

1. Non-Technical Summary

1.1 Overview of Activities

The MSD Animal Health Production facility at Milton Keynes ("MSD AH") is an existing facility manufacturing vaccines from approximately thirty (30) strains of micro-organism. MSD is a trade name of Merck & Co., Inc., with headquarters in Kenilworth, N.J., U.S.A. The site is part of the manufacturing division, specialising in vaccines for the animal health market.

The vaccines are licenced for use in specific target animals, both domestic and livestock.

The vaccines are manufactured using inactivated sterile antigens produced on the site, formulated with proprietary adjuvant and buffered saline. The inactivated sterile antigens from this facility are used in the formulation of multi-valent vaccines both at Milton Keynes and at other MSD sites in the Netherlands and Spain.

1.2 Operating Techniques

The current antigen production facility operates the following production processes:

- Whole cell antigen, with inactive Downstream Processing (DSP) – *Salmonella*, *Pasteurella* & *Mannheimia*;
- Whole cell antigen with inactive DSP – *Mycoplasma*; and
- Inactivated toxins and cells from a range of *Clostridium*.

Growth media and solutions for antigen preparation are prepared in the general services area and transferred by fixed pipework to the fermenters. The media can be sterilised by filtration or by heat, using steam within the fermenter vessels themselves.

Cell cultures are produced in negative pressure isolators typically up to volumes of 10 litres. These cultures are transferred either by fixed pipework or single use tubing to 250 litre capacity seed fermenters, which in turn are used to inoculate either 2,000 or 3,000 litre production fermenters.

The cell cultures are produced by batch fermentation and the product of the fermentation is clarified and concentrated either by continuous centrifugation or Ultra-filtration.

All antigens are stored inactivated. Chemical inactivation, using formalin (formaldehyde solution) or Binary Ethyleneimine, takes place in either the bulk antigen or the final concentrated antigen stages.

The antigens are currently stored in 50 litre polypropylene carboys at +2°C to +8°C. Antigens such as *Mycoplasma* and *Erysipelothrix rhusiopathiae* M2 are shipped to other MSD sites in single use bag systems. The remaining antigens are formulated into vaccines at the Milton Keynes facility.

Vaccine formulation begins with the preparation of a vaccine base. Containers of aluminium hydroxide gel are transferred from the warehouse to the production facility. The gel is pumped from the containers into a preparation vessel and diluted with buffered saline. The prepared base is then transferred through pipework to either a holding or blending vessel for sterilisation. Antigens are added to the sterile vaccine base following formulations specific for each vaccine. Following successful testing the vaccines are filled into LDPE (low density polyethylene) bottles through an aseptic semi-automated filling line.

1.3 Raw Materials

Raw materials used in the on-site processes are stored in various non-bulk container types such as: 25 litre plastic carboys, 45 to 205 litre steel and plastic drums, 5 litre "demijohn" chemical containers and general small-scale chemical reagent containers less than 5 litres. No process-related raw materials are stored in bulk containers/tanks.

The choice of raw materials for each process is determined by the product (animal vaccine) dossier, which is licenced by the Veterinary Medicines Directorate (VMD) and therefore there is no opportunity for substituting the materials used at the installation.

1.4 Waste

Waste from the site generally comprises process wastes, mixed recyclables, packaging materials, chemical laboratory waste, engineering waste (from maintenance) and general office, factory and canteen materials from kitchen areas.

Waste is stored in a designated waste storage area which is surfaced with hardstanding. Waste generated at the site is managed on-site by MSD and site services cleaners. Wastes are regularly transferred from the site by registered third party contractors.

Vessel wash water, containing trace quantities of thiomersal, is stored in an external bunded tank and managed under a standard operating procedure. The tank level is monitored, and the tank is emptied via a registered waste contractor.

The installation maintains a Waste Inventory Register as required under the Waste Prevention and Management Policy.

Initiatives for waste reduction are driven by corporate reporting key performance indicators (KPI's). In 2018, approximately 5% of site waste was sent to landfill and 80% of the waste was incinerated or incinerated with energy recovery. The remainder (15%) was recycled / recovered.

1.5 Water Use

Water for the site is provided by the regional mains water provider, Anglian Water, and is used as an ingredient in manufacture and for equipment cleaning, fire-prevention, boiler water feed and sanitary uses. Water consumption is monitored, logged and tracked.

Water destined for use in vaccine production undergoes purification prior to use in order to prevent product contamination. Boiler feed water undergoes softening in order to prevent corrosion / fouling of the boilers.

MSD ensures all water supplies are maintained to the correct quality standard in accordance with applicable regulatory and corporate requirements.

KPIs are set at a corporate level, to maintain global water use at or below 2015 levels, and by 2020 to develop water conservation plans for sites in high risk locations (i.e. locations which are stressed with regards to water supply in accordance with the Aqueduct Water Risk Atlas). The site is required to track their site water use quarterly and report any increases to MSD corporate.

