Determination of an Application for a PPC Permit under the Pollution Prevention and Control (England and Wales) Regulations 2000 (SI 2000 No.1973)

Decision document recording the decision-making process

Note: all references to the "PPC Regulations" are to the Pollution Prevention and Control (England and Wales) Regulations 2000 (SI 2000 No.1973), as amended.

Administrative details

Duly made application date	29 March 2006
Permit number (the "Permit")	BS5401IK
Applicant (the "Applicant")	Novartis Vaccines and Diagnostics Ltd.
Address/location of installation (the "Installation")	Gaskill Road Speke Liverpool L24 9GR
Name of Authorising Officer	M J Peacock

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INTRODUCTION

Purpose of this document

The decision document explains how the applicant's application has been determined and why the specific conditions in the permit have been imposed. It is a record of the decision-making process to show how all relevant factors have been taken into account.

The permit contains many conditions taken from our standard non-landfill PPC permit template (version 3). We developed these conditions in consultation with industry having regard to the legal requirements of the PPC regulations and other relevant legislation. This decision document does not include an explanation for these standard conditions. Where they are imposed we have considered the application and accepted the details are sufficient and satisfactory to control that aspect of the operation. This decision document does however, provide an explanation for the use of alternate conditions where our permit template allows for two or more options. Emission and monitoring compliance levels and any additional conditions that have been imposed in order to take installation-specific factors into account are explained

Summary of the decision

We have decided to grant a permit for the operator, subject to the conditions in the permit. Where the permit includes standard conditions (see above), these have been considered to be appropriate for the installation, in particular in ensuring that all appropriate measures will be taken against pollution and that no significant pollution will be caused. We consider in reaching that decision we have taken into account all relevant considerations and legal requirements and that the permit will ensure that all appropriate measures will be taken against pollution and that no significant pollution will be caused.

This Permit relates to a single installation that is made up of four sites: Evans Road (Site 1), Gaskill Road (Site 2), Speke Boulevard (Site 3) and Renaissance Way (Site 4). Prior to the issue of this Permit, activities were regulated by means of the following:

- IPC Authorisation (AO0768) for Sites 1, 2 & 3; and
- PPC Permit (KP3330LF) for Site 4.

This determination is based on the two "part" PPC Permit Applications submitted by the Operator:

- PPC Permit Application (KP3330LF) for the Site 4 part installation. This related to an application for a new facility. At the time of writing, Site 4 is almost complete but not yet operational. The Agency agreed that the Operator could apply for the Site 1, 2 and 3 part installation at a later date (during the application window defined in the PPC Regulations); and
- PPC Permit Application (BS5401IK) for Sites 1, 2, 3 & 4.

This Decision Document covers Sites 1-4. More detailed information for Site 4 can be found in the earlier Decision Document for Permit KP3330LF, dated 06/04/06.

PART A – GENERAL ISSUES

A1 Administration

This section includes administrative information relating to the application and information about the applicant and the installation.

The application was duly made on 29 March 2006.

The operator has not made a claim for commercial confidentiality. We have not received any information in relation to this application that appears to be confidential in relation to any party.

The application was advertised and consulted in accordance with the regulations. Details of the advertising and consultation are on the public register. Any responses received are summarised in Annex 1. We have taken these into consideration as described in Annex 1 when determining the application.

Further information was requested during the course of the determination, the key information being:

- improved descriptions for the 'sources' of emissions to air and sewer;
- the specification of Site 1-3 boilers and their stack heights;
- the status of those areas of the site previously occupied by MedImmune; and
- confirmation of the control and responsibility for the activities undertaken by the waste contractor operating at the installation.

A response was received from the Operator on 11/12/06. After reviewing the content of the response, it was not considered necessary to forward the content to any of the statutory consultees.

Prior to issue, a copy of the draft Permit was forwarded to the Operator and their feedback was taken into consideration.

The requirements of PPD do not apply to this application.

A2 Description of the installation

A brief description of the installation is in the introductory note to the permit.

The installation comprises of four technically connected locations on Evans Road (Site 1), Gaskill Road (Site 2), Speke Boulevard (Site 3) and Renaissance Way (Site 4) in Speke. Site 4 is currently under construction. The installation, Grid Reference SJ 4374 8388, is located approximately 10 km south-east of Liverpool and is surrounded by a variety of industrial units, a bus depot, a railway line, and residential properties.

The Operator manufactures influenza and yellow fever vaccines and this represents the principal listed activity falling under Section 4.5 A(1)(a) of the PPC Regulations. Production of seasonal and pandemic influenza vaccines is based on primary seeds obtained from external public health bodies. The process involves inoculating eggs

with virus from the seed laboratory and, after incubation, harvesting the allantoic fluid. Following a series of concentration and purification stages the material is stored prior to blending and filling into syringes / vials. Production of yellow fever vaccine requires the inoculation of eggs with an attenuated strain of the virus. After appropriate incubation the eggs are harvested and the virus is formulated and filtered prior to freeze drying in vials. Each product is manufactured to the strict standards specified in the product licences issued by the pharmaceutical regulatory authorities. This Permit supersedes the earlier authorisation under the Environmental Protection Act 1990 (Reference Number AO 0768) for Sites 1, 2 & 3 and an earlier permit under the PPC Regulations (Reference Number KP3330LF) for Site 4.

A number of directly associated activities also take place including the production of high quality water, the operation of heating, ventilation and air conditioning systems (HVAC), refrigeration activities and the operation of combustion equipment to generate steam mainly used for sanitisation and sterilisation purposes.

The manufacturing processes result in emissions to air from release points associated with the operation of the combustion plant, HVAC systems, process vents and the storage of raw materials and waste products. In addition, periodic fumigation with formaldehyde or hydrogen peroxide of manufacturing areas also results in emissions to air. Emissions associated with the storage of egg waste at site 4 are vented via activated carbon odour abatement systems in order to minimise the risk of potentially odorous releases.

Process effluent sources from areas that may contain significant mercury or nonylphenol ethoxylate content are segregated for off-site treatment and disposal. Other process effluent sources are discharged to the sewer with the effluent from site 4 receiving physical treatment (pH and temperature adjustment) prior to discharge. The process effluent discharge to sewer receives further treatment at Sandon Dock Wastewater Treatment Works prior to discharge into the River Mersey.
Given the nature of the process and the land use surrounding the site, the Agency does not consider that noise from the installation will give reasonable cause for annoyance.

The closest designated habitat to the installation is the Mersey Estuary (RAMSAR site, Special Protection Area & Site of Special Scientific Interest) at approximately 3km. An Agency assessment of the impact of emissions to air concluded that the installation is unlikely to have significant effect on the European habitats alone, or in combination with other plans and projects.

Activities at Sites 1, 2 & 3 are subject to a Climate Change Levy Agreement (CCLA) operated by the Chemical Industries Association (CIA). The Operator is committed to extending the agreement to include site 4 once it is fully operational.

The Operator is committed to developing a formal environmental management system.

A3 Operator competence

We are satisfied that the applicant (now the operator) is the person who will have control over the operation of the installation after the grant of the permit. We are

satisfied that they will be able to operate the installation so as to comply with the conditions we have included in the permit. The Operator has experience of complying with previous regulatory regime as Sites 1, 2 & 3 having been subject to a previous authorisation under the Environmental Protection Act 1990 (Reference Number AO 0768).

A4 Requirements for SWMAs

The operator has replied to application question B7.1 stating that the installation does not contain an SWMA and we agree with this assessment.

A5 EPOPRA profile

We are not fully satisfied that the EPOPRA profile submitted with the application remains accurate following the determination of the application and we have amended the EPOPRA score to 175 for the following reason:

- to account for the increase in Band C attribute scores (from 40 to 45).

The revised EPOPRA score will be used as the basis for subsistence and other charging. In accordance with our EPOPRA Scheme however, the operator's EPOPRA profile for the installation may change over time.

[As the emissions for Site 4 in the EPOPRA are based on estimated releases, it is recommended that the EPOPRA for the installation is reviewed following receipt of actual data, particularly areas relating to emissions and waste arising. It should also be noted that the development of a formal Environmental Management System required through a specific improvement condition in the Permit should result in a significant reduction in the Operator Performance band.]

PART B : THE INSTALLATION AND ITS MANAGEMENT

B1 General Management

Permit condition 1.1

Based upon the information submitted in the application, we are not fully satisfied that appropriate management systems and management structures are in place for this installation.

Section 2.3 of the Application for Sites 1-4 details the existing systems and procedures and includes proposals to address the deficiencies identified. The Operator has included the implementation of a formal Environmental Management System (EMS) as part of their proposed improvement programme and, given the complex activities undertaken at the installation, an improvement condition has been included in the Permit requiring this.

Regarding "Staffing and Training", the information provided in response to Questions in Section 2.3 of the Application indicates that the installation will be operated by an adequate number of staff, who are suitably trained and supervised. Written operating

instructions are available, and a system is in place for the recording of staff training (training records, which record outstanding training needs and the training provided, are subject to external auditing). The Operator runs a large National Vocational Qualification (NVQ) training programme for staff that incorporates environmental training requirements. Contractors at the site undergo an induction process that includes environmental issues.

In respect of "Operation and Maintenance", the Operator has a formal maintenance system which includes the prioritisation of plant for which a preventative maintenance regime is appropriate and a Preventative Maintenance Programme. However, the following deficiencies in this area were identified:

- Procedures need to be developed to control operations that may have an adverse impact on the environment.
- Procedures need to be developed for monitoring emissions or impacts.
- The maintenance system should be subject to an auditing process.

Regarding "Incidents and Complaints", the Operator has an incident/complaint logging and response system in place. However, the following deficiency in this area was identified:

- Procedures need to be developed for handling and reporting actual or potential non compliance with operating procedures or emission limits.

Regarding the "Organisation", the Operator has an environmental policy and procedures in place relating to the control of process change. An Organisational structure has also been provided in Figure 8 of the Application. The following key deficiencies in this area were identified:

- A formal programme needs to be developed to identify objectives / targets and report on performance.
- Auditing of the EMS needs to be introduced.
- A formal system for records needs to be introduced.

The superseded PPC Permit for Site 4 (KP3330LF) included a pre-operational condition requiring the implementation of a documented system of environmental management techniques. This is covered by the improvement condition detailed above.

B2 Accidents that may cause pollution Permit Condition 1.2

Based upon the information submitted in the application, we are not fully satisfied that appropriate measures are in place to ensure that accidents that may cause pollution are minimised.

