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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Vector Control Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Bayer (Pty) Ltd
Corporate address of manufacturer	Bayer 5000 Centre Green way, Suite 400 Cary (NC) United States 27513
Inspected site	
Name & address of inspected manufacturing site(s)	5th Avenue Vorsterkroon 1490 Nigel South Africa
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	11-12 October 2021
Type of inspection	Initial inspection. The inspection was to establish the compliance of the site with requirements of ISO 9001:2015.
Introduction	
Brief description of the manufacturing activities	The manufacturing activities were related to the production of K-Othrine WG250 & K-Othrine WG250, Ficam WP, WP-SB and Fludora Fusion and included filling, and packaging.
General information about the company and site	Most of the products manufactured on the Nigel site could be classified as "pesticides" and were controlled in terms of the provisions of the South African legislation, the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act No. 36 of 1947. In addition, bait blocks and ectoparasiticides were manufactured on the Nigel site. All production processes were batch processes. Herbicides were formulated and packed in dedicated facilities; fungicides and insecticides were formulated in dedicated facilities; ectoparasiticides were formulated in dedicated facilities; fungicides, insecticides and ectoparasiticides were packed in shared facilities.
History	This was the first WHO audit of the site

Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	**Document review including but not limited to:** • Quality Manual • Training • Risk management • Management review • Job descriptions and responsibilities of key personnel • Complaints • Non-conforming products • Product release • Control of changes • Internal audits • Calibration and equipment maintenance **Physical areas:** • Raw material warehouse • Production area
Exclusions and Non-applications of requirements in the QMS	Design and development were not applicable as the site was not involved in design and development.
Out of scope	Manufacture and testing of products not submitted to WHO for prequalification. The inspection was limited to the scope of products indicated in the section below (WHO products covered by the inspection).
Restrictions	The inspection was performed under restrictions related to the COVID-pandemic state.
WHO products covered by the inspection	• K-Othrine WG250 & K-Othrine WG250-SB – Filling (insecticide) • Ficam WP, WP-SB – Filling (anti-mosquitoes) • Fludora Fusion –Filling (anti mosquitoes)
Abbreviations	**Meaning**
CoA	Certificate of analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
QMS	Quality Management System
LLIN	Long Lasting Insecticide treated Nets

Part 2	Brief summary of the findings and comments

1. **Organizational roles, responsibilities, and authorities**
The organogram reflected the reporting hierarchy of the company. The quality control and production departments were independent of each other with different reporting lines. Currently, since the Head of Production had left the company in April, the position was assigned to the Head of Administration.

The Job Descriptions were stored in the organization's SAP system while the training documentation and resumes were kept with the respective employee. Randomly selected job descriptions were reviewed. Roles and responsibilities were adequately defined, and the respective training was provided in a timely manner. Furthermore, documentation was provided to officially assign the new tasks as Head of production to Head of Administration.

The non-conformity related to the Organization roles, responsibilities, and authorities was adequately addressed in the respective CAPA plan.

2. **Quality policy and quality objectives**
The quality policy was available in the organization's quality management system and included a commitment for continual improvement, transparency and efficiency of the quality management system and was appropriate to the purpose of the organization.

The Procedure for monitoring and measurement was reviewed. Key KPIs which were vital for the daily running of the site were clearly defined in the SOP. In addition, it was demonstrated that the KPI and quality objectives were presented to the management on a regular basis to be monitored and measured.

Nigel site Quality objectives 2021 were presented and categorized.

3. **Management review**
Management review meetings were conducted in accordance with the respective SOP for Management Review. Management review meeting was required to be held at least annually. There were also monthly management reviews that mainly focused on the site set objectives and targets (KPI) which included QHSE objectives and targets.

The non-conformities related to the Management review were adequately addressed in the respective CAPA plan.

4. Leadership

The quality policy and quality objectives reviewed. The quality objectives were consistent with the quality policy. The implementation of the quality objectives was ensured through KPIs and they were communicated to all respective employees through the system.

Integration and implementation of the quality management system was carried out through internal audits and management review meetings. The manufacturer had determined and provided the resources needed to implement the QMS, to maintain its effectiveness, and to meet regulatory and customer requirements through digital quality management system.

The non-conformity related to the Leadership was adequately addressed in the respective CAPA plan.

5. Control of documented information

The SOP for the control of documents was reviewed. The process provided guidance on how SOPs must be structured, prepared, and maintained. The roles and responsibilities were also defined. The procedure described the creation, distribution, and retrieval of documents. The master list of documented information and distribution lists were incorporated in the organization's QMS.

