monitoring to be carried out in relation to the emission points specified in schedule 3 tables S3.1 and S3.2 unless otherwise agreed in writing by the Environment Agency.

4 Information

4.1 Records

- 4.1.1 All records required to be made by this permit shall:
- (a) be legible;
 - (b) be made as soon as reasonably practicable;
 - (c) if amended, be amended in such a way that the original and any subsequent amendments remain legible, or are capable of retrieval; and
 - (d) be retained, unless otherwise agreed in writing by the Environment Agency, for at least 6 years from the date when the records were made, or in the case of the following records until permit surrender:
 - (i) off-site environmental effects; and
 - (ii) matters which affect the condition of the land and groundwater.
- 4.1.2 Any records required to be made by this permit shall be supplied to the Environment Agency within 14 days where the records have been requested in writing by the Environment Agency.
- 4.1.3 The operator shall keep on site all records, plans and the management system required to be maintained by this permit, unless otherwise agreed in writing by the Environment Agency.

4.2 Reporting

- 4.2.1 The operator shall send all reports and notifications required by the permit to the Environment Agency using the contact details supplied in writing by the Environment Agency.
- 4.2.2 A report or reports on the performance of the activities over the previous year shall be submitted to the Environment Agency by 31 January (or other date agreed in writing by the Environment Agency) each year. The report(s) shall include as a minimum:
- (a) a review of the results of the monitoring and assessment carried out in accordance with the permit including an interpretive review of that data;
 - (b) where the operator's management system encompasses annual improvement targets, a summary report of the previous year's progress against such targets;
 - (c) the annual production /treatment data set out in schedule 4 table S4.2; and

- (d) the performance parameters set out in schedule 4 table S4.3 using the forms specified in table S4.4 of that schedule.
 - (e) details of any contamination or decontamination of the site which has occurred.
- 4.2.3 Within 28 days of the end of the reporting period the operator shall, unless otherwise agreed in writing by the Environment Agency, submit reports of the monitoring and assessment carried out in accordance with the conditions of this permit, as follows:
- (a) in respect of the parameters and emission points specified in schedule 4 table S4.1;
 - (b) for the reporting periods specified in schedule 4 table S4.1 and using the forms specified in schedule 4 table S4.4 ; and
 - (c) giving the information from such results and assessments as may be required by the forms specified in those tables.
- 4.2.4 The operator shall, unless notice under this condition has been served within the preceding four years, submit to the Environment Agency, within six months of receipt of a written notice, a report assessing whether there are other appropriate measures that could be taken to prevent, or where that is not practicable, to minimise pollution.

4.3 Notifications

- 4.3.1 In the event:
- (a) that the operation of the activities gives rise to an incident or accident which significantly affects or may significantly affect the environment, the operator must immediately—
 - (i) inform the Environment Agency,
 - (ii) take the measures necessary to limit the environmental consequences of such an incident or accident, and
 - (iii) take the measures necessary to prevent further possible incidents or accidents;
 - (b) of a breach of any permit condition the operator must immediately—
 - (i) inform the Environment Agency, and
 - (ii) take the measures necessary to ensure that compliance is restored within the shortest possible time;
 - (c) of a breach of permit condition which poses an immediate danger to human health or threatens to cause an immediate significant adverse effect on the environment, the operator must immediately suspend the operation of the activities or the relevant part of it until compliance with the permit conditions has been restored.
- 4.3.2 Any information provided under condition 4.3.1 shall be confirmed by sending the information listed in schedule 5 to this permit within the time period specified in that schedule.
- 4.3.3 Where the Environment Agency has requested in writing that it shall be notified when the operator is to undertake monitoring and/or spot sampling, the operator shall inform the Environment Agency when the relevant monitoring and/or spot sampling is to take place. The operator shall provide this information to the Environment Agency at least 14 days before the date the monitoring is to be undertaken.
- 4.3.4 The Environment Agency shall be notified within 14 days of the occurrence of the following matters, except where such disclosure is prohibited by Stock Exchange rules:
- Where the operator is a registered company:
- (a) any change in the operator's trading name, registered name or registered office address; and
 - (b) any change to particulars of the operator's ultimate holding company (including details of an ultimate holding company where an operator has become a subsidiary); and

