ENVIRONMENT AGENCY

Variation Notice with introductory note

Pollution Prevention and Control (England & Wales) Regulations 2000

Gaskill Road, Speke Vaccines

Novartis Vaccines and Diagnostics Limited
Gaskill Road
Speke
Liverpool
L24 9GR

Variation Notice Number

YP3531UV

Permit number

BS5401IK

Gaskill Road, Speke Vaccines
Permit Number BS5401IK/YP3531UV

Introductory note

This introductory note does not form a part of the permit

The following notice is issued under regulation 17 of The Pollution Prevention and Control (England and Wales) Regulations 2000 (S.I.2000 No. 1973 (as amended) (the Regulations) to vary the conditions of a permit issued under the Regulations to operate an installation. The notice comprises schedule 1 containing conditions to be deleted, schedule 2 conditions to be amended and schedule 3 conditions to be added.

Permit BS5401IK

The main features of the installation are as follows:

The installation comprises 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, incubation and harvesting of 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 AO0768) 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 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.

Purpose of Variation YP3531UV

This variation enables the implementation of four plant modifications that will have negligible impact on the environment and one modification that involves changes to the nature and function of the process.

The four low impact changes comprise:

- Moving the formulation suite in Site 2 to Site 3. This requires the addition of a new emission point at site 3, referenced A36, to enable the release of small quantities of propan-2-ol to air.
- Approval for a potential change to the method of centrifugation
- The use of a temporary standby boiler until a permanent replacement is installed
- The use of temporary chiller units until parallel operations on Sites 1 and 4 cease.

The more significant modification concerns:

- An egg waste and waste water treatment plant. This will perform two functions: to heat treat egg waste to ensure the complete destruction of any virus that may be present, and; to treat the waste water discharges to remove mercury and nonyl phenol ethoxylate that may be present.

Finally, a modification to the permit has been made to modify the sampling regime for releases from emission point S3. It was not possible to collect representative samples on a flow proportional basis, so this requirement has been changed so that samples are collected on a time proportional basis.

Status Log of the permit

Detail	Date	Response Date
Application BS5401IK	Duly made 29/03/06	
Response to request for further information.	Request dated 16/11/06	11/12/06
Permit issued	21/12/06	
Application for variation YP3531UV	Duly made 28/09/07	
Variation issued	20/12/07	

Superseded Authorisations relating to this installation

Holder	Reference Number	Date of Issue	Fully or Partially Superseded
Evans Medical Ltd.	AO0768 (as varied)	21/12/94	Fully superseded
Chiron Vaccines Limited	KP3330LF	06/04/06	Fully superseded

End of Introductory Note

Variation Notice

Permit number
BS5401IK
Variation number
YP3531UV

The Environment Agency (the Agency) in exercise of its powers under Regulation 17 of the Pollution Prevention and Control (England and Wales) Regulations 2000 (SI 2000 No 1973) hereby varies the permit held by you
Novartis Vaccines and Diagnostics Limited ("the operator"),

whose registered office is
Frimley Business Park
Frimley
Camberley
Surrey
GU16 7SR

company registration number **3970089**

to operate an installation at
Gaskill Road
Speke
Liverpool
L24 9GR

to the extent set out in schedules 1 to 3 of this variation notice .

The notice shall take effect from 21 December 2007

Signed	Date
Catherine Shaw	21 December 2007

Catherine Shaw

Authorised to sign on behalf of the Agency

SCHEDULE 1 – CONDITIONS TO BE DELETED

1. None

SCHEDULE 2 – CONDITIONS TO BE AMENDED

2. Table S1.1 (Activities), referred to in Condition 2.1.1 of the permit, shall be amended to show the additional activities permitted by this variation. The amended Table S1.1 (Activities) is shown below.
3. Table S1.2 (Operating Techniques), referred to in Condition 2.3.1 of the permit, shall be amended to show the additional operating techniques permitted by this variation. The amended Table S1.2 (Operating Techniques) is shown below
4. Table S4.1c (Site 3 Point source emissions), referred to in Condition 3.6.1 of the permit, shall be amended to show the added emission point A36. The amended Table S4.1c (Site 3 Point source emissions) is shown below
5. Table S4.3b (Site 2 Point source emissions), referred to in Condition 3.6.1 of the permit, shall be amended to show the modified reference period for certain emission points. The amended Table S4.3b (Site 2 Point source emissions) is shown below