The Operator has provided details of the methodology to be used to identify the hazards posed by the installation and assess the risk of accidents and their possible consequences. Potential "root causes" have been identified, although this Process Hazard Review has yet to be completed for Sites 1-3 (Site 4 is complete). The Operator has, however, compared the actual techniques employed to reduce the risk of accidents with those detailed in Section 2.8 of TGN S4.02 which are considered relevant at most installations.

The Operator is committed to the completion of a structured accident management plan (taking into account site specific hazards identified in the Process Hazard Review) for Sites 1-3 and the establishment of an Emergency Response Plan. These plans will form part of the EMS which is the subject of a specific improvement condition.

B3 Energy efficiency Permit condition 1.3

Based upon the information submitted in the application, we are satisfied that appropriate measures are in place to ensure that energy is used efficiently**.**

Energy sources (electricity, natural gas and medium fuel oil) together with consumption figures have been provided for Sites 1-3. Given the lack of sub-metering at Sites 1, 2 & 3, the Operator has not been able to quantify consumption in key areas however equipment likely to consume significant quantities of energy have been identified.

a) Electricity (fans and pump motors associated with the boilers, chilled water units, air compressor, blast chillers and process equipment);
b) Gas (3 gas-fired steam raising boilers); and
c) Medium Fuel Oil (2 medium fuel oil fired boilers – Site 2).

The Operator will establish a more detailed energy baseline, following Permit issue, against which energy efficiency plans can be monitored. The Energy efficiency plan will form part of the EMS. It is suggested that progress in this area is monitored at a future inspections.
Energy consumption, Specific Energy Consumption (SEC) and associated environmental emissions have been provided.

At Site 4, electricity and natural gas will satisfy the energy requirements and energy efficiency has been taken into account during the design stage, the following key demands have been identified:

d) Electricity (chilled water units, HVAC, Blast chillers, water purification, process equipment (zone 1 & 2) and effluent handling/pH control; and
e) Gas (Steam raising boilers).

In terms of the basic energy requirements at Site 4, the Operator has demonstrated how energy efficiency was taken into consideration in the selection of gas boilers, chilled water units, air compressors, blast chillers and heating and ventilation units (HVAC). At Sites 1-3, appropriate operating and maintenance procedures are in place for most equipment. For some of the boilers, written procedures or O & M manuals are not available, however they remain subject to daily testing and inspection in accordance with the Pressure Systems Safety Regulations. N.B. Any deficiencies in the Operations and Maintenance Procedures will be addressed through the development of the EMS. Basic low cost physical techniques have been implemented following a review.

Sites 1-3 are currently covered by a Climate Change Levy Agreement (CCLA) operated by the Chemical Industries Association (CIA), the Operator states that this will extend to include Site 4 in the future.

In respect of Condition 2.7.1, the Operator is required to report Energy Consumption relating to electricity and natural gas use.

The operator is required to report with respect to energy usage natural gas, fuel oil and electricity consumption under condition 4.2.1/2 and Schedule 5.

B4 Efficient use of raw materials

Permit condition 1.4

Based upon the information submitted in the application we are satisfied that the appropriate measures are in place to ensure the efficient use of raw materials and water.

Section 2.4 of the Site 1-4 Application provides a raw material and auxiliary material inventory which includes details of the chemical nature, approximate usages, purpose, fate, potential environmental impact and an assessment of alternatives. The information provided meets the requirements of indicative BAT. Regarding the assessment of alternative products, the Agency accepts that many of the raw materials are dictated by the product licences issued by the pharmaceutical regulatory authorities and that any substitution would require extensive validation work and approval from the regulatory authorities. However, the Operator has established two working groups with the objective of ultimately replacing Thiomersal (which contains mercury) and nonylphenol ethoxylate. It is recommended that progress be monitored periodically at future inspections.

For Site 4, waste minimisation has been a consideration during the design stage and the Application details a number of the measures and targets identified.

For Sites 1, 2 & 3, a limited waste minimisation audit has been carried out by a waste management contractor with experience of the pharmaceutical sector. This has resulted in increased plastic and cardboard recycling, and the introduction of disposable plastic bags for media which reduces the amount of cleaning required for containers and vessels. The Operator has stated that a formal waste minimisation audit will be undertaken within two years of Permit issue and this has been included as an improvement condition in the Permit.

Significant quantities of water are consumed at the installation, mainly for washing, sterilising and sanitising purposes, however, as a large proportion of the water must meet a specified quality dictated by the relevant pharmaceutical regulatory authority, this limits many of the opportunities for recycling/re-use.

The following water sources are used:
a) Raw Water;
b) Softened Water;
c) Purified Water (PW) – treated by means of reverse osmosis (RO) and electro-deionisation (EDI) units; and
d) Water for Injection (WFI) – PW further purified by distillation.

At Site 4, water minimisation was a consideration at the design stage and each source of water will be metered separately. Water minimisation measures include the use of

CIP systems, washing machines (for trolleys and trays), disposable process equipment such as irradiated tubing / bags, and closed heat transfer systems. The Operator has stated that the rotors of the zone 2 ultracentrifuges will initially be cleaned manually but that trials of an automated washing system are to take place, it is suggested that the outcome of these trials are reviewed at future inspections.

At Sites 1-3, the Operator does not have the ability to monitor water consumption at key points which is necessary to allow baseline mapping. The Operator has stated that appropriate water monitoring techniques will be introduced, followed by a formal water minimisation audit. An improvement condition requiring a water minimisation audit to be carried out has been included in the Permit.

B5 Avoidance, recovery and disposal of wastes produced by the activities

Permit condition 1.5

Based on the information submitted in the application we are satisfied that the appropriate measures are in place such that waste production will be avoided as far as possible, and where waste is produced it will be recovered unless technically and economically impossible. We are satisfied that the operator's justification for their proposed waste disposal option shows that such waste that does arise from the installation that can not be recovered will be disposed of using a disposal method that avoids or reduces any impact on the environment.

Table 2.5.1 in the Application details the waste types, quantities and fate of the waste streams from the installation. In addition, details of the segregation strategy, waste records and the measures to prevent emissions from waste storage and handling activities have been identified. The Table shows that 64 tonnes of autoclaved glassware are disposed of to landfill and it is suggested that potential recycling/re-use options are considered at a future inspection. The management of waste at the installation has been contracted by the Operator to a specialist company with experience of the pharmaceutical sector. Clarification that Novartis remain responsible for compliance with legislation and are also responsible for managing the waste contractor has been received. A number of skips containing non hazardous dry waste are located on unmade ground between Site 2 and 3. The Operator is to construct a designated skip storage area with hardstanding to address this issue. It is recommended that that progress on this development be monitored at future inspections.

Each waste stream has undergone an assessment based on the waste minimisation hierarchy (although the opportunities for reuse are limited due the nature of the fully validated pharmaceutical process). A summary is provided in Table 2.6.1 of the Application. Egg waste is a category 2 Animal By-Product and requires rendering. Segregation of a contaminated liquid waste serves to isolate those waste streams that potentially contain trace quantities of mercury and nonylphenol ethoxylates, thereby reducing the quantity requiring treatment prior to disposal. The Operator is also considering the introduction of disposable plastic bags for media, this approach is supported by the pharmaceutical regulatory authorities as it reduces the likelihood of product contamination. This approach will result in an additional waste stream (some of which may be subsequently recycled), however it offers benefits particularly in terms of reduced water and energy consumption by reducing the cleaning of bottles

and process vessels. Given the potential waste generated as a result of product contamination, the use of disposable plastic bags is considered to represent BAT. It is recommended that progress on the phased introduction of plastic bags is reviewed at future inspections and the fate of the waste bags generated.

B6 Site Security

Permit condition 1.6

Based upon the information submitted in the application, we are fully satisfied that appropriate infrastructure and procedures are in place to ensure that site remains secure.

The site is manned at all times by an external security company. Site boundaries are protected by security fencing and CCTV surveillance. Access to the site by personnel is by means of an electronic card operating system.

B7 Multiple operator installations

Permit condition 1.7

This is not a multi-operator installation

The Application refers to areas of the site leased to MedImmune UK Ltd. Further clarification was sought on this relationship which was received from the Operator in a fax dated 12 April 2006. This information superseded some of the information in Section 2.12 of the Application. At Site 1, MedImmune receive Specific Pathogen Free (SPF) eggs that are washed and incubated prior to transfer to either Novartis or other MedImmune facilities. The eggs do not come into contact with live virus and the operation of this Primary Incubation Unit is considered as a raw material supply system and does not fall within the scope of the installation. At site 2, MedImmune have a production facility, however no processing is taking place.

[During the determination, the Operator confirmed that all areas previously occupied by MedImmune have been returned to the control of Novartis Vaccines.]

B8 The permitted activities

Permit condition 2.1

We have determined that the installation comprises the following activities listed in Part 1 of Schedule 1 to the PPC Regulations and the following directly associated activities.

<u>Listed Activities</u>

a) Section 4.5 Part A(1)(a) – Producing pharmaceutical products using a chemical or biological process. Seasonal and pandemic influenza vaccine manufacture at Sites 1-4.
b) Section 4.5 Part A(1)(a) – Producing pharmaceutical products using a chemical or biological process. Yellow fever vaccine manufacture at Site 2.
c) Section 5.3 Part A(1)(c)(ii) – Disposal of non-hazardous waste in a facility with a capacity of more than 50 tonnes per day by physico-chemical treatment, not being treatment specified in any paragraph other than paragraph D9 in Annex IIA to

Council Directive 75/442/EEC, which results in final compounds or mixtures which are discarded by means of any of the operations numbered D1 to D12 in that Annex. Physical treatment of process effluent from site 4 prior to discharge to the sewer.

Directly Associated Activities

- Operation of combustion plant for heating, sanitisation and sterilisation purposes;
- Operation of Heating Ventilation & Cooling (HVAC) systems;
- Operation of blast chillers; and
- Purification of raw water.

The Application details activities at sites 1 to 4, these can be briefly summarised as the following:

- Site 1
  a) preparation of seasonal and pandemic influenza production seeds, inoculation/incubation of eggs, harvesting and preservation of allantoic fluid and inactivation of the virus.
- Site 2
  a) Production of monoblend for seasonal and pandemic influenza vaccine. Blending of monovalents to produce trivalent blends.
  b) the manufacture of freeze dried attenuated yellow fever vaccine. The primary antigen is stored in the vapour phase of liquid nitrogen before blending to produce the freeze dried product.
- Site 3
  a) filling of finished vaccine into vials and syringes for seasonal and pandemic influenza vaccine production.
- Site 4
  a) the manufacture of seasonal and pandemic influenza vaccine. Production of monoblend as detailed above.