The revision of the SOPs was defined and both revision and retention of obsolete SOPs were automated through the digital QM system. This system was globally used throughout the organization to manage the QMS. The entire staff had access to the system with a specific username and password.

The Quality Manual was a roadmap to the integrated MS of Bayer Nigel, covering three MS ISO 9001 and ISO 14001 and ISO 45001.

The QMS consisted of six types of documentation in an illustrated hierarchy:

- Policies
- Manual
- IMS procedures
- SOPs
- Work Instructions
- Records, form and requests

The applicable staff were automatically notified through the system when the respective SOP was revised.

For working instructions related to operational activities, the respective staff would receive an onsite training to be recorded on specific forms. The completed forms were kept in designated piles, signed by the trainee.

6. Personnel competence and training

The procedure for training and Training matrix Bayer Nigel Site Quality Onboarding Training Program was reviewed. The basic process regarding training was defined in the Bayer Policy: People development, Staff training and development. The purpose was to further detail actions and responsibilities for ensuring that the appropriate training and certification processes took place with all employees. The procedure implemented was to set standards

- To identify site relevant training needs
- To set standards for training
- To ensure relevant training is done
- To ensure training quality and objectives are met
- To ensure training records were maintained

The training matrix was prepared by the Head of each department, arranged by topic and individual employee. Training updates were carried out in accordance with the respective competency form.

The training plan was incorporated in the process for development dialogue, i.e., Performance and development program through the respective system, organized Bayer HQ.

The non-conformity related to the Personnel competence and training was adequately addressed in the respective CAPA plan.

7. Risks and opportunities

Risk and opportunities were specified in the Bayer IMS manual (integrated management system). This document was a site-specific document.

The manufacturer had a documented procedure (Risk Management procedure) that covered risks and opportunities that was set according to ISO 9001:2015. The procedure had a well-documented risk matrix that was followed.

8. Planning of changes

Planning of changes was done to establish how quality, technical, and organization changes should be managed without leading to unacceptable hazards and risk which compromise quality, health, safety and environment. It covered:

- The purpose of the changes and their potential consequences
- The integrity of the quality management system
- The availability of resources
- The allocation or reallocation of responsibilities and authorities

Randomly selected examples were reviewed and confirmed.

9. Internal Audits

SOP for Internal Audits, as well as audit plan for 2020 and 2021 and audit report for internal audit performed on September 2021 were reviewed.

The report of internal audit performed on Sep 2021 was provided in an Excel format. Information such as date of inspection, auditors, audit topics, participants and observations, was mentioned on the report (day by day).

The management of audit findings and the respective follow up activities through the organization's DMS electronic system were demonstrated during the inspection.

The non-conformity related to the Internal audits was adequately addressed in the respective CAPA plan.

10. Control of nonconforming products

The non-conforming products were identified during the QC process in accordance with SOP for Brief instruction for sampling and analyzing of all Semi-finished product. The SOP was available to ensure that quality control was always maintained, and reports were correctly recorded.

If the product was found to be Out of Specification, SOP for Out of Specification samples would be followed.

The procedures described how non-conforming products were to be handled and controlled and allowed for investigations. The QA department and the Laboratory were responsible for investigating, analyzing, and determining the root cause. Corrective actions following the investigations were performed following the procedure for corrective actions.

11. Performance evaluation

There were site wide key Performance indicators for product quality deviations, customer complaints, non-conformances, and HSE incidents, which were tracked monthly and reviewed during the performance management review meeting.

The list of parameters to be monitored and measured was provided in the SOP for monitoring and measurement, such as Overall Equipment Efficiency (OEE), planning, raw material availability etc. The outcome of the respective analysis was discussed during the Management Review and the corrective actions were presented.

During inspection the quality control laboratory was visited. The methods for monitoring, measurement, analysis, and evaluation needed to ensure valid results were in place and available:

- Incoming samples registration
- Inspection plan specifying test to be performed
- Formulation specifications
- Methods of analysis
- Certificates of Analysis (CoA)

Randomly selected worksheets were reviewed. Calculations were done manually and were double checked. Content of CoA was checked by laboratory manager and entered to the SAP. Certificate of analysis was signed by the laboratory manager.

The analytical methods were developed and validated/verified in accordance with the respective WHO specification by Bayer HQ and provided to the Nigel site to be used in their practice.

12. Design and development of products

Design and development were not applicable. The site was not involved in design and development activities.

13. Support

Infrastructure

According to the company policy, equipment (e.g., production lines production equipment) should be fit for intended use. Buildings – utilities maintenance schedule was presented during inspection.

