Environment Agency Permitting decisions

Bespoke Permit/Variation

We have decided to issue the minor technical variation for Gaskill Road, Speke Vaccines operated by Novartis Vaccines and Diagnostics Limited.

The permit number is EPR/BS5401IK

We consider in reaching this decision we have taken into account all relevant considerations and legal requirements so that the permit will ensure that the appropriate level of environment protection is provided.

In brief the variation introduces the following changes:

A non-technical description of the variation is given in the application but the main features of the Variation include:

- There is a change to sodium hydroxide receipt, storage and process introduction on site 4 south apron from usage of IBC's to bulk storage. Additional facilities and accident management facilities and procedures have been introduced for containment of tanker off loading operations. Two new sodium hydroxides tanks totalling 35m3 are contained within appropriate bunding (one tank for industrial grade and one for pharmaceutical grade caustic). The annual usage of sodium hydroxide for activities as listed below is unchanged at 370 m3 approximately.
- There is a change to phosphoric acid receipt, storage and process introduction on site 4 south apron from usage of IBC's to bulk storage. Additional facilities and accident management facilities and procedures have been introduced for containment of tanker off loading operations. Two new phosphoric acid tanks totalling 28m3 are contained within appropriate bunding (one tank for industrial grade and one for pharmaceutical grade acid). The annual usage of phosphoric acid for activities as listed below is unchanged at 130 m3 approximately.

The industrial grade caustic and phosphoric acid are utilised for pH correction of the waste streams in the Effluent Treatment Area (ETA) and the industrial grade caustic also utilised as a scrubbing fluid for odour abatement scrubber in the ETA. In addition the industrial grade caustic and phosphoric acid are utilised in the Cleaning in Place cycles within the ETA. Pharmaceutical grade caustic and phosphoric acid are supplied directly for cleaning process equipment as part of Cleaning in Place (CIP) cycles.

This current variation will not result in new raw materials usage or in any increased usage levels of existing raw materials.
The facilities have been designed to minimise environmental impact and the risk of additional environmental impact is insignificant.

The operator has highlighted that future site 4 production capacity increases leading to potential increased raw material usage including sodium hydroxide and phosphoric acid will be introduced by a further future variation. The future changes proposed are linked to a third new harvest line.

Purpose of this document

This decision document:

- explains how the application has been determined
- provides a record of the decision-making process
- shows how all relevant factors have been taken into account
- justifies the specific conditions in the permit other than those in our generic permit template.

Unless the decision document specifies otherwise we have accepted the applicant's proposals.

Structure of this document

- Key issues
- Annex 1 the decision check list.

Key Issues

In light of this variation being a minor technical change without any new raw materials or existing raw material usage increases plus no production capacity increases and no new emission points it is considered proportionate to utilise the checklist tables below to summarise the impact of this variation. The following key issues section only covers small extra points linked to an additional information response dated 24/09/10 from the operator not otherwise covered in checklist table:

1. Energy

An additional response received dated 24/09/10 confirmed the additional electrical energy consumption as 0.75 MWH.

In brief this additional usage is linked to eight new pumps. Four of them are electrical pumps and there are also four off air driven pumps with associated electrical consumption to compress the air. Four of the pumps are for feeding of material from tanker offload point to the storage tanks. Each tanker offload point is clearly labelled to avoid errors. In addition there are two pairs of pumps for discharging caustic and phosphoric acid in to the process/effluent treatment area facilities. There is a duty and standby pump for each material housed in a contained fashion on a separate raised plinth within each of the main tanks bunds

This is an insignificant energy increase.

2. Liquid containment and Sump volume

After a site visit dated 22-09-10 the following observations were made about the sump containment linked to catastrophic tanker/pipe work failure. There are four tanks with two pairs of tanks for each chemical phosphoric acid and caustic soda.

- Phosphoric acid (18 m3 clean grade and 10 m3 industrial grade 10 m3).
- Caustic soda (clean grade 25 m3 and 10 m3 for industrial grade caustic)

This compares with approximately 19 one m3 IBC's of phosphoric acid and 19 one m3 IBC's of caustic soda on site at any time.

The pairs of tanks sit within separate bunds each of volume > 110 % of individual tanks working volume and > 25 % of combined working tank volumes.

The main sump is of volume 30 m3. Details of its usage are summarised in operating procedure section.

3. Operating procedure

The operator confirmed in additional response dated 24/09/10 that a formal written operating procedure for the tanker off-loading and bulk chemical storage will be completed by wet commissioning phase which is not expected before December 2010. On the basis of the summary of the operating procedure being provided for emergency tanker off loading as detailed above under heading Liquid containment and sum

The operator confirmed regarding the operating procedure and facility:

- All tanker offloads will function via a written formal procedure.
- All tanker offloads will be supervised.
- Connections to pipe work for acid and caustic are different to avoid error (in combination with clear labelling)
- A sloping tanker bay runs off to a 3 m3 sump.
- There is a new automatic level probe to fitted to this existing sump with a high level setting automatically initiates sump pump operation
- The material is transferred to a larger approximately 30 m3 sump which is able to hold a complete tanker volume of 20 m3.
- Material will then be assessed and as required tankered off site by a licensed waste contractor
- Spill kits will be available locally to further minimise risk of caustic and phosphoric acid discharging to surface water drains. Drains are approximately 12 metres from the tanker off loading bay allowing for remedial action. In addition the operator already has training in place for the usage of spill kits
- The emergency procedure for tanker/ pipe work failure as outlined above will be included in overall formal written operating procedure.

On the basis of the above the Environment Agency is satisfied with the sufficiency of these commitments to ensure an adequate operating procedure will be in place to minimise environmental impact. On this basis it is considered a pre-operational condition to formally review operating procedure is not required.