Prior to the issue of this Permit, activities at sites 1, 2 and 3 were subject to an IPC authorisation (AO 0768) while those at site 4 were subject to a PPC Permit (KP3330LF). The application for the consolidated installation has been made within the tranche window of 1st January to 31st March 2006. After considering the criteria defined in Regulatory Guidance Note No.5 "Interpretation of Installation in the PPC Regulations", the Agency has concluded that the above activities comprise a single installation. In particular, the stationary technical units are technically connected by means of specialist transport vehicles which transport seasonal and pandemic influenza vaccine intermediates between sites for activities which form successive steps in one overall integrated industrial activity.

The following areas have been excluded from the installation as they do not meet the criteria for a Directly Associated Activity, based on the criteria defined in Regulatory Guidance Note No. 5: car parking areas, 'empty' areas, and canteen areas.

B9 The site

Permit condition 2.2

The operator has provided a plan which we consider is satisfactory, showing the site of the installation and its extent. A plan is included in the permit at Schedule 2, and the operator is required to carry on the permitted activities within the site boundary.

Part C : Operations and releases

C1 Operating techniques

Permit condition 2.3/table S1.2

We have specified that the applicant must operate his installation in accordance with the following descriptions in his application

Description	Parts	Justification
The response to section 2.1 and 2.2 in the Application.		
Receipt of additional information to the application (11/12/06)	a) Revised drainage plan (Figure 6) and references to effluent discharge locations (Table 1); b) Details of boiler specification and operation (Table 3); c) Revised installation layout plan (Figure 3); and d) Revised H1 assessment.	Additional information regarding the boiler specification. Revisions made to drainage plan, H1 assessment and installation plan.

C2 Off-site conditions

Permit condition 2.4

Based on the information submitted in the application, we consider that it is not necessary to impose any off-site conditions.

C3 Improvement Conditions

Permit condition 2.5

Based on the information in the application we consider that we do need to set improvement conditions. These are listed in annex 2 with justification provided at the relevant section of the decision document.

C4 Pre-operation conditions

Permit condition 2.6

Based on the information on the application, we consider that we do need to impose any pre-operational conditions. Pre-operational conditions, present in the superseded PPC Permit (KP3330LF) for Site 4 remain outstanding and have been included in this Permit, namely:

- the fitting of oil droplet abatement systems on the centrifuge exhausts in zone 2;
- the fitting of a recirculating liquid ring vacuum pump or dry vacuum pump (or an alternative vacuum system agreed with the Agency) to be used for harvesting activities in zone 1; and
- inclusion of any additional noise attenuation measures, required to meet BAT, identified during the detailed design stage.

C5 Closure and decommissioning

Permit condition 2.7

The Operator has prepared a Site Closure procedure for the installation that will, on implementation, lead to the development of a Site Closure Plan. The Site Closure Plan will ensure that the appropriate measures are in place for the closure and decommissioning of the installation. It should be noted that the Operator plans to close and decommission Sites 1 and 2 once Site 4 achieves full scale production.

C6 Site protection and monitoring programme

Permit condition 2.8

The applicant has provided a site report the main elements of which are:

- Site Setting – The site is located approximately 10 km south-east of Liverpool (Grid Reference SJ 4374 8388). The surrounding area includes several automotive support facilities, bus depot, railway line, residential properties (approx. 3-400m from sites 3 & 4), car production plant, other vaccine manufacturer and various light industrial units. The nearest designated habitat is the Mersey estuary, approximately 3km from the site. The area is an internationally important wildfowl habitat comprising inter-tidal sand and mudflats.

  The area occupied by site 1 has been used for the production of fine chemicals (bleach and iodine) prior to vaccine /pharmaceutical production by various Operators. The area occupied by site 2 was used as a Research Laboratory for a pharmaceutical works prior to vaccine manufacture starting in the 1970s. Site 3 was constructed in the 1990s at the site of an earlier engineering works. Site 4 has historically been used predominantly for warehousing of medical, pharmaceutical and laboratory chemicals.

  The geology below the site comprises the following layers: made ground, underlain by drift deposits of glacial clay, underlain by glacial sand (at some locations), underlain by solid deposits of pebble bed / sandstone. The sandstone formation (of which the Pebble beds form part) is classed as a major aquifer. The major aquifer is within a Groundwater Source Protection Zone (Zone 3).

- Potentially polluting substances – A number of historic site investigations have been referenced which have quantified pollutants in soil and groundwater at the installation and compared the results with guideline values:
  Site 1 – A study focussed on the area of the former Fine Chemicals plant, this confirmed elevated levels of arsenic in some soil samples, total hydrocarbon in groundwater and total polycyclic aromatic hydrocarbons (PAHs) in some soil samples.

Site 2 – A study focussed on the area around the Utilities Building, the source of an earlier oil spill incident. Hydrocarbon contamination was visible during some sampling and elevated levels of mineral oil found in the soil. Some groundwater samples were found to have elevated COD values and total hydrocarbon; and mercury was recorded in excess of the UK Drinking water standard at one location.
Site 3 – Soil samples confirmed elevated levels of arsenic in one sample, lead in one sample, cadmium in one sample, mineral oil and phenol in one sample.
Site 4 - Intrusive testing identified the following metals and metalloids (above the detection limit of the test) in some samples: As, Cd, Cr, Cu, Pb, Ni, Zn. Organic substances including PAHs and significant hydrocarbon and toluene contamination were also noted in some areas. Sources of historic contamination were identified, linked to the storage of diesel, gas oil, oil and solvents on or adjacent to the site.

For each potentially polluting substance, intermediate and waste product to be used or handled at the installation, the Application Site Report/Application identifies the quantities to be stored, storage location, environmental properties and pollution potential.

- Pollution Prevention Measures – The key measures can be summarised as the following:
  a) Primary measures – Raw materials are stored in bottles (e.g. Thiomersal and β-propiolactone), bags/drums/IBCs (e.g. chemicals and oil) and bulk tanks (e.g. brine, fuel oil, HCl, NaOH). Bulk waste tanks are used for Thiomersal contaminated wastes and egg wastes. Solid and liquid hazardous waste is stored in a dedicated compound. In terms of underground structures, a number of underground sumps have been identified together with a contaminated process effluent tank at Site 3.
  b) Secondary measures – Many of the small volume raw materials, process intermediates are not bunded but are stored inside process buildings, which provide an impervious surface and secondary containment.
  At Site 4, all above ground storage tanks will be located within bunds except for the brine tank. However, this 38m^3 glass reinforced resin tank which will store 36.4% NaCl, will have a high level alarm, be located away from watercourses and be protected by crash barriers. Waste storage tanks are fitted with high level alarms and bunded. Sump 1 (contaminated waste) consists of a glass reinforced plastic (GRP) tank located in a resin lined concrete sump, sumps 2 & 3 (non contaminated waste) are resin lined concrete sumps. The tanker spill containment sump is constructed from concrete and fitted with a pump to allow transfer of any waste spilled during tanker operations.
  Regarding Sites 1-3, the underground process effluent tank at Site 3 is located within a concrete sump which provides secondary containment. All of the bulk tanks are bunded except for the liquid egg waste tanks at Site 1. HCl and NaOH in IBCs is stored on a platform above a bunded compound for the main storage tanks and, as such, is at risk of accidental damage. The hazardous waste storage compound is not bunded.
  c) Tertiary measures – External areas are concrete or tarmac, the condition was observed to be good. It was noted that a number of open skips are located on areas without hardstanding.

An improvement condition has been included in the Permit requiring the production of a plan which details the measures to be used to control fugitive emissions to surface water, sewer and groundwater. This will serve to address the above deficiencies.

- Possibility of pollution – The ASR identifies that there is "Little Likelihood of Pollution" from the activities identified and the Agency accepts this conclusion but notes the following: For Site 4, no assessment of the drainage system has been carried out, however, construction is based on stainless steel pipe fittings using double lip seals. The Applicant has proposed to confirm the integrity of the drainage system during commissioning using closed circuit television (CCTV)/pressure testing techniques. For Sites 1- 3 a number of spillage incidents have been documented including Site 1 contaminated process waste during transfer to tanker, contaminated process waste due to overfilling of storage tank, fuel oil during a delivery and as the result of a breach of the site 2 drainage system. Appropriate actions were taken to investigate and measures have been taken to reduce the risk of an incident occurring again. These measures will be reviewed as part of the fugitive emissions plan required by the above improvement condition.
- Conceptual Site Model (CSM) – The text and graphical summary provided takes into account the sources, pathways and receptors detailed in the ASR and identifies the uncertainties in the CSM.

In summary, we consider that this report adequately describes the condition of the site and in particular identifies any substance in, on or under the land that may constitute a pollution risk.

To ensure the continued effectiveness of pollution prevention measures to protect the land we are requiring the operator to implement and operate a Site Protection and Monitoring Programme, the design of which must be reported to the Agency within four months from the date of permit issue.

C7 Emissions to water, air or land.

Permit condition 3.1

We have reviewed the techniques used by the operator at the 4 sites and compared these with the relevant guidance notes. The indicative BAT techniques relevant to this installation have been extracted and developed from related Technical Guidance Note IPPC S4.02 "Guidance for the Speciality Organic Chemicals sector". The Agency has assessed the Operator's BAT proposals as set out in sections 2.1 and 2.2 of the Application and compared them against the indicative standards that have been developed from the information sources identified above.
This comparison is summarised below in Table 1.

