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

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Phyteurop S.A
Corporate address of manufacturer	Bayer S.A.S. 16 rue Jean-Marie Leclair, CS 90106 Lyon 69266, France
Inspected site	
Name & address of inspected manufacturing site(s)	Phyteurop S.A located at ZI de la Grande Champagne 49260, Montreuil-Bellay, France
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	16 – 18 May 2022
Type of inspection	Initial inspection. The criteria for the inspection were based on the ISO 9001:2015 standard.
Introduction	
Brief description of the manufacturing activities	Phyteurop has been engaged in the industrial formulation and packaging of plant protection products since 1966. Phyteurop produces a range of products in the following product categories: Herbicides, Insecticides, Fungicides, Growth regulators, Seed treatment products among others. The activities involved in the manufacture of K-Othrine Polyzone included preparation of the premix, milling, mixing, filling, labelling, and packaging. Phyteurop S.A manufactured K-Othrine Polyzone on contract for Bayer SAS. Bayer SAS was responsible for marketing the product.
General information about the company and site	Phyteurop was ISO 9001:2015 certified. ISO certificate number FR055383-11. Issued 19th January 2020 Expiry: 18th January 2023. Scope: "Toll manufacturing and internal transfer formulation and packaging of Agrochemical products. Assistance to customers." The certificate was issued by Bureau Veritas.
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 • Batch processing records • Control of changes • Internal audits • Calibration and equipment maintenance **Physical areas:** • Raw material and finished goods • Production areas • Quality control laboratory
Exclusions and Non-applications of requirements in the QMS	None.
Out of scope	The manufacture of herbicides, insecticides, fungicides, growth regulators, seed treatment products and other products not submitted to the WHO Prequalification Qualification scheme were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	K-Othrine Polyzone SC-PE (62.5 g/L) – 008-004
Abbreviations	**Meaning**
CoA	Certificate of analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
QMS	Quality Management System

Part 2	Brief summary of the findings and comments

1. Organizational roles, responsibilities and authorities
Roles and responsibilities were clearly defined in job descriptions. The job descriptions of a Laboratory Analyst, Supervisor - Fill and Pack, Shift Leader and Quality Manager were reviewed. The Quality Manager was responsible for ensuring that the quality management system conforms to the requirements of ISO 9001:2015 standard, reporting on the performance of the quality management system to top management and ensuring that processes are delivering their outputs as intended. The job descriptions had been signed by the responsible persons. An organigram was in place. The Quality Manager, Head of Quality Control and Head of production all reported independently to the Director.

2. Quality policy and quality objectives
The manufacturer had an established quality policy and quality objectives. The quality policy and quality objectives were displayed throughout the facility. The quality objectives were measurable. Performance indicators had been defined for each quality objective. The quality objectives related purchasing, commercial preparation, manufacturing, storage, Human resource, management, quality management system, leadership etc. had been defined. The quality objectives were discussed in management review.

3. Management review
The relevant procedure for Management Reviews was discussed. The objective of the management reviews was to ensure that the quality management system is efficient, satisfies the requirements of ISO 9001 and meets customer requirements. Management reviews were held at least once a year. The management review minutes were reviewed. The management review inputs included Changes, feedback from interested parties, key performance indicators and quality objectives, non-conformances, corrective actions and preventive actions, audit results etc. This was found satisfactory.

4. Leadership
Top management had established a quality policy and defined quality objectives. Top management ensured that the quality management system achieved its intended results through management reviews, internal audits, trainings and ensuring that the required resources were available. The manufacturer had a appointed a Quality Manager who monitored the performance of the quality management system.

5. Control of documented information
The procedure for control of documents was reviewed. Documents were divided into categories in four levels namely: Quality Manual, Procedures and process files, work instructions, and forms. Procedures were reviewed every 2 years. A list of the current procedures was in place. Procedures and work instructions were approved by the Quality Manager. Batch manufacturing records were retained for six years. Documents were in both hard and soft copy forms. Soft copy records including all information in the ERP was backed up daily on an offsite server.

6. Personnel competence and training

The relevant training procedure was reviewed. The procedure applied to training of temporary and full-time employees. Training records were maintained. A competency summary file was in place. It was the responsibility of the manager of the specific department to ensure that on-job training have been completed. External trainings were under the responsibility of the training department. Training of temporary staff was performed by the department manager of delegate. Some of the internal trainings conducted included: Cross Contamination Training, Safety training – working in explosive production area, how to extinguish a fire, how to operate a fire extinguisher, forklift Driver training, first aid, training of internal auditors etc. The training on cross contamination was given to all staff including those in the laboratory, maintenance, and warehouse.

7. Risks Management

The relevant risk management procedure was reviewed. Risk registers were in place. Risks and opportunities related to the following were reviewed: safety, cross contamination, Hazards, work environment, interested parties, economy, technology, production, personnel etc. The risk related to Cross contamination were assessed using the Hazard and Operability Analysis (HAZOP) approach. Risk assessment took into consideration the severity and probability of occurrence of an event. This was found satisfactory.