- (c) any steps taken with a view to the operator going into administration, entering into a company voluntary arrangement or being wound up.
- 4.3.5 Where the operator proposes to make a change in the nature or functioning, or an extension of the activities, which may have consequences for the environment and the change is not otherwise the subject of an application for approval under the Regulations or this permit:
- (a) the Environment Agency shall be notified at least 14 days before making the change; and
 - (b) the notification shall contain a description of the proposed change in operation.
- 4.3.6 The Environment Agency shall be given at least 14 days notice before implementation of any part of the site closure plan.
- 4.3.7 Prior written notification shall be given to the Agency of the following events and in the specified timescales:
- (a) as soon as practicable prior to the permanent cessation of any of the activities;
 - (b) cessation of operation of part or all of the activities for a period likely to exceed 1 year; and
 - (c) resumption of the operation of part or all of the activities after a cessation notified under (b) above.

4.4 Interpretation

- 4.4.1 In this permit the expressions listed in schedule 6 shall have the meaning given in that schedule.
- 4.4.2 In this permit references to reports and notifications mean written reports and notifications, except where reference is made to notification being made “immediately”, in which case it may be provided by telephone.

Schedule 1 – Operations

Activity listed in Schedule 1 of the EP Regulations	Description of specified activity	Limits of specified activity
Section 4.5A(1)(a) Producing pharmaceutical products using a chemical or biological process.	Producing pharmaceutical products using a chemical or biological process including fermentation plant and associated gas storage and supply facilities.	From receipt of raw materials to dispatch of finished products
Directly Associated Activity		
Steam-raising boiler	Operation of boiler plant with a thermal capacity of less than 1MW on natural gas or fuel oil.	From receipt of natural gas or oil fuel to emissions from combustion process
Water purification	Purification of towns water by ion-exchange and distillation	From input of water to use within the installation (including boiler plant)
Storage of waste	Storage areas for interim storage of materials before disposal	Receipt of material from processing areas to despatch from site
Operation of stand-by diesel-fired generator	Emergency generation of electricity by combustion of diesel fuel.	From receipt of diesel fuel to emissions from combustion process

Table S1.2 Operating techniques		
Description	Parts	Date Received
Application YP3437SP	The response to section 2.1, excluding 2.1.3 and 2.1.5, and 2.2 in the Application.	31/03/06
Application EPR/YP3437/V003	The response to part C2, question 5b including site plans 224/9/0116 and 224/09/117	01/08/11
	The response to part C3, question 1 and 3a	01/08/11
	Additional information – revised site plan v3	05/09/11
Application EPR/YP3437SP/V004	Response to application form C2, question 2b including associated supporting information in document Lonza Variation 2015 dated 08/02/16.	01/02/17
	Revised Site plan 228/1/0632 Rev7	15/02/17

Table S1.3 Improvement programme requirements		
Reference	Requirement	Date
IC1	The operator shall develop written procedures for the review and control of raw materials within the installation, as specified in section 2.4.1 of Agency Guidance Note S4.02. The operator shall submit for the approval of the Agency a written summary of the procedure, including a timetable for review of materials used, and any changes or substitutions proposed along with a timetable for such changes or substitutions.	Complete
IC2	The operator shall carry out a review in writing of the continued use of soakaways in the installation. This review shall take into account the information contained in Agency Sector Guidance Note S4.02 and shall include a review of the management of firewater from the site.	Complete
IC3	The operator shall carry out a water resource usage audit across the installation, in accordance with section 2.4.3 of Agency Guidance Note S4.02. A written report shall be submitted for the approval of the Agency describing the methodology used, and including an action plan for improvements in water usage, along with a timetable for implementation of such improvements.	Complete
IC4	The operator shall report for the approval of the Agency in writing on progress against the improvements in energy efficiency following the report from the Carbon Trust. This report shall include a review of the proposed improvements, and the effect of implementation, along with any further improvements identified and a timetable for their implementation	Complete
IC5	The operator shall review their Environmental Management System against the requirements of section 2.3 of Agency Guidance Note S4.02. The Operator shall submit a proposed timetable of improvement/s, for any deficiencies identified, for the approval of the Agency	Complete
IC6	The operator shall report, in writing, for the approval of the Agency progress against each of the 27 proposed improvement conditions set out in section B9 of the Application	Complete