Table 1

Process Activity	Techniques	BAT Assessment
Ventilation systems	The manufacture of pharmaceutical products requires strict particulate control and standards are imposed by regulatory bodies e.g. the Medicines and Healthcare Products Regulatory Agency. The standard is achieved through the use of Heating Ventilation and Cooling (HVAC) systems and/or the maintenance of pressure differentials between rooms. The HVAC systems filter the incoming air through a series of sequential filters. To compensate for the 10-15% fresh air make-up, extraction points are located on the side of buildings. N.B. "once-through" HVAC systems are used where particulate generation is likely to be high e.g. wash areas where water droplets will be present.	The purpose of the HVAC systems is to maintain the required air quality in the clean rooms and, therefore in most cases the releases from the associated exhausts are unlikely to be significant. The Agency accepts this conclusion. The Application has considered the concentration, mass flow and air impact from the ventilation exhausts and identified release points that may contain substances used in the process e.g. during fumigation.
	For Sites 1-3, the Operator has stated that the potential for noise has been categorised as "low". At Site 4, the HVAC equipment selected will have a maximum noise level of 79dB(A) at 1m and discharge louvers on the HVAC exhausts will minimise the risk of contamination of rainwater run-off.	Though the Agency accepts the conclusion that the potential for noise is low, once Site 4 is fully operational, the Operator plans to re-configure Site 3 and close Sites 1 & 2. Given that the existing Site 3 noise profile is likely to change, an improvement condition has been included in the Permit requiring noise levels at the re-configured Site 3 to be assessed and those from Site 4 to be verified.
	For Sites 1-3, the Operator states that there are no abatement systems as they are not necessary. Regarding Site 4, a number of abatement systems have been proposed, namely: • An oil droplet removal system to minimise emissions from the centrifuge area of zone 2 (emission point A28). • Carbon filter abatement systems will be fitted to the β-propiolactone vent header systems in zones 1 & 2 (emission points A20 and A30). This	This is supported by the impact assessment, however since the assessment is largely based on estimated emissions an improvement condition has been included in the Permit requiring the verification of the key emissions identified. A pre-operational condition has been included in the Permit requiring the inclusion of oil droplet abatement systems on emissions from the centrifuges in zone 2. Emissions of β-propiolactone together with the performance of the carbon filters will be verified by means of an improvement condition

	technique will minimise emissions of β-propiolactone to air by adsorption.	included in the Permit.
Over-pressure protection systems	For site 4, The number of pressure relief systems has been minimised through design by providing intrinsic protection against over pressure scenarios, where possible, for example, without bursting discs on vessels. For sites 1-3, where necessary, pressure protection systems have been taken into consideration.	All relief systems have been subject to systematic Hazard and Operability (HAZOP) study. The number of relief systems has been minimised through design as far as is practicable. This is considered to represent indicative BAT. The Operator has provided limited information and it is recommended that the systems in place be reviewed at a future inspection.
Vacuum systems	For site 4, the Application referred to a single once through water based vacuum system. However, at a site meeting on 2/1/06, the Operator confirmed that this system (associated with the harvesting process) is likely to consume significant quantities of water and that a recirculating liquid ring pump or dry vacuum pump will be used. At sites 1-3, a number of liquid ring once-through water based vacuum systems are employed. The Operator will review any replacement systems to ensure that they represent BAT.	Various systems exist (steam ejectors, liquid ring pumps, and dry vacuum pumps) which may represent BAT in different circumstances. The inclusion of a vacuum system based on a recirculating liquid ring pump or dry vacuum pump has been specified as a pre-operational condition in the Permit. The use of once-through sealing water may consume significant amounts of water (information not provided). An improvement condition has been included in the Permit requiring a water audit to be carried out. If water consumption in this area is highlighted, this should prompt targeted improvements.
Pumps	Generally, the aqueous nature of the main process simplifies pump selection. Typically, the following pump types are used: • Centrifugal pumps; • Peristaltic pumps; • Rotary lobe/mechanical seal pumps; and • Diaphragm pumps. At Site 4, through system design the number of pumping systems has been minimised, for example, by using	The prevention of seal leakage from process duties is considered a priority from the point of view of product quality and continuous Good Management Practice (GMP) requirements. Pump selection for Site 4 is based on practical experience from successful systems on the similar duties at the Operator's other sites and section 2.1.24 of the TGN. Pump selection is considered to represent site specific BAT.

	pressurised transfer systems between vessel transfers.	
Valves	Typically process systems operate at low temperature and pressure, the exception being the steam distribution pipework. Diaphragm based systems have been selected for process valves with ball valves on steam duties.	The use of glandless diaphragm valves / ball valves is appropriate and considered to represent site specific BAT.
Heating and Cooling systems	a) Heating systems: Heat transfer for process fluids is by means of jacketed process equipment which is considered to offer a higher degree of integrity. Heat transfer systems are constructed from stainless steel (316L) selected for its high corrosion resistance. Double tube sheet shell and tube heat exchangers are used in a number of non product fluid duties, for example Water for Injection (WFI) and Purified Water (PW) heating/cooling duties. This double tube design includes an air gap that aids visual leak detection. b) Chilled water system (5-11°C): For Site 4, a plant wide chilled water system will supply the HVAC system and other process cooling duties. Closed circuit, air cooled chilling will be provided by up to 5 x R134A package chiller units. The units are operated in sequence to satisfy demand efficiently. The system falls under the Pressure Systems Regulations and, as such, will be subject to independent inspection. Water quality will also be monitored for corrosion. The chiller units are located externally and low noise systems have been selected. At sites 1-3 there are many chilled water systems based on either closed loop	All heat exchange systems have the potential for process streams to leak into the heating/cooling fluid, or vice versa. The Operator has taken into account the potential for leaks and corrosion in the design of the heating systems. In respect of the IPPC BREF Note for Industrial Cooling Systems: The design of the chilled water system has been assessed using HAZOP methodology. Non refrigerant based systems have been considered but are not suitable for the required temperature range. Energy consumption is minimised by the sequential operation of chiller units and the use of variable speed recirculation pumps. Water / treatment chemical consumption is low and emissions to air are minimised through the use of a closed, dry, recirculatory techniques. The use of a closed system, coupled with external pressure testing and scheduled maintenance will minimise the risk of a leak and the inclusion of a low-level alarm will provide an early detection. The chilled water system design is considered to represent BAT. The improvement condition in the Permit requiring a water audit to be

	refrigerated plant or once-through water systems. The application does not provide information on the key items detailed in the BREF note i.e. energy consumption, water consumption and the potential for noise. Regarding the latter, Section 2.9 of the Application concludes that the potential for noise from this area is "low"	carried out will identify significant consumption areas. Energy consumption in chiller units has been highlighted and, following Permit issue, the Operator will establish a detailed energy baseline and Energy Efficiency Plan, highlighting areas requiring improvement.
	c) Blast Chillers (3°C) – Refrigerant based systems are used to cool the eggs following incubation.	Non-Refrigerant are not appropriate for the required temperature. The design of the chilled water system for Site 4 has been assessed using HAZOP methodology.
	d) Process Temperature Control Units (Site 4 only) – various stand alone, dry, closed loop systems are to be provided for process heating and cooling duties in Zones 1 & 2. Heating to greater than 121.5°C is necessary for heat sanitisation / sterilisation purposes. Primary circuits typically comprise a heat exchanger and jacketed vessel with an aqueous based heat transfer fluid. Secondary circuit will be either refrigerant cooled or steam heated depending on duty.	The TCU units have been assessed using HAZOP methodology. The Application states that the primary circuit heat transfer fluids will be confirmed during the detailed design stage. [At the site meeting of 1/2/06, the Operator confirmed that the primary circuit heat transfer fluid is to be ethylene glycol.]
	e) Plant Steam – mainly used to 'Sanitise in Place' (SanIP) or 'Sterilise in Place' (SIP).	
	Site 1 operates duty and standby gas fired boilers (1.42 & 2.06MW).	NO_x emissions of 64-77mg/m^3, based on limited monitoring.
	Site 2 operates duty and standby fuel oil (<1% Sulphur) fired boilers (2 x 5MW).	NO_x emissions of 283-317mg/m^3, based on limited monitoring. SO_2 emissions of 723-725mg/m^3, based on limited monitoring.
	Site 3 operates one 1.42 MW gas-fired boiler	NO_x emissions of 77mg/m^3, based on limited monitoring.
	Site 4 operates two 5.4 MW gas-fired boilers (duty and standby) fitted with low NO_x burners and heat recovery system. The boilers will be subject to a regular service/maintenance programme (at least annual).	The low NO_x emissions (80mg/Nm^3) and heat recovery system represents BAT.

	f) Clean Steam Generator – the quality of the condensate is equivalent to that of the Water for Injection and it is used for SanIP and SIP activities in product contact areas. This minimises the risk of product contamination. Clean steam is produced by multiple effect distillation of Purified Water (PW).	The nature of the pharmaceutical product dictates the quality of the steam required for cleaning purposes in terms of chemical, microbial and endotoxin constituents. The use of multiple effect distillation is considered BAT.
Reaction stage	The reaction stage occurs within inoculated eggs, the process has been approved by the regulatory authority in the UK and external markets into which the products are sold. The site does not carry out any product development. The Operator has a continuous improvement philosophy to reduce the environmental impact of the processes as a whole and has targeted the following potential improvement areas: • production of a mercury free preservative product. • reduction in waste arising (disposable bags and square rigs)	The established manufacturing processes employed at the site have been developed externally over many years. While it is accepted that any changes to the approved process would be subject to extensive validation work, it is recommended that progress against these potential improvements be monitored at future inspections.
Separation / Purification stages	a) Water for Injection (Site 4) – is distilled from purified water feedstock in package units. b) Centrifugation – this activity takes place during clarification and ultracentrifugation. c) Cartridge filters are used at a number of stages in the Influenza and Yellow Fever vaccine processes. Filter aids are not used and the filters are replaced daily without backwashing in order to minimise the risk of batch to batch cross contamination. d) Ultrafiltration (UF) is used in Sites 1, 2 and 4. Some re-use of the UF cassettes after washing will take place subject to operational constraints.	WFI is generated by package unit the design of which has been subjected to a HAZOP study. No VOCs are used in these process activities, however oil is used for lubrication (refer to comments in the Ventilation section of this Table). High usage, however considered to represent site specific BAT. Cartridge filters are used to remove solid matter contamination. Priority given to minimising the risk of contamination. Risk of solids breakthrough is likely to be low as the cartridges are changed daily. Centrifugation and UF used in the separation and purification stages of manufacture. Consideration given to the re-use of waste streams, however in most cases the risk of contamination is deemed unacceptable.

Point source emissions to air / H1 assessment

This section details the assessment of emissions to air, further information regarding emissions to air from Site 4 can be found in the Decision Document associated with superseded PPC Permit KP3330LF. Where appropriate, in-combination effects have been summarised in this document.

The following table details 18 release points to air identified by the Operator at sites 1, 2 & 3.