SCHEDULE 3 – CONDITIONS TO BE ADDED

6. None

Table S1.1 Activities

Activity listed in Schedule 1 of the PPC Regulations	Description of specified activity	Limits of specified activity
Section 4.5 Part A(1)(a) – Producing pharmaceutical products using a chemical or biological process.	The manufacture of seasonal/pandemic influenza and yellow fever vaccines.	From the receipt of raw materials to the manufacture, storage and despatch of finished product (including the cleaning and fumigation of process plant, and the storage and handling of waste/wastewater arising from the process).
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.	Treatment of process effluent from Site 4.	Physical treatment (pH and temperature control) prior to discharge into the public sewer.
Section 6.8 Part A(1)(c) – disposing of or recycling animal carcasses or animal waste, other than by rendering, at a plant with a treatment capacity exceeding 10 tonnes per day of animal carcasses or animal waste or, in aggregate, of both.	Treatment of egg waste from Site 4.	Collection of egg waste through to filtration, drying and collection prior to site disposal
Directly Associated Activity		
Steam Supply	Operation of the following combustion plant for heating, sanitisation and sterilisation purposes: • Site 1 – 1.4MW & 2.1MW gas-fired boilers; • Site 2 – two 5.0MW fuel oil-fired boilers; • Site 3 – 1.4MW gas-fired boiler; and • Site 4 – two 5.4MW gas-fired boilers.	From the receipt, handling and combustion of fuel to steam generation (including the storage of heavy fuel oil).
Heating Ventilation & Cooling	Maintenance of workplace environment and air quality.	Operation of Heating Ventilation & Cooling (HVAC) systems
Refrigeration	The operation of Blast Chillers.	The cooling of eggs following incubation.
Water Purification.	The production of Purified Water (PW) and Water for Injection (WFI).	Water purification using softeners, reverse osmosis, electro-deionisation and distillation techniques.

Table S1.2 Operating techniques

Description	Parts	Date Received
Application	The response to section 2.1 and 2.2 in the Application.	29/03/06
Response to request for additional information.	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.	11/12/06
Application for variation YP3531UV	The response to section 2 in the Application for the variation	28 September 2007
Additional information	Two letters clarifying aspects of the variation	15 October 2007 12 December 2007

Table S4.1c (Site 3) Point source emissions to air – emission limits and monitoring requirements						
Emission point ref. & location (as detailed on Figure 5, rev B dated 12/12/07)	**Parameter**	**Source**	**Limit (including unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method[1]**
A9	No parameters set	VPL suite	No limit set	-	-	-
A10	No parameters set	RSL suite	No limit set	-	-	-
A11	Oxides of Nitrogen (expressed as NO2) (mg/m3)	Boiler 1	No limit set	Hourly average	As requested by the Agency	ISO 10849
A36	Propan-2-ol	HVAC system	No limit set	-	Annual	Mass balance

Note 1: Permanent sampling access not required.

Table S4.3b (Site 2) Point source emissions to sewer, effluent treatment plant or other transfers off-site– emission limits and monitoring requirements						
Emission point ref. & location	**Parameter**	**Source**	**Limit (incl. Unit)**	**Reference period**	**Monitoring frequency**	**Monitoring standard or method**
S2 (Point W6 on Figure 6, received 11/12/06) to Gaskill Road sewer.	Total Mercury	Process Effluent & Surface Water run-off.	10µg/l	Weekly flow proportional composite sample[1].	Weekly	Cold vapour atomic absorption technique.
S2 (Point W6 on Figure 6, received 11/12/06) to Gaskill Road sewer.	Total Mercury (µg/l)	Process Effluent & Surface Water run-off.	No limit set	Spot sample	Monthly	UKAS accredited
S3 (Point W7 on Figure 6, received 11/12/06) to Speke Boulevard sewer.	Total Mercury	Process Effluent & Surface Water run-off.	10µg/l	Weekly time proportional composite sample[1].	Weekly	Cold vapour atomic absorption technique.
S3 (Point W7 on Figure 6, received 11/12/06) to Speke Boulevard sewer.	Total Mercury (µg/l)	Process Effluent & Surface Water run-off.	No limit set	Spot sample	Monthly	UKAS accredited
S3 (Point W7 on Figure 6, received 11/12/06) to Speke Boulevard sewer.	Nonylphenol ethoxylate (µg/l)	Process Effluent & Surface Water run-off.	No limit set	Weekly time proportional composite sample[1].	Monthly	UKAS accredited
S4 (Point W8 on Figure 6, received 11/12/06) to Speke Boulevard sewer.	Total Mercury	Process Effluent & Surface Water run-off.	10µg/l	Weekly flow proportional composite sample[1].	Weekly	Cold vapour atomic absorption technique.
S4 (Point W8 on Figure 6, received 11/12/06) to Speke Boulevard sewer.	Total Mercury (µg/l)	Process Effluent & Surface Water run-off.	No limit set	Spot sample	Monthly	UKAS accredited
S4 (Point W8 on Figure 6, received 11/12/06) to Speke Boulevard sewer.	Nonylphenol ethoxylate (µg/l)	Process Effluent & Surface Water run-off.	No limit set	Weekly flow proportional composite sample[1].	Monthly	UKAS accredited

Note 1: A daily composite sample shall be used until installation, no later than 30/04/07, of a weekly flow proportional sampling device.