8. Control of changes

The change control procedure was reviewed. The procedure applied to changes related to documents, processes, equipment, active ingredients, and personnel. Changes were categories into two i.e., Minor and Major changes. Changes were authorized by the Plant Manager. The documented changes were reviewed. The impact and effectiveness of the changes was evaluated. This was found satisfactory.

9. Internal Audits

The relevant internal audit procedure was reviewed. The objective of the internal audits was to determine the areas for improvement, increase internal integrity, verify the efficiency and conformity of the Quality Management System to ISO 9001:2015 standard. The manufacturer implemented a cross functional approach that ensured that the person from a specific department cannot audit their own department. The following are some of the processes audited: Leadership, Commercial Preparation Procurement, Production, Logistics, Storage Delivery, Formulation and Research, Human Resources, Equipment Management etc. The internal audit program for the year 2021 was in place. Quality Manager was responsible for preparation of the audit program. The Quality Manager was also responsible for ensuring that nonconformities are closed within the defined timelines in conjunction with Auditor and Department Manager.

10. Control of nonconforming products

The relevant established procedure for management of nonconformances was discussed. The procedure applied to raw materials, packaging materials, semifinished products, and finished goods. The quality manager was responsible for handling nonconformance in collaboration with the department manager responsible for the nonconformance. There were dedicated areas for storage of nonconforming products. Nonconforming products were also controlled using the ERP inventory control system to ensure that nonconforming products were not used in any process. Reference was made to the procedure for Corrective actions which described the actions to be taken. A register for nonconforming products was also in place.

11. Performance evaluation

The parameters evaluated included the quality and environmental indicators, customer satisfaction and complaints, verification of effectiveness of trainings, effectiveness of corrections and corrective actions, audit results, nonconformances etc. The results from the analysis and evaluation of these parameters were discussed in management review.

12. Design and development of products

The design and development of the product was undertaken by Bayer S.A.S. Phyteurop S.A is a contract manufacturer of the product. This was therefore not included in the scope of the audit.

13. Support

Infrastructure and work environment

The infrastructure was generally well maintained. Personnel in production were appropriately dressed in PPE. Safety measures and MSDS were in place.

Monitoring and measuring resources

The calibration and maintenance records were maintained. The calibration records for the thermometer, balances and checkweighers (load cells) were reviewed. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

14. Production and service provisions

Control of Production

The manufacturer had 11 formulation lines. Three of these lines were dedicated to the manufacturer of Suspension Concentrates (SC). K-Othrine Polyzone was manufactured on any the three Suspension Concentrates lines.

The manufacture of K-Othrine Polyzone involved the mixing of different ingredients with water, pre-grinding, milling using a bead mill, preparation of the thickener premix, mixing of all the ingredients, packaging, and labelling. The in-process controls included granulometry and viscosity. K-Othrine Polyzone was packaged as a bulk product.

Batch production records were maintained. The batch production records for K-Othrine Polyzone – were reviewed. The batch numbers of the raw materials used in production were recorded in the batch production records. Labels were adequately controlled, and records maintained. Cleaning instructions were in place. Cleaning verification was performed whenever there was a product change. A cleaning matrix was also in place. Cleaning was confirmed by testing of the final rinse.

The laboratory was well equipped. The laboratory was equipped with a HPLCs, GC, balances, viscometers, granulometry equipment among others. The analytical method validation report for determination Deltamethrin in K-Othrine Polyzone was reviewed. Samples were registered in the Informatics laboratory system. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Identification and traceability

The ERP inventory software, production records and the informatics laboratory software allowed for adequate traceability of raw materials, samples, and products. Equipment were identified.

15. Preservation

The ERP inventory software was used to manage inventory in the warehouse. There was a weigh bridge on which incoming trucks were weighed before and after unloading. The materials were supplied along with a delivery note and certificate of analysis. There was a dedicated area for storage of nonconforming materials. The status (i.e., approved, quarantine or rejected) and locations in which the materials were stored could be traced in the ERP software.

16. Post-delivery Activities

Samples were adequately labelled with information such as product name, lot number, line from which the sample was collected etc. Audit trails were activated. The Deltamethrin standard was stored appropriately, and the Certificate of Analysis was in place. A sample of every batch was retained. Retention samples were stored in a cool and well-ventilated place. Retention samples were kept for 3 years.

17. Control of externally provided processes, products, and services

The procedure for purchasing was discussed. The procedure described the selection, and criteria for evaluation of suppliers. There was also a procedure for selection of tests for raw and materials. The procedure described the tests that were to be performed on the raw materials and packaging materials from new suppliers. A database for approved suppliers was in place. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

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 ***Phyteurop S.A*** located at ***ZI de la Grande Champagne 49260, Montreuil-Bellay, France*** 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 manufacturer, 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. 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/