Table 1

H1 Description	Location	Activity or Activities	Effective Height (m)	Efflux Velocity (m/s)	Total Flow (m^3/h)
A1	Fumigation Inoculation	Site 1	0	1.87	13942.8
A2	BPL Release	Site 1	1.66	1.5	1080
A3	Boiler 1	Site 1	3.07	13.1	15562.8
A4	Boiler 2	Site 1	3.07	8.4	11642.4
A5	Fumigation Centrifugation Stage	Site 2	1.66	3.3939	11700
A6	Peroxide Release Zone YB	Site 2	3.32	14.99	14400
A7	Boiler 1	Site 2	8.4	17.1	34350
A8	Boiler 2	Site 2	8.4	11.2	22498
A9	Fumigation VPL	Site 3	0	7.09	22986
A10	Peroxide Release (RSL)	Site 3	0	15	14400
A11	Boiler 1	Site 3	0	1.7	6732
A12	Fumigation Incubation	Site 1	0	2.245	18763.2
A13	Fumigation Harvest	Site 1	0	2.245	8820
A14	Fumigation formulation (sterile)	Site 2	0	19.7	14364
A15	Fumigation media	Site 2	0	5.168	13712.4
A16	Fumigation zone YA Yellow Fever	Site 2	1.66	11.7679	10216.8
A17	Fumigation Tech Dev GMP Lab.	Site 2	1.66	6.576	5918.4
A18	Fumigation Centrifugation (ext)	Site 2	1.66	3.3939	11700

The Operator's Impact Assessment was based on Agency H1 methodology and is summarised in Table 2 below.

Table 2

Substance	Long Term EAL ($\mu g/m^3$)	Short Term EAL ($\mu g/m^3$)	Long Term Effects			Short Term Effects		
			Process contribution ($\mu g/m^3$)	% PC of EAL	> 1% EAL?	Process contribution ($\mu g/m^3$)	% PC of EAL	> 10% EAL?
Nitrogen dioxide (ecological receptor)	30	-	324	1082	**Yes**	7446	-	-
Hydrogen Peroxide	14	280	0.103	0.736	No	2.68	0.957	No
Formaldehyde	5	100	3.13	62.5	**Yes**	82.3	82.3	**Yes**
β-propiolactone	15	-	0.000889	0.00593	No	0.0232		
Nitrogen dioxide (human health receptor)	40	200	324	811	**Yes**	7446	3723	**Yes**
Sulphur dioxide (ecological receptor)	20	-	582	2912	**Yes**	12819	-	-
Sulphur dioxide (human health receptor)	50	267	582	1165	**Yes**	12819	4801	**Yes**
Carbon Monoxide	350	10000	23.9	6.82	**Yes**	619	6.12	No

For those substances where the long or short term Process Contribution exceeds initial screening threshold of 1% and 10% respectively, background air quality was also taken into account. These results are summarised in Table 3 below.

Table 3

Substance	Background ($\mu g/m^3$)	Long Term Effects				Short Term Effects	
		Process contribution ($\mu g/m^3$)	% PC of headroom	Predicted Environmental Concentration ($\mu g/m^3$)	% PEC of EAL	Process contribution ($\mu g/m^3$)	% PC of headroom
Nitrogen dioxide (ecological receptor)	24.5[1]	324	5899	349	**1163**	7446	- -
Formaldehyde	0	3.13	62.5	3.13	62.5	82.3	82.3
Nitrogen dioxide (human health receptor)	24.5[1]	324	2093	349	**872**	7446	**4931**
Sulphur dioxide (ecological receptor)	4.96[2]	582	3870[3]	587[3]	**2935[3]**	12819	- -
Sulphur dioxide (human health receptor)	4.96[2]	582	1292[3]	587[3]	**1174[3]**	12819	**5006[3]**
Carbon Monoxide	385[2]	23.9	-	408.9[3]	**116[3]**		

[1] The Operator's background figure of 24.5$\mu g/m^3$ was comparable with figures on www.airquality.co.uk (2004 database): NO_2 (2004)=22.7$\mu g/m^3$, NO_2 (2005)=22.8$\mu g/m^3$ at 343500, 383500.
[2] The Operator's H1 assessment did not include background figures for SO_2 and CO and was recalculated by the Agency using figures from www.airquality.co.uk (2001 database): SO_2 (2001)=4.96$\mu g/m^3$ and CO(2001)=0.385mg/m^3 at 343500, 383500.
[3] Revised by the Agency based on estimated background concentration for SO_2 & CO.

a) Emissions to air from Combustion Activities

Site 1 has two boilers (duty and standby) that use natural gas as the main fuel source (release points A3 & A4). Site 2 has two boilers (duty and standby) that use medium fuel oil as the main fuel source (release points A7 & A8). Site 3 has a single boiler that uses gas as the main fuel source (release point A11). Site 4 has two boilers that use natural gas as the main fuel source (release point A23). Site 4 is not yet operational and estimated emissions from the two boilers are not included in the above H1 assessment.

The following observations relate to the Operator's H1 assessment:

- It was noted that effective stack heights had been applied following correction for building height. For example, this resulted in an effective stack height of 0m being used for the boiler Site 3.
- It was assumed that all of the boilers were operating continuously, whereas in practice, at sites 1 & 2, the boilers operate as a "duty" and "standby" system with the duty boiler typically running at 50-60% loading.
- Background SO_2 and CO concentrations were assumed to be 0$\mu g/m^3$. The figures in Table 3 have been revised by the Agency to include an estimate of background air quality.

- The emission concentrations for NO_2, SO_2 and CO applied in the H1 are based on limited monitoring and are lower than benchmark figures provided in AQ23(04) – Amendments of PG 1/3 (95) Boilers and Furnaces 20-50MW.

Table 2 concludes that the long term and short term PCs (where appropriate) for NO_2 (ecological and human receptors), SO_2 (ecological and human receptors) and CO all significantly exceed the initial screening threshold for significance, with the exception of the PC_{ST} for CO.

After taking into account background air quality, the H1 assessment concludes that that the relevant short and long term EALs (Air Quality Objectives and Standards) are likely to be exceeded (Table 3).

Given the conservative nature of the H1 assessment, the Agency also carried out some additional assessments.

The AQMAU screening tool was used to model the emissions of NO_2 and SO_2 based on the Operator's H1 inputs and the operation of the duty boilers only (release points A7, A3 & A11). Where a duty and standby boiler system operated, the boiler with the highest mass emission rate in H1 was assumed to be the "duty" boiler). This screening exercise did not include any building effects and assumed an emission temperature of 180^0C. The results of this screening is summarised in Table 4 below.

Table 4

Substance	**Background (µg/m³)**	**Long Term Effects**				**Short Term Effects**	
		Process contribution (µg/m³)	**% PC of headroom**	**Predicted Environmental Concentration (µg/m³)**	**% PEC of EAL**	**Process contribution (µg/m³)**	**% PC of headroom**
Nitrogen dioxide (ecological receptor)	24.5	44.7	813	69.2	**231**	301.2	-
Nitrogen dioxide (human health receptor)	24.5	44.7	288	69.2	**173**	301.2	**199**
Sulphur dioxide (ecological receptor)	4.96	37.9	252	42.9	**214**	993.1	-
Sulphur dioxide (human health receptor)	4.96	37.9	84	42.86	86	993.1	**388**

The output of the Agency's AQMAU screening shows a significant reduction in PCs compared with those in the Operator's H1 assessment. However, the relevant short and long term EALs are likely to be exceeded in each case with the exception of the PC_{LT} for SO_2 (human health impact).

The Agency also estimated the long term emissions based on actual fuel consumption. Combined long term emission rates were calculated from historic fuel consumption (fuel oil and gas), the maximum sulphur content of the fuel oil and/or typical emission factors. These figures are compared with those provided in the Operator's H1 assessment in Table 5 below.

Table 5

Emission rate based on Operator's H1 (duty and standby boilers operating)		Emission rate based on Operator's H1 (duty boilers only operating)		Emission rate based on actual fuel consumption and typical emission factors	
Substance / Source(s)	g/s	Substance / Source (s)	g/s	Substance / Source (s)	g/s
NO_x (A3, A4, A7, A8 & A11)	5.48	NO_x (A3, A7, & A11)	3.50	NO_x (calculated from gas and MFO consumption)	0.64
SO_2 (A3, A4, A7, A8 & A11)	11.47	SO_2 (A3, A7, & A11)	6.93	SO_2 (calculated from gas and MFO consumption)	1.02

Based on actual fuel consumption, it appears that the emission rates used in the Operator's H1 assessment and the Agency's AQMAU screening may represent a significant overestimate. The following table recalculates the Agency's AQMAU screening results, based on the following pro-rata factors:
NO_x = 0.64/3.50 and SO_2 = 1.02/6.93.
[N.B. It is not directly applicable to apply these factors which are based on annual consumption figures to the potential short term effects.]

Table 6

Substance	**Background (µg/m³)**	**Long Term Effects**				**Short Term Effects**	
		Process contribution (µg/m³)	**% PC of headroom**	**Predicted Environmental Concentration (µg/m³)**	**% PEC of EAL**	**Process contribution (µg/m³)**	**% PC of headroom**
Nitrogen dioxide (ecological receptor)	24.5	8.2	-	32.7	109	55.1	-
Nitrogen dioxide (human health receptor)	24.5	8.2	-	32.7	82	55.1	36.5
Sulphur dioxide (ecological receptor)	4.96	5.6	-	10.56	53	146.2	-
Sulphur dioxide (human health receptor)	4.96	5.6	-	10.56	21	146.2	57

In addition to the impact of the boilers at Sites 1, 2 & 3, the installation also includes two boilers at Site 4 which are not yet operational. The operation of these new boilers will also contribute to the overall emissions of NO_2, SO_2 and CO. The impact of site 4 boiler emissions alone were the subject of a comprehensive modelling exercise which is detailed in the Decision Document associated with superseded Permit KP3330LF. In issuing the Permit for Site 4, it was concluded that the boiler technology employed represented BAT and that the impact of emissions was unlikely to be significant. N.B. The assessment took into account background pollutant concentrations which were taken to include the "existing" emissions from Sites 1, 2 & 3. It is planned that once

Site 4 is fully operational, the boilers will replace existing Site 1 and 2 boiler capacity at Sites 1 & 2. Site 1 & 2 activities are scheduled to transfer to Sites 3 & 4 resulting in the closure of the sites.

In conclusion, the Operator's H1 assessment for Sites 1, 2 & 3 indicates that the emissions from the boilers are likely to result in significant breaches of the EALs for NO_2, SO_2 and CO. Additional assessment by the Agency suggests that although the Operator's H1 assessment is likely to significantly overestimate the impact of emissions, breaches of Air Quality Objectives/Standards may take place.