Schedule 2 – Waste types, raw materials and fuels

Table S2.1 Raw materials and fuels	
Raw materials and fuel description	Specification
-	-

Schedule 3 – Emissions and monitoring

Table S3.1 Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location	Source	Parameter	Limit (including unit)	Reference period	Monitoring frequency	Monitoring standard or method
A1 [Point A1 on site plan in Schedule 7]	Fermenter Hall Extract	No parameters set	-	-	-	Permanent sampling access not required
A2 [Point A2 on site plan in schedule 7]	Boiler Plant	No parameters set	-	-	-	Permanent sampling access not required

Table S3.2 Point source emissions to sewer, effluent treatment plant or other transfers off-site– emission limits and monitoring requirements						
Emission point ref. & location	Source	Parameter	Limit (incl. Unit)	Reference period	Monitoring frequency	Monitoring standard or method
S1 on site plan in schedule 7	Effluent discharge building 228	pH	6 to 11	Weekly flow proportional sample	Weekly	pH meter
		Chemical Oxygen Demand	1000 mg/l	Monthly flow proportional sample	Monthly	Gravimetric determination
S2 on site plan in schedule 7	Effluent discharge building 224	No parameters set	-	-	-	-
S3 on site plan in schedule 7	Effluent discharge from building 640	No parameters set	-	-	-	-

Schedule 4 – Reporting

Parameters, for which reports shall be made, in accordance with conditions of this permit, are listed below.

Table S4.1 Reporting of monitoring data			
Parameter	Emission or monitoring point/reference	Reporting period	Period begins
Emissions to sewer Parameters as required by condition 3.5.1.	S1	Every 12 months	01/01/07

Table S4.2: Annual production/treatment	
Parameter	Units
Total production	kg

Table S4.3 Performance parameters		
Parameter	Frequency of assessment	Units
Water usage	Annually	tonnes
Energy usage	Annually	MWh

Table S4.4 Reporting forms		
Media/parameter	Reporting format	Date of form
Sewer	Form sewer 1 or other form as agreed in writing by the Environment Agency	02/10/06
Water usage	Form water usage 1 or other form as agreed in writing by the Environment Agency	02/10/06
Energy usage	Form energy 1 or other form as agreed in writing by the Environment Agency	02/10/06
Other performance indicators	Form performance 1 or other form as agreed in writing by the Environment Agency	02/10/06

Schedule 5 – Notification

These pages outline the information that the operator must provide.

Units of measurement used in information supplied under Part A and B requirements shall be appropriate to the circumstances of the emission. Where appropriate, a comparison should be made of actual emissions and authorised emission limits.

If any information is considered commercially confidential, it should be separated from non-confidential information, supplied on a separate sheet and accompanied by an application for commercial confidentiality under the provisions of the EP Regulations.

Part A

Permit Number	EPR/YP3437SP
Name of operator	Lonza Biologics Plc
Location of Facility	Slough
Time and date of the detection	

(a) Notification requirements for any malfunction, breakdown or failure of equipment or techniques, accident, or emission of a substance not controlled by an emission limit which has caused, is causing or may cause significant pollution	
To be notified within 24 hours of detection	
Date and time of the event	
Reference or description of the location of the event	
Description of where any release into the environment took place	
Substances(s) potentially released	
Best estimate of the quantity or rate of release of substances	
Measures taken, or intended to be taken, to stop any emission	
Description of the failure or accident.	