1.6 Emissions and their Control

Point Source Emissions to Air

Abatement of Point Source Emissions to Air

Point source emissions to air include the combustion operations for raising steam and hot water for use in the process, as well as heating during the process. Significant point source emissions to air include oxides of nitrogen (NO_x). The primary combustion units, the boilers, are fired on natural gas and use low NO_x burners.

Minor emissions of formaldehyde and hydrogen peroxide used in isolator fumigation between production cycles, are emitted via the HVAC systems for buildings 71 and 73.

All combustion, isolator plant and HVAC equipment are subject to regular planned maintenance to ensure efficient operation, as part of the installation's planned preventative maintenance (PPM) programme.

Control of Fugitive Emissions to Air

Fugitive emissions of Volatile Organic Compounds (VOCs) are generated from the use of Isopropyl Alcohol (IPA) / cleaning wipes and spray used internally in laboratory and production areas.

There are no fugitive emissions of dust from the installation.

All raw materials and products are kept in closed containers to protect the product and prevent fugitive dust emissions.

Room environments are controlled using HVAC systems fitted with a HEPA filter, in accordance with Good Manufacturing Practice (GMP). Local exhaust ventilation systems (LEVs) are provided in accordance with COSHH regulations to protect employees from potential exposure.

Point Source Emissions to Surface Water

Rainwater run-off from non-process areas is collected within the surface water drains and discharges to the municipal surface water system (emission points W1 and W2), which flow to the River Ouzel located 215m west of the installation. There are no other point source emissions to surface water from the installation.

The site surface water system (including areas outside of the installation boundary) has the potential for isolation, and containment of the drain contents, via the operation of five (5) surface water isolation points (consisting of valves / bladders).

Point Source Emissions to Sewer

Process waste water from the manufacturing processes is treated in an on-site waste water conditioning plant employing equalisation (buffering) and pH adjustment. Treated waste water is discharged to sewer in accordance with the conditions specified in a Trade Effluent Discharge Consent held by MSD AH with Anglian Water.

Emissions to Land

There are no releases of hazardous substances or non-hazardous pollutants, as defined under The Water Framework Directive (WFD) and Groundwater Daughter Directive (GWDD), to land or groundwater from the installation activities.

Odour

The manufacturing processes are undertaken inside buildings and there are appropriate abatement systems with regards to emissions and subsequent potential odour emissions.

The on-site waste water conditioning plant does not utilise biological treatment and is subject to regular planned maintenance as part of the installation's planned preventative maintenance (PPM) programme, hence the risk of odours is minimal. A procedure is in place to respond to odour complaints should they arise.

Noise & Vibration

The facility is an existing facility which has been involved in the research, development and manufacture of animal health vaccines since the 1970's. The closest noise sensitive receptors to the site are residential properties located along Abells Close, located approximately 20m south of the installation. No recorded noise or vibration complaints have been received by the facility since 2001.

A noise impact assessment of the installation has been undertaken (AECOM report dated 26 April 2019) in accordance with the methodology and procedures detailed in BS 4142:2014 *'Method for rating and assessing industrial and commercial sound'*.

The noise impact assessment, which included short-term and long-term noise monitoring, indicates that operational plant noise emission levels exceed the existing daytime and night-time background levels, however they do not exceed the

level at which there would be an onset of an adverse impact. The report concludes that, when considering the site context, the overall impact of plant noise is considered to be of low impact for both the daytime and night-time periods. A Noise Management Plan is not required for the facility.

1.7 Monitoring

Monitoring of Emissions to Air

The site operates four (4) gas fired boilers (emission points A1 to A4) which routinely provide hot water and steam to the process. In addition, there are three (3) small diesel powered emergency generators, which are operated periodically (emission points A5 to A7) as part of the sites maintenance and emergency preparedness provisions. Performance monitoring (as opposed to compliance monitoring) of the emissions to atmosphere from the boilers (emission points A1 to A4) is currently undertaken as part of an annual service by site-based technicians, to ensure that efficient operation of the plant continues. A single round of boiler emissions monitoring was undertaken in March 2019 to provide data to support the Environmental Risk Assessment for this application. The boilers will fall under the Medium Combustion Plant Directive (MCPD) and the associated monitoring regime from 2030.

Minor emissions of formaldehyde and hydrogen peroxide used in isolator fumigation between production cycles, are emitted via the HVAC systems for building 71 and 73 (emission points A8 and A9).

Monitoring of Emissions to Sewer

The discharge of waste water to sewer (following treatment in the waste water conditioning plant) is consented via a Trade Effluent Discharge Consent with Anglian Water, which requires compliance with a series of pollutant discharge conditions. Quarterly external monitoring and analysis for all consent parameters is undertaken to demonstrate compliance with the Discharge Consent. This is in accordance with the site's annual waste water monitoring plan. The emission to sewer also has in-line operational control monitoring for pH and Chemical Oxygen Demand (COD).