In practice, the Agency considers that this is unlikely for the following reasons:

- The area is not designated as an Air Quality Management Area for these substances;
- Sites 1, 2 & 3 are existing and therefore already contribute to the background air quality; and
- The boilers at Sites 1, 2 & 3 are relatively small, equating in size to the continuous operation of a 4MW combustion unit running at maximum load. The boilers at Sites 1, 2 & 3 are also located some distance apart.

However, given the potential impact of combustion emissions, a specific improvement condition has been included in the Permit to verify this. It requires an assessment of the combined impact of emissions from Sites 1-4 (worst case scenario) and the modelling of the combined emissions from Sites 3 & 4 assuming the transfer of activities from Sites 1& 2 (representing the impact following the closure of Sites 1 & 2). The improvement condition also a timetable for the implementation of any improvements identified.

As two of the boilers at Sites 1 and 2 provide standby cover and the duty boilers typically operate at only 50-60% loading, the reporting of annual mass emissions of SO_2 and NO_x has been included in the Permit to allow trends to be monitored. This will also serve to allow changes following the closure of sites 1 & 2 to be monitored.

Emission Limit Values of 150mg/m^3 for NOx have been included in the Permit for the boilers at Site 4 as these are new, although regular monitoring has not been specified (further background can be found in the Decision Document for superseded Permit KP3330LF). ELVs have not been included for the Site 1-3 boilers, though monitoring "as requested by the Agency" has been specified. It is recommended that this situation is reviewed based on the outcome of the above improvement condition.

<u>b) Emissions to air of Hydrogen Peroxide</u>

Site 2 has one hydrogen peroxide release point (A6) and Site 3 also has one hydrogen peroxide release point identified (A10). [Site 4 also has hydrogen peroxide releases to air, refer to the Decision Document associated with superseded Permit KP3330LF. N.B. Emissions from Site 4 are not taken into account in the above H1 assessment.]

The Operator's H1 assessment for Sites 1, 2 & 3 (based on estimated emissions) calculates the long and short term PCs to be 0.736% and 0.957% of the respective EALs. As such, the emissions are unlikely to be significant. If these results are added to the equivalent long and short term figures from the Site 4 H1 assessment (0.58%

and 0.74% of the EALs respectively), the combined PCs equate to 1.316% of the long term EAL and 1.697% of the short term EAL.

Although the overall long term PC is marginally higher than the initial 1% screening threshold, it is considered that emissions are unlikely to be significant for the following reasons

- the H1 assessment does not take into account the distance between the four sites;
- the background concentration of hydrogen peroxide is likely to be negligible; and
- Hydrogen peroxide is used for periodic fumigation and therefore the Operator's H1 assessment is likely to represent a significant overestimate of the long-term impact.

c) Emissions to air of Formaldehyde

The Operator's H1 assessment quantifies formaldehyde releases from three release points at Site 1 (A1, A12 & A13) and states that fumigation takes place up to twice per year. Other potential release points for formaldehyde have been identified, though emission concentrations are estimated to be 0mg/m^3 (Release points A5, A9, A14-A18) [There are no emissions of formaldehyde from Site 4.]

The Operator's H1 assessment for Sites 1, 2 & 3 (based on estimated emissions) calculates the long and short term PCs to be 62.5% and 82.3% of the respective EALs. As such, the emissions exceed the initial 1% and 10% significance thresholds, below which emissions are unlikely to be significant.

Assuming that the background concentration of formaldehyde is 0µg/m^3, the long term PC, expressed as a percentage of the EAL is 62.5% while the short term PC represents 82.3% of the headroom between the EAL and the background. The former is close to the threshold above which further modelling is typically required while the latter exceeds the "significance threshold" for short term effects. Formaldehyde is used for periodic fumigation, typically over an 8 hour period and therefore the Operator's H1 assessment is likely to represent a significant overestimate of the long-term impact.

The overall mass emissions of formaldehyde are modest during a fumigation event and the substance has a relatively short half-life. For these reasons, together with the fact that the Operator is committed to replacing formaldehyde, it is not considered necessary to investigate emissions of formaldehyde any further. It is, however, recommended that progress regarding the phasing out of formaldehyde be reviewed at future inspections.

d) Emissions to air of β-propiolactone

Site 1 has one β-propiolactone release point (A2). [Site 4 also has β-propiolactone releases to air, refer to the Decision Document associated with superseded Permit KP3330LF. N.B. Emissions from Site 4 are not included in the above H1 assessment.]

The Operator's H1 assessment for Sites 1, 2 & 3 (based on an estimated emission) calculates the long term PC to be 0.00593% of the EAL. As such, the emissions are unlikely to be significant. If this result is added to the equivalent long term figure from the Site 4 H1 assessment (11.75% of the EAL), the combined PC equates to 11.756% of the long term EAL. The long term EAL was derived by the Operator following the guidance in Appendix D of IPPC H1.

Although the overall long term PC is marginally higher than the initial 1% screening threshold, it is considered that emissions are unlikely to be significant for the following reasons:

- the H1 assessment does not take into account the distance between the two sites;
- the background concentration of β-propiolactone is likely to be negligible;
- the assessment of emissions from Site 4 is based on an emission rate calculated from the annual consumption of β-propiolactone i.e. it was assumed that all will be released to air (the worst case scenario); and
- Given the low volatility of this substance, it is unlikely to result in significant emissions to air, the majority of the β-propiolactone is consumed in the reaction and the calculation does not take into account the performance of the abatement systems on emission points A20 and A30.

An improvement condition in the Permit requires the monitoring of actual β-propiolactone releases for Site 4, this will allow the estimated emissions to be verified and the performance of the abatement systems employed to be assessed.

<u>e) Emissions to air of NaOH, H_2S, Hg and compounds from release points at Site 4</u>

Refer to the Decision Document associated with superseded Permit KP3330LF.

<u>Point source emissions to sewer / H1 assessment</u>

This section details the assessment of emissions to sewer from Sites 1, 2 & 3. The assessment includes the following discharge points:

- S1 - Site 1
- S2 - Site 2, sample point a
- S3 - Site 2, sample point b
- S4 - Site 2, sample point c
- S5 - Site 3

The combined effluent flow rate from the above discharge points, applied in the Operator's H1 assessment, is 0.005363 m^3/s which equates to 463m^3/day.
For emissions to sewer from Site 4 reference should be made to the Decision Document associated with superseded PPC Permit KP3330LF. Where appropriate, in-combination effects are also been summarised in this document.

The following table summarises the Operator's H1 assessment for Sites 1, 2 and 3 for emissions of COD, H_2S and Mercury and its compounds. N.B. Some errors were identified in the Operator's original H1 assessment which were discussed with, and accepted by, the Operator during the course of the determination.

Table 7

Substance	Long Term EAL (µg/l)	Short Term EAL (µg/l)	Long Term Effects			Short Term Effects		
			Process contribution (µg/l)	% PC of EAL	> 1% EAL?	Process contribution (µg/m^3)	% PC of EAL	> 1% EAL?
COD	3000	3000	85.4 39.5[1]	2.85 1.32[1]	**Yes**	85.4 39.5[1]	2.85 1.32[1]	**Yes**
Hydrogen sulphide	10	10	0.248 0.115[1]	2.48 1.15[1]	**Yes**	0.248 0.115[1]	2.48 1.15[1]	**Yes**
Mercury and its compounds	0.5	0.5	0.000181 0.000140[1]	0.0362 0.0279[1]	No	0.000181 0.000140[1]	0.0362 0.0279[1]	No

[1] Agency revised H1 assessment as detailed below.

In addition to the Operator's assessment, the Agency has also assessed the impact of emissions to sewer applying a number of revisions to the Operator's H1 assessment:

- A dispersion rate of 10 m^2/s has been applied for the Mersey (considered a freshwater estuary with high dispersion). The Operator had applied a river flow figure of 7.7m^3/s;
- A sewage treatment factor of 0.6 has been applied for COD and H_2S. The Operator had assumed no reduction in concentration at the wastewater treatment works, this factor assumes a typical removal rate; and
- IPPC H1 does not include an EAL for COD, a figure of 3000 µg/l has been included to allow a crude comparison (this figure corresponds to the BOD_5 EAL for designated fisheries and is likely to represent a worst case scenario).

a) <u>Emissions to sewer of Mercury and its Compounds</u>

Emissions figures used in the Operator's H1 assessment are based on the average of actual monitoring results. The Process Contribution for emissions of mercury and its compounds, is calculated to be 0.000181µg/l and 0.000140µg/l based on the Operator's H1 assessment and the Agency revised H1 assessment respectively.
These figures equate to significantly <1% of the EAL (EQS in this case), at 0.0362% and 0.00279% and, as such, are unlikely to be significant.

Assuming that the release concentrations were 10µg/l (corresponding to the previous IPC authorisation) this would increase the calculated Process Contribution to 0.00697µg/l and 0.00537µg/l based on the Operator's H1 assessment and the Agency revised H1 assessment respectively. These figures equate to 1.4% and 1.08% of the EAL (EQS in this case), and, as such marginally exceed the initial screening threshold.

The Process Contribution calculated in the Site 4 H1 assessment was calculated to be 0.00201µg/l, representing 0.401% of the EQS. Combining effluent discharges from Sites 1-4 (assuming a discharge concentration of 10µg/l at all release points) produces a combined Process Contribution that represents 1.48% - 1.80% of the EQS.

Although the overall PC is marginally higher than the initial 1% screening threshold, it is considered that emissions are unlikely to be significant for the following reasons:

- Actual emissions from Sites 1, 2 & 3 are known to be significantly lower than 10µg/l i.e. the above represents the worst case scenario. Actual emissions from

Site 4 are also expected to be lower than those at Sites 1, 2 & 3 as a result of improved segregation techniques; and

- It is assumed that no removal will take place at the wastewater treatment works.

The combined emission rate for Sites 1-3, based on actual monitoring, equates to approximately 44g/annum.

Mercury is present in the Thiomersal ($C_9H_9HgNaO_2S$ – 49.5% Hg w/w) and trace quantities of are also present in the sodium hydroxide solutions consumed.