(b) Notification requirements for the breach of a limit	
To be notified within 24 hours of detection unless otherwise specified below	
Emission point reference/ source	
Parameter(s)	
Limit	
Measured value and uncertainty	
Date and time of monitoring	
Measures taken, or intended to be taken, to stop the emission	

Time periods for notification following detection of a breach of a limit	
Parameter	Notification period

(c) Notification requirements for the detection of any significant adverse environmental effect	
To be notified within 24 hours of detection	
Description of where the effect on the environment was detected	
Substances(s) detected	
Concentrations of substances detected	
Date of monitoring/sampling	

Part B – to be submitted as soon as practicable

Any more accurate information on the matters for notification under Part A.	
Measures taken, or intended to be taken, to prevent a recurrence of the incident	
Measures taken, or intended to be taken, to rectify, limit or prevent any pollution of the environment which has been or may be caused by the emission	
The dates of any unauthorised emissions from the facility in the preceding 24 months.	

Name*	
Post	
Signature	
Date	

* authorised to sign on behalf of the operator

Schedule 6 – Interpretation

“accident” means an accident that may result in pollution.

“annually” means once every year.

“application” means the application for this permit, together with any additional information supplied by the operator as part of the application and any response to a notice served under Schedule 5 to the EP Regulations.

“authorised officer” means any person authorised by the Environment Agency under section 108(1) of The Environment Act 1995 to exercise, in accordance with the terms of any such authorisation, any power specified in section 108(4) of that Act.

“emissions to land” includes emissions to groundwater.

“EP Regulations” means The Environmental Permitting (England and Wales) Regulations SI 2010 No.675 and words and expressions used in this permit which are also used in the Regulations have the same meanings as in those Regulations.

“emissions of substances not controlled by emission limits” means emissions of substances to air, water or land from the activities, either from the emission points specified in schedule 3 or from other localised or diffuse sources, which are not controlled by an emission limit.

“groundwater” means all water, which is below the surface of the ground in the saturation zone and in direct contact with the ground or subsoil.

“Industrial Emissions Directive” means DIRECTIVE 2010/75/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 24 November 2010 on industrial emissions

“MCERTS” means the Environment Agency’s Monitoring Certification Scheme.

“quarter” means a calendar year quarter commencing on 1 January, 1 April, 1 July or 1 October.

Where a minimum limit is set for any emission parameter, for example pH, reference to exceeding the limit shall mean that the parameter shall not be less than that limit.

Unless otherwise stated, any references in this permit to concentrations of substances in emissions into air means:

- in relation to emissions from combustion processes, the concentration in dry air at a temperature of 273K, at a pressure of 101.3 kPa and with an oxygen content of 3% dry for liquid and gaseous fuels, 6% dry for solid fuels; and/or
- in relation to emissions from non-combustion sources, the concentration at a temperature of 273K and at a pressure of 101.3 kPa, with no correction for water vapour content.

“year” means calendar year ending 31 December.

Permit Number: YP3437SP

Operator: Lonza Biologics Plc

Installation: Slough Biopharmaceuticals Plant

Form Number: Sewer1 02/10/06

Reporting of emissions to sewer for the period from to

Emission Point	Substance / Parameter	Emission Limit Value	Reference Period	Result ^[1]	Test Method ^[2]	Sample Date and Times ^[3]	Uncertainty ^[4]
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				

[Type here]

Emission Point	Substance / Parameter	Emission Limit Value	Reference Period	Result ^[1]	Test Method ^[2]	Sample Date and Times ^[3]	Uncertainty ^[4]
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				

[Type here]

Emission Point	Substance / Parameter	Emission Limit Value	Reference Period	Result ^[1]	Test Method ^[2]	Sample Date and Times ^[3]	Uncertainty ^[4]
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				

[Type here]

Emission Point	Substance / Parameter	Emission Limit Value	Reference Period	Result ^[1]	Test Method ^[2]	Sample Date and Times ^[3]	Uncertainty ^[4]
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				

[Type here]