The pH meters and COD analyser are routinely calibrated and are included within the site's PPM system.

1.8 Environmental Risk Assessment

An Environmental Risk Assessment has been completed for the installation and is reported separately in AECOM's Environmental Risk Assessment (ERA) Report (report ref: 60576703/LORP003).

The ERA Report on the operations, together with the Relevant Hazardous Substances (RHS) ERA in the Site Condition Report (report ref: 60576703/LORP002), conclude that it is considered unlikely that the operations or the RHS would cause pollution of soil and groundwater given the physical and procedural measures in place to reduce the risk of releases. In addition, the results of a Phase II Environmental Site Assessment (Phase II Environmental Site Assessment Report, Site S080, no. 0143303, dated January 2012, ERM), a copy of which is appended to the Site Condition report, did not identify any significant pollutant linkage.

MSD understands that the Industrial Emissions Directive (IED) requires groundwater monitoring every five (5) years and soil monitoring every (10) years during the permit lifetime, where there is a risk of pollution from hazardous substances and a baseline has been set.

H1 Environmental Impact Assessment Screening & Dispersion Modelling

Impact assessment screening of the point source emissions to air and water has been undertaken using the EA H1 Environmental Impact Assessment software and guidance.

Emissions to Air

The principal pollutant to air from the installation is nitrogen oxides (NO_x) associated with the combustion plant (boiler) operations and these, along with carbon monoxide (CO) emissions have been assessed for the boiler plant (emission points A1 to A4) using one set of monitoring results for the emissions.

Formaldehyde emissions, within the HVAC discharge from building 71 (emission point A8), from the fumigation of the isolators in the Seed Laboratory, have also been assessed.

Emissions of hydrogen peroxide, within the HVAC discharges from buildings 71 and 73 (emission points A8 and A9) from the fumigation of the isolators, have not been assessed. The hydrogen peroxide is degraded into water and oxygen prior to discharge.

The formaldehyde emissions are screened out in the H1 assessment as being "insignificant" for both the long-term and short-term impacts and no further investigation of potential impacts is therefore required.

The results of the H1 screening assessment in relation to the combustion sources indicated that, whilst CO emissions were screened out as being "insignificant", dispersion modelling was required in relation to NO_x.

Dispersion modelling undertaken has shown that annual average impacts of NO₂ can be screened at the second stage as being "not significant", at all locations beyond the installation boundary. Hourly average impacts at all human health receptors can be considered to be "insignificant". Emissions of NO₂ from the boilers are therefore considered highly unlikely to compromise the attainment of the NO₂ Air Quality Standard (AQS) objectives within the vicinity of the installation.

Emissions to Sewer

Emissions to sewer (emission point S1) have been assessed using the H1 tool. The emissions of all of the priority hazardous substances have been screened out from requiring further assessment by both the Specific Chemicals Assessment and the Annual Load Screening Assessments.

1.9 Energy

The primary sources of energy used at the installation comprise natural gas (to raise steam and generate hot water) and electricity imported from the national grid.

Meters are installed across the site to record electricity and natural gas use and continuous readings are taken of energy consumption. The readings and consumption levels are tracked, looking for anomalies and efficiency of use.

The installation operates under an energy management third party certification scheme to ISO50001:2011.

The boilers and hot water heaters (4 items of plant) will be covered by the Medium Combustion Plant Directive (MCPD) (2015/2193) as existing plant and they will need to be registered by 1st January 2029 (and meet the MCPD Emission Limit Values by 1st January 2030).

1.10 Environmental Management Systems (EMS)

The installation operates under an environmental management third party certification scheme to ISO14001:2015.

BSI regularly assess the compliance of the installation operations against the requirements of the ISO14001:2015 standard, (currently 8 audit days per year).

Between compliance audits, line managers ensure continued compliance against the requirements of the EMS through regular internal audits and site / system inspections.

The installation has a dedicated engineering team who undertake maintenance inspections in accordance with the requirements of the planned preventative maintenance (PPM) programme.

1.11 Incident and Non-Conformance Management

Accident and incident risks are identified within AECOM's Environmental Risk Assessment (ERA) Report (report ref: 60576703/LORP003).

Written procedures are in place to manage the identified risks, including procedures relating to spill response, emergency preparedness and response to major emergencies. Notably the site has an Emergency Preparedness and Response Policy, which outlines the processes to follow to ensure adequate systems, resources and training are in place to effectively prevent and minimise the impact of an incident.

1.12 Closure and Decommissioning

MSD has a company policy which covers the generation of a Site Closure and Decommissioning Plan in relation to the cessation of site activities. The plan will ensure all closure and decommissioning activities are undertaken in line with country legal and regulatory requirements, corporate procedures and "Duty of Care" responsibilities.