4. Post storage tank process changes
Apart from the four discharge pumps as listed in section 1 above the changes on discharge side of bulk tanks is minimal. Existing process pipe work will be utilised currently linked to the IBC's which will be replaced by the bulk system. The positioning of the bund close to current IBC station has further led to pipe work modifications to tie into these existing lines to be kept to a minimum. There are therefore no environmental issues on the discharge side of these bulk tanks.

Annex 1: decision checklist

This checklist should be read in conjunction with the Duly Making checklist.

Activity	Justification / Detail	Determination criteria met	
		Yes	N/A
Receipt of submission			
Confidential information	A claim for commercial or industrial confidentiality has not been made. The decision was taken in accordance with our guidance on commercial confidentiality.	✓	
Consultation			
Scope of consultation	No consultation required for minor technical change		✓
Operator			
Control of the facility	We are satisfied that the applicant (now the operator) is the person who will have control over the operation of the facility after the grant of the permit. The decision was taken in accordance with EPR RGN 1 Understanding the meaning of operator.	✓	
European Directives			
Applicable Directives	All applicable European Directives have been considered in the determination of the application.	✓	
The site			
Extent of the site of the facility	The installation boundary has not changed and therefore no site plan is required. The operator has provided an unaltered site plan for information only	✓	
Site condition report (installations, waste operations and relevant mining waste operations only - not mobile plant)	No site condition report required as installation boundary unchanged.	✓	
Biodiversity, Heritage, Landscape and Nature Conservation	The variation has not introduced additional hazards to local habitats. Therefore no habitat assessment has been made. The decision was taken in accordance with our guidance.	✓	
Environmental Risk Assessment and operating techniques			
Environmental risk (use when the operator has carried out the risk assessment)	We have reviewed the operator's assessment of the environmental risk from the facility. The operator considers this risk assessment is satisfactory. The assessment shows that, applying the conservative criteria in our guidance on Environmental Risk Assessment all emissions may be categorised as environmentally insignificant. In brief the H1 screening assessment confirmed ● No additional odour impact ● No additional fugitive emission impact. Caustic soda and phosphoric acid tanks are all suitably bunded and usage of fixed volume deliveries and high level alarms minimises spillage even within bunds. ● Noise levels – insignificant increase. No residential properties within one km. Some improvements with reduced frequencies of tanker arrivals relative to IBC deliveries and removals. ● Accident management – a H1 screening assessment has highlighted potential hazards linked to phosphoric acid and/or caustic soda catastrophic failure of tanker/pipes feeding storage tanks. Additional response is discussed in Key Issues but in brief this response dated 24/09/10 confirms that a sump is dedicated to receive such spillages and the tanker bay is designed to flow away into this sump. There are no new emission points needing environmental assessment. In brief controls introduced have allowed an assessment that environmental risks linked to this permit variation are insignificant	✓	
Operating techniques	We have reviewed the techniques used by the operator and compared these with the relevant guidance notes.	✓	

Activity	Justification / Detail	Determination criteria met	
		Yes	N/A
	Key operating techniques include the usage of high level alarms for new storage tanks, restricted volume deliveries to prevent overfills , adequate bunding > 110 % of individual tank working volumes and > 25 % of combined tank working volumes, process control system automated control of tanker off-loading, automatic shut offs at high levels and sumps to collect emergency scenario tanker leakage. The operator has committed to regular inspection of the bunds and to annual bund integrity tests. A formal operating procedure is to be put in place and mandatory operator supervision of tanker off-loading at all times. In addition the operator has committed to setting up a preventative maintenance schedule on critical instruments e.g. level indications and alarms on complete of commissioning. 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 appropriate techniques for the facility.		
The permit conditions			
Use of conditions other than those from the template	No non-standard permit conditions are utilised in this variation.	✓	
Odour alternative conditions (installations and waste operations only)	No additional odour sources and hence no additional risks linked to this variation.	✓	
Noise alternative conditions (installations and waste operations only)	The noise of tankers will have minimal impact as frequency is low ● 2 tankers of caustic soda per month ● 1 tanker of phosphoric acid per month This is offset by the removal of regular receipt at site of phosphoric acid and caustic IBC deliveries (13 per month prior to variation changes). In addition there is no residential properties within more than one km of the site 4 boundary and no noise complaints have been received within the four years since original permit determination.	✓	
Raw materials (installations and waste operations only)	No additional raw materials are utilised as a result of this variation and the raw material annual consumption of phosphoric acid and caustic soda is unchanged.	✓	
Pre-operational conditions	Based on the information on the application, we consider that there is no need to impose pre-operational conditions. Please see reasoning in operating techniques section within key issues section of this document.	✓	
Improvement conditions	Based on the information on the application, we consider that we do not need to impose improvement conditions.	✓	
Emission limits	There are no changes to emission limits or introduction of new emission limits linked to this variation.	✓	
Monitoring	We have decided that no further monitoring linked to this variation. This is based on no new emission points linked to this variation.	✓	
Reporting	There are no new reporting requirements linked to this variation.	✓	
Operator Competence			
Environment Management System	There is no known reason to consider that the operator will not have the management systems to enable it to comply with the permit conditions. The decision was taken in accordance with RGN 5 on Operator Competence.	✓	
Relevant Convictions (installations, waste operations and relevant mining waste operations only)	The National Data Base was checked for relevant convictions. No relevant convictions were found.	✓	
Financial provision (installations, waste operations and mining waste operations only)	There is no known reason to consider that the operator will not be financially able to comply with the permit conditions. The decision was taken in accordance with RGN 5 on Operator Competence.	✓	
OPRA			
OPRA Score (Tier 3 operations that are not C for D only)	The OPRA score has not changed as a result of this variation. It remains at 166.	✓	