Emission Point	Substance / Parameter	Emission Limit Value	Reference Period	Result ^[1]	Test Method ^[2]	Sample Date and Times ^[3]	Uncertainty ^[4]
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				
S1	pH	Min 6 to Max 11	Weekly flow proportional sample				

[Type here]

Emission Point	Substance / Parameter	Emission Limit Value	Reference Period	Result ^[1]	Test Method ^[2]	Sample Date and Times ^[3]	Uncertainty ^[4]
S1	Chemical Oxygen Demand	1000 mg/l	Monthly flow proportional sample				
S1	Chemical Oxygen Demand	1000 mg/l	Monthly flow proportional sample				
S1	Chemical Oxygen Demand	1000 mg/l	Monthly flow proportional sample				
S1	Chemical Oxygen Demand	1000 mg/l	Monthly flow proportional sample				
S1	Chemical Oxygen Demand	1000 mg/l	Monthly flow proportional sample				
S1	Chemical Oxygen Demand	1000 mg/l	Monthly flow proportional sample				
S1	Chemical Oxygen Demand	1000 mg/l	Monthly flow proportional sample				
S1	Chemical Oxygen Demand	1000 mg/l	Monthly flow proportional sample				
S1	Chemical Oxygen Demand	1000 mg/l	Monthly flow proportional sample				
S1	Chemical Oxygen Demand	1000 mg/l	Monthly flow proportional sample				
S1	Chemical Oxygen Demand	1000 mg/l	Monthly flow proportional sample				

[Type here]

Emission Point	Substance / Parameter	Emission Limit Value	Reference Period	Result ^[1]	Test Method ^[2]	Sample Date and Times ^[3]	Uncertainty ^[4]
S1	Chemical Oxygen Demand	1000 mg/l	Monthly flow proportional sample				

Notes:

- [1] The result given is the maximum value (or the minimum value in the case of a limit that is expressed as a minimum) obtained during the reporting period, expressed in the same terms as the emission limit value. Where the emission limit value is expressed as a range, the result is given as the 'minimum – maximum' measured values.
- [2] Where an internationally recognised standard test method is used the reference number is given. Where another method that has been formally agreed with the Agency is used, then the appropriate identifier is given. In other cases the principal technique is stated, e.g. gas chromatography.
- [3] For non-continuous measurements the date and time of the sample that produced the result is given. For continuous measurements the percentage of the process operating time covered by the result is given.
- [4] The uncertainty associated with the quoted result at the 95% confidence interval, unless otherwise stated.

Signed
 (Authorised to sign as representative of Lonza Biologics plc

Date.....

Permit Number: YP3437SP

Operator: Lonza Biologics

Installation: Slough Biopharmaceuticals Plant

Form Number: WaterUsage1 02/10/06

Reporting of Water Usage for the year:

Water Source	Usage (m ³ /year)	Specific Usage (m ³ /KG output)
Total water usage		

Operator's comments :

Signed
(authorised to sign as representative of Lonza Biologics plc

Date.....

[Type here]

Permit Number: YP3437SP

Operator: Lonza Biologics Plc

Installation: Slough Biopharmaceuticals Plant

Form Number: Energy1 02/10/06

Reporting of Energy Usage for the year:

Energy Source	Energy Usage		Specific Usage (MW/KG output)
	Quantity	Primary Energy (MWh)	
Electricity *	MWh		
Natural Gas	tonnes		
Diesel Fuel	tonnes		
TOTAL	-		

* Conversion factor for delivered electricity to primary energy = 2.6

Operator's comments :

Signed
(Authorised to sign as representative of Lonza Biologics plc)

Date.....

[Type here]

Permit Number: YP3437SP

Operator: Lonza Biologics Plc

Installation: Slough Biopharmaceuticals Plant

Form Number: Performance1 02/10/06

Reporting of other performance indicators for the period to

Parameter	Units
Total production	Kgs

Operator's comments :

Signed
(Authorised to sign as representative of Lonza Biologics plc)

Date.....

[Type here]