Statutory required/calibration schedule was managed via a system. A system designated to generate job cards for equipment maintenance and calibration was available.

Scheduled maintenance was managed via manual excel sheets. Maintenance "Utilization check list" (job card for specific employee) was provided.

IT information and communication technology were managed by the Corporate IT department.

Transportation was outsourced to the external service provider.

Environment for operation of processes

Use of suitable infrastructure and environment for the operation of processes was managed by Environment occupation and health survey – provided by accredited service provided. Evaluation criteria were, but not limited to:

- Noise
- Illumination
- Product exposure
- T &RH

This survey was done every two years. The survey reports were provided.

14. Production and service provisions

Preservation of product

The site preserved finished goods to ensure that during production and service provision the conformity of the products to requirements was ensured through testing of products against specification prior to release for sale and dispatch.

Identification and traceability

All raw materials were identified on delivery through RFID (identification of raw materials) and the batch number of the raw materials were recorded to ensure that all raw materials conform to specification. Some raw materials were tested, and some were accepted with Certificate of Analysis. All manufactured products were tested to ensure that they met the given specification with validated methods and calibrated equipment to ensure conformity to specifications

All finished products had a unique batch number which could be traced back after manufacturing and delivery to the customer should there be any customer complaints or dissatisfaction. Finished product batch numbers were generated by SAP.

Inspectors made a site tour to the raw materials warehouse. Procedures were in place to ensure traceability and identification:

- Purchase order
- Delivery note:
  - Name of the product
  - Site address
  - Purchase order number
- Check list before loading/ of loading a truck or container
- Stores receiving checklist

Above mentioned documents were also used for receipt of packaging materials and contained required information for identification and traceability.

The non-conformity related to the identification and traceability was adequately addressed in the respective CAPA plan.

Release of products and services

Planned arrangements were in place to verify that the product and service requirements were met.

The release of products and services to the customer was initiated after planned arrangements had been satisfactorily completed. Release was done according to the Process flow diagram.

Certificates of analysis and list of release products were maintained in SAP system.

Documented information on the release of products and services specified:

- Evidence of conformity with the acceptance criteria
- Traceability to the persons authorizing the release

15. Preservation

The site preserved the finished goods to ensure that during production and service provision the conformity of the products to the requirements was ensured through testing of products against specification prior to the release for sale and dispatch.

16. Post-delivery Activities

Post-delivery activities with products and services were defined and the following was considered:

- Statutory and regulatory requirements
- The potential undesired consequence associated with products and services
- The shelf life of products and their intended use had been determined
- This also included customer feedback and requirements

17. Control of externally provided processes, products and services

The site ensured that the externally provided processes, products and services met the requirements through:

- Assessments of organizations that provided services or products with regards to the Quality Management System
- Assessment of the organization through its ability to provide the required products or services in terms of meeting contractual agreements requirements.

External organizations should be assessed and evaluated in terms of their ability to execute the requirements and if requirements could not be met, the contract would be terminated, or no business could be executed on behalf of Nigel site. An auditable quality management system was a prerequisite for an external service provider to be approved. All statutory obligations in relation to the service providers' line of business must be met prior to the approval of the service provider. Nigel specific requirements with regards to the process, products and services were clearly communicated via Contractual Agreements and Quality Assurance Agreements which were in place for all external service providers.

List of externally provided processes, products and services was managed via SAP system.

Part 3	Conclusion – Inspection outcome

Based on the areas inspected, the people met, and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, as well as the corrective actions taken and planned ***Bayer (Pty) Ltd.*** located at ***5th Avenue Vorsterkroon, 1490 Nigel, South Africa***. was considered to be operating at an acceptable level of compliance with the ISO 9001: 2015 Standard.

All the non-conformances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the site, to a satisfactory level, prior to the publication of the WHOPIR.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 4	List of Standards and Guidelines referenced in the inspection report

1. Quality management systems – Requirements, International Standard (ICS 03.120.10), 5th edition (2015), ISO/FDIS 9001: 2015 ***Short name: ISO 9001:2015***
   https://www.iso.org

2. Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange, Final Document, Global Harmonization Task Force, November 2, 2012, GHTF/SG3/N19:2012
   https://www.imdrf.org

3. Manual on the Development and Use of FAO and WHO Specifications for Pesticides, First edition - third revision. Pesticide specifications. FAO plant production and protection paper (228), FAO/WHO Joint Meeting on Pesticide Specifications (JMPS), Rome 2016
   http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/jmps/manual/en/