Although the document "Guidance on Directive 76/464/EEC (Dangerous Substances) and PPC Permitting", dated 11/10/05, indicates that it may not be necessary to impose an ELV for mercury in the Permit, given the quantity of the list I Dangerous Substance consumed in the process and the potential for mercury to enter the sewer if the segregation system is breached and/or via trace contamination in the sodium hydroxide, an ELV of 10 µg/l for the "non contaminated" process effluent release points has been included in the Permit. This will allow the effectiveness of the segregation techniques to be monitored.

b) Emissions to sewer of Hydrogen Sulphide

Emissions of hydrogen sulphide, produced by the degradation of process effluent, have been estimated for release point S1. The Process Contribution is calculated to be 0.248µg/l and 0.115µg/l based on the Operator's H1 assessment and the Agency revised H1 assessment respectively.
These figures equate to 2.48% and 1.15% of the EAL and, as such, marginally exceed the initial screening threshold, below which emissions are generally regarded as insignificant.

The Process Contribution calculated in the Site 4 H1 assessment was 0.121µg/l, representing 1.21% of the EAL. Combining effluent discharges from Sites 1-4 produces a combined Process Contribution that represents 2.36% - 3.69% of the EAL.

Although the overall PC is marginally higher than the initial 1% screening threshold, it is considered that emissions are unlikely to be significant for the following reasons:

- Oxidation is likely to take place during off-site aerobic treatment at Sandon Dock Wastewater Treatment works; and
- The Site 4 release concentration applied in the H1 assessment is based on the likely maximum trade effluent consent limit, Site 1-3 releases are based on estimates.

It is not considered necessary to impose ELVs.

c) Emissions to sewer of Chemical Oxygen Demand

Emissions data used in the Operator's H1 assessment is based on the average of actual monitoring. The Process Contribution is calculated to be 85.4µg/l and 39.5µg/l based on the Operator's H1 assessment and the Agency revised H1 assessment respectively.

These figures equate to 2.48% and 1.15% of the EAL and, as such, marginally exceed the initial screening threshold, below which emissions are generally regarded as insignificant.

The Process Contribution calculated in the Site 4 H1 assessment was calculated to be 27.7µg/l, representing 0.92% of the EAL. Combining effluent discharges from Sites 1-4 produces a combined Process Contribution that represents 2.24% - 3.77% of the EAL (although it should be noted that the EAL applies to BOD_5 and not COD and is not directly applicable).

It is not considered necessary to impose ELVs.

d) Emissions to sewer of Nonylphenol Ethoxylate

Nonylphenol ethoxylate (NPE) is listed in the Operator's H1 assessment, which stated that emissions were likely to be of trace quantities. The release points to sewer that may contain NPEs have been identified. An ongoing monitoring requirement for NPE from appropriate release points to sewer (S3, S4, S5 & S7) has been included in the Permit. In addition, an improvement condition has been included in the Permit requiring the characterisation of NPE emissions, an assessment of the impact of releases and a timetable for the implementation of any measures identified to minimise their release. This will allow the effectiveness of the segregation techniques to be assessed and ELVs to be set at a later date, where appropriate.

Summary

We have reviewed the operator's assessment of the environmental impact of emissions from the installation and also carried out additional screening.

The proposed techniques / emission levels for priorities for control are in line with the benchmark levels contained in the TGN and we consider them to represent BAT for the installation.

A number of substances have been identified which are emitted in significant quantities or require further monitoring and/or verification. These include NO_x & SO_2 (in releases to air from combustion plant), formaldehyde (emissions from fumigation activities), β-propiolactone (releases to air from inactivation activities) and NPE/Mercury (releases to sewer). These substances are subject to ELVs, monitoring requirements or improvement conditions in the Permit.

It is considered that the ELVs/ equivalent parameters or technical measures described above will ensure that significant pollution of the environment is prevented and a high level of protection for the environment secured.

C8 Fugitive emissions of substances

Permit condition 3.3

Based upon the information we are not fully satisfied that the appropriate measures are in place to prevent fugitive emissions.

Section 2.2.4 of the Application refers to the control of fugitive emissions to air and considers dust and VOCs in particular. Potentially dusty materials are used in the media department during the manufacture of media solutions, however emissions are minimised through the HEPA filters within the HVAC systems N.B no filters on the exhaust vents. Routine inspection of raw material and waste storage areas ensure that potential dust emissions are minimised. Potential fugitive emissions of VOCs exist, mainly via the solvent based hand sprays and from medium fuel oil storage, given the small quantities of the hand sprays used and the low volatility of the medium fuel oil, the risk of significant fugitive VOC emissions is considered to be low.

Section 2.2.5 of the Application refers to the control of fugitive Emissions to Surface Water, Sewer and Groundwater. The following areas have been taken into account: subsurface structures (sumps and drains), surfacing, above ground tanks and storage areas. In the case of Sites 1-3 a number of deficiencies, when compared with indicative BAT, were identified (though little detail was provided). No such deficiencies apply to Site 4. The Operator has proposed a review of the existing measures and the introduction of new measures to prevent fugitive emissions, namely:

- Establish appropriate inspection, maintenance and testing programmes (subsurface structures, sumps, surfacing, above ground tanks and storage areas).
- Review primary and secondary containment systems and leak detection or high level indicator techniques for subsurface structures.
- Review the quality of hardstanding for areas not been equipped with an impervious surface, spill contaiment kerbs, sealed construction joints and connection to a sealed drainage system.
- Review the quality of bunding to ensure that there are no outlets present or penetration of containment by pipework.
- Review the storage arrangements including signage, labelling and incompatible substances etc.

An improvement condition has been included in the Permit requiring the development of a fugitive emissions plan which will take into account the above. The ongoing maintenance of the physical measures also falls within the scope of the SPMP.

C9 Conditions relating to Odour

Permit condition 3.4

Based upon the information in the application we are satisfied that the appropriate measures are in place to prevent annoyance from odour.

There is no history of odour complaints except for one to the Agency in June 2001 that related to an item of process equipment that has since been decommissioned.

Section 2.2.6 of the Application for Sites 1, 2 & 3 states that processes are inherently odour free and that odour is well controlled where potential exists. The only source identified was the egg waste tanks that are located within a building at Site 1 (fitted with breather pipes without abatement), although it was noted in another section of the application that egg shell skips were identified as a potential odour source. The Operator has stated that a basic site boundary odour survey will be included as part of the workplace inspection programme. It is recommended that the outcomes of such surveys are reviewed at future inspections.

Section 2.2.6 of the Application for Site 4 also identified the potential for odour from the egg waste tanks as well as bulk liquid waste tanks. The egg waste tanks are located externally and venting will take place via activated carbon filters to minimise the potential for odour.

An improvement condition has been included in the Permit requiring an odour assessment be carried out to verify the effectiveness of the measures in place to minimise potentially odorous emissions from Site 4. The storage of egg waste and bulk liquid waste will be considered together with the optimisation and monitoring of the activated carbon odour abatement systems and interpretation of hydrogen sulphide monitoring results.

C10 Noise and vibration

Permit condition 3.5

Based upon the information in the application we are satisfied that the appropriate measures are in place to prevent annoyance from noise.

Section 2.9 of the Application states that the process activities are inherently quiet and that all main manufacturing operations take place in purpose built buildings. In addition, the multi skilled rooms required for pharmaceutical manufacture provide an acoustic barrier. There is no history of noise complaints relating to Sites 1, 2 & 3 (Site 4 is not yet operational).

Specific noise sources at Sites 1, 2 & 3 are identified in Table 2.9.1 and Figure 9, in each case the potential impact of the noise is considered to be low. Noise sensitive receptors are identified in Table 2.9.2 and Figure 10. Though residential properties are close to Site 2, the installation and receptors are separated by a busy main road.

Similarly for Site 4, a number of noise sources are identified in Table 2.9.1 and Figure 8, these include a number of sources where specific noise attenuation will be considered during the detail design stage, namely, the chiller units (located externally), pressure relief valves on combustion plant, zone 1 & 2 vents and zone 4 & 5 decontamination vents. A pre-operational condition for Site 4 has been included in the Permit requiring the implementation of any abatement measures identified during the detailed design stage. As above for Sites 1-3, the Operator has provided details of noise receptors (Table 2.9.2 and Figure 9).

The Operator has stated that all equipment is subject to routine planned preventative maintenance and that the selection of equipment has taken into account potential noise emissions. Given the local predominant noise sources (including road and airport traffic) and the location of potentially sensitive receptors, the Agency believes that although some activities to be carried out at the installation have the potential to cause noise, such noise is not likely to cause annoyance and the Applicant's proposals in respect of noise control represent BAT.

An improvement condition has been included in the Permit requiring noise surveys to be carried out for Site 4 (once operational) and also Site 3 (following the transfer of activities from Sites 1 & 2). This condition will serve to verify that noise from these

areas is not likely to cause annoyance and allow the performance of noise attenuation measures to be assessed for Site 4. In the case of Site 3, the improvement condition will allow the noise impact of the re-configured site to be assessed.

C11 Monitoring

Permit condition 3.6

We have decided that monitoring should be carried out for the parameters listed in tables S4.1a, S4.1b, S4.1c, S4.1d, S4.3a, S4.3b, S4.3c, S4.3d in schedule 4 using the methods and to the frequencies specified in those tables. These monitoring requirements have been imposed in order to ensure that, in the case of discharges to sewer, compliance with ELVs is maintained and to allow trends in process effluent quality to be recorded. In the case of emissions to air, monitoring may be requested by the Agency on an ad hoc basis to demonstrate compliance with ELVs or to allow comparison with appropriate benchmark figures.

Based on the information in the application we are not fully satisfied that the operator's techniques, personnel and equipment have either MCERTS certification or MCERTS accreditation as appropriate. A specific improvement condition has been included in the Permit to address this area.

C13 Reporting

We have specified reporting as detailed in Schedule 5 to allow the periodic reporting of monitoring data for emissions to air (where required by the Agency) and the monthly reporting of the monitoring of the emissions to sewer from the installation. The latter allows the segregation techniques employed at the installation for mercury and nonylphenol ethoxylate to be regularly assessed.

C14 Miscellaneous

a) Relevant Secretary of State Directions

There are no Secretary of State Directions made under the Pollution Prevention and Control (England and Wales) Regulations 2000, as amended, which are relevant to the determination of this Application.

b) Implementation of the Solvent Emissions Directive (SED) (1999/13/EC)

The Installation does not include any activity listed in Annex I of the Directive or activity which, whilst listed in Annex I, is above the relevant threshold in Annex IIA. so no provisions of the SED apply.

c) Environment Act 1995 – Section 81 (National Air Quality Strategy)

In determining the conditions for this Permit, the Agency has had regard to the National Air Quality Strategy. The Agency considers that it has taken its decision in compliance with the NAQS, and that there are no additional conditions that should be included in this Permit.

d) Groundwater Regulations 1998

The installation does not permit the direct discharge of List I/II substances to groundwater and the necessary measures are in place to prevent an indirect discharge.

e) Water Framework Directive Regulations 2003

Consideration has been to whether any additional requirements should be imposed in terms of the Agency`s duty under regulation 3 to secure the objectives of the Water Framework Directive through (inter alia) PPC permits, but it is felt that existing conditions are sufficient in this regard and no other appropriate requirements have been identified.

f) Waste Management Licensing Regulations (WMLR 1994) - (pursuit of the relevant objectives where there is the disposal or recovery of waste)

The installation includes no activities for the disposal or recovery of waste.

g) Waste Oils Directive

The installation does not contain waste disposal or recovery activities involving waste oils to which the Directive applies.

h) Hazardous Waste Directive

The installation does not contain hazardous waste disposal or recovery activities to which the Directive applies.

i) The Conservation (Natural Habitats etc) Regulations 1994

The following European site is approximately 2.5 km from the installation:

- Mersey Estuary (SPA/RAMSAR site)

The combustion process at the PPC installation is not considered '*relevant*' for assessment under the Agency's procedures which cover the Conservation (Natural Habitats &c.) Regulations 1994 (Habitats Regulations). This was determined by referring to the Agency's guidance 'AQTAG014: Guidance on identifying 'relevance' for assessment under the Habitats Regulations for installations with combustion processes.' Thus no detailed assessment of the effect of the releases from the installation's combustion processes on SACs, SPAs and Ramsar sites is required.

Regarding other 'non combustion' emissions from the installation, a stage 2 (HR01) assessment was completed and forwarded to Natural England. This concluded that the installation is unlikely to have a significant effect 'alone or in combination' on the European site. This conclusion was supported by Natural England.

j) Countryside and Rights of Way Act 2000 (CROW 2000)
Section 85 duty concerning Areas of Outstanding Natural Beauty (AONB)

There is no AONB which could be affected by the Installation.

k) Section 28G Wildlife and Countryside Act 1981 (WCA 1981) duty concerning SSSIs

There are no SSSIs within the 2km 'screening distance'.

l) Environment Act 1995 – Section 7 (Pursuit of Conservation Objectives)

Consideration has been given to whether any additional requirements should be imposed in terms of the Agency's duty to have regard to the various conservation objectives set out in s 7 EA 1995, but it is felt that existing requirements are sufficient in this regard and no other appropriate requirements have been identified.

ANNEX 1 : CONSULTEE AND PUBLIC RESPONSES

Advertising and statutory consultation

Summary of responses to advertising and statutory consultation and the way in which we have taken these into account in the determination process:

Brief summary of issues raised	**Response received from**	**Summary of actions taken or show how this has been covered**
Subject to satisfactory management, it is considered unlikely that any adverse effects to public health would result from vaccine production at this site.	Central Liverpool PCT (11 September 2006)	No specific action required.
1. Noted that the H1 assessment concludes that emissions of formaldehyde to air are significant but that the Operator is working towards the elimination of formaldehyde based fumigation. 2. Emissions of mercury to sewer are above 1% of the EAL. The Applicant should consider suitable abatement to control releases. 3. Provided that the Operator complies with the relevant parts of the TGN, it is unlikely that there will be any unacceptable effects on the human food chain.	Food Standards Agency (11 May 2006)	1. An improvement condition has been included in the Permit requiring the monitoring of formaldehyde releases during fumigation activities. This will allow the impact to be fully quantified and action taken, where appropriate. Progress regarding the substitution of formaldehyde will be monitored at future inspections. 2. This was an error in the Application (confirmed with the Operator). Actual emissions are <1% of the EAL. ELVs for Mercury have been included in the Permit. 3. No specific action required.
1. Site 4 does not yet have a discharge consent, when issued it is expected to include limits on mercury and alkyl phenol ethoxylate. 2. Agree with the statement that the trade effluent has a low impact on the operation of the receiving WwTW. 3. Agree that for this small volume bidegradable effluent, treatment at the WwTW represents BPEO/BAT.	United Utilities (30 May 2006)	1. Monitoring of mercury and nonylphenol ethoxylate has been included in the Permit. 2. No specific action required. 3. No specific action required.

ANNEX 2 Improvement conditions

Ref no	Condition	Date	Reason
1	The Operator shall carry out a noise assessment for Sites 3 and 4 of the Permitted Installation in accordance with the requirements of BS4142: 1997 – Method for Rating Industrial Noise affecting mixed Residential and Industrial Areas. The assessment shall consider the background noise climate and the impact of operations during daytime and night-time periods. A report summarising the outcome of the assessment, including a timetable for the implementation of any improvements identified, shall be submitted to the Agency.	Within 6 months of the commencement, at Site 4, of activities covered by the description in Section 4.5 A(1)(a) in Schedule 1 of the PPC Regulations (unless otherwise agreed in writing with the Agency).	This condition requires the Operator to carry out a quantitative assessment of noise from Site 4, once operational, and Site 3 following the transfer of activities from Sites 1 & 2. A deadline (within 6 months of the listed activity being carried) has been set. However an alternative date may be agreed with the Agency, where this is appropriate e.g. if full scale production at Site 4 is not achieved within the 6 month period.
2	The Operator shall, having regard to Agency Guidance Note IPPC H4 Odour Part 2 – Assessment and Control, verify the effectiveness of the measures in place at Site 4 to minimise potentially odorous emissions from the Permitted Installation. A written summary of the assessment shall be submitted to the Agency, which shall include, but not be limited to, the following: • the handling and storage of egg waste and bulk liquid waste; • the maximum storage period for egg waste and bulk liquid waste; • the optimisation and monitoring of the activated carbon odour abatement systems; • interpretation of the results of the monitoring for hydrogen sulphide from emission points A24, A25, A26 & A27, detailed in improvement condition 3; and • a timetable for the implementation of any improvements identified.		This condition requires an assessment of the effectiveness of the measures in place to minimise odour from the installation, once it is operational. The condition is considered necessary as the activities to be carried out have the potential to cause odour. A deadline (within 6 months of the listed activity being carried) has been set. However an alternative date may be agreed with the Agency, where this is appropriate e.g. if full scale production at Site 4 is not achieved within the 6 month period.
3	The Operator shall, having regard to Agency Guidance Note M2: Monitoring of Stack Emissions to Air, undertake monitoring to verify the estimated emissions to air, of the following substances: • β-propiolactone from emission points A20, A29 & A30; • Mercury and its compounds from emission point A20; • Hydrogen sulphide from emission points A24, A25, A26 & A27; and • Oxides of nitrogen from emission point A23. The emissions of β-propiolactone and mercury and its compounds shall be monitored during periods corresponding with maximum β-propiolactone and Thiomersal consumption. A report summarising the monitoring, including details of the methodology used and interpretation of the results, shall be submitted to the Agency.		This condition requires the verification of key emissions from the installation, once operational. The results are to be compared with the estimated emission figures provided in the Application to ensure that the conclusions of the H1 assessment remain valid. A deadline (within 6 months of the listed activity being carried) has been set. However an alternative date may be agreed with the Agency, where this is appropriate e.g. if full scale production at Site 4 is not achieved within the 6 month period.
4	The Operator shall, having regard to Agency Guidance Note H1, undertake an exercise to	30/09/07	This condition requires further assessment of the emissions from

	assess the combined impact of the emissions to air from combustion plant at the installation. A report summarising the exercise shall be submitted to the Agency, which shall include, but not be limited to, the following: • details of, and justification for, the methodology used; • assessment of the combined impact of emissions from Sites 1 to 4; • assessment of the combined impact of emissions from Sites 3 and 4 (assuming the transfer of activities from Sites 1 & 2); and • a timetable for the implementation of any improvements identified.		installation combustion plant. Two scenarios have been identified: Sites 1-4 and Sites 3 & 4 (the latter reflecting the future impact following the closure of Sites 1 & 2 and the reconfiguration of Site 3). Given the size of the boilers, the assessment should be proportionate to the risk and, alternative approaches to comprehensive modelling may be acceptable e.g. submission of original stack height design calculations etc.
5	A report shall be submitted to the Agency detailing the emissions of nonylphenol ethoxylates to sewer from the Installation. The report shall include the following: • characterisation of the emissions; • an assessment of their impact; and • a timetable for the implementation of any measures identified to minimise their release.	30/09/07	This condition will allow the effectiveness of the segregation techniques to be reviewed and an assessment of the impact of nonylphenol ethoxylate emissions to sewer to be carried out. The assessment will be based on actual monitoring data, not available at the time of the Permit application.
6	A written procedure shall be submitted to the Agency detailing the measures to be used so that monitoring equipment, personnel and organisations employed for the emissions monitoring programme shall have either MCERTS certification or accreditation in accordance with condition 3.6.3 where this is appropriate. The notification requirements of condition 2.5.2 shall be deemed to have been complied with on submission of the procedure.	31/12/07	At the time of Permit issue, and, where appropriate, not all of the operator's techniques, personnel and equipment have either MCERTS certification or MCERTS accreditation.
7	A fugitive emission management plan shall be submitted to the Agency, detailing the measures to be used to control fugitives emissions to surface water, sewer and groundwater which shall be in accordance with Section 2.2.5 of Agency Guidance Note IPPC S4.02. The plan shall be implemented by the operator from the date of approval in writing by the Agency	31/12/07	The operator proposed a review of the measures in place to prevent fugitive emissions in areas where there may be deficiencies (generally relating to inspection, maintenance and testing programmes). Given that there have been documented spillages/leaks from the drainage system it is considered appropriate to include this specific improvement condition.
8	The Operator shall, having regard to Section 2.4 of Agency Guidance Note IPPC S4.02, carry out a waste minimisation audit and water use audit of the Installation. A report summarising the audits, including details of the methodology used and a timetable for the implementation of any improvements identified, shall be submitted to the Agency.	31/12/08(unless otherwise agreed in writing with the Agency).	Waste/Water audits have not been carried out and, once completed, standard Permit conditions will require periodic review. An alternative deadline date can be agreed with the Agency, where this is appropriate e.g. if full scale production at Site 4 has not been achieved by the deadline.
9	The Operator shall develop and implement a formal Environmental Management System, having regard to Section 2.3 of Agency Guidance Note IPPC S4.02.	31/12/07	This improvement condition will address the deficiencies identified in the Application. Refer to section B1 of this document for further detail.