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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	Industrias Químicas del Vallés S.A.U.
Corporate address of manufacturer	Envu, 2022 Environmental Science FR S.A.S Lyon Vaise Business Center, 1 Place Giovanni Da Verrazzano 69009 LYON, FRANCE
Inspected site	
Name & address of inspected manufacturing site(s)	Industrias Químicas del Vallés S.A.U. Av. Comarques del Pais Valencia, 267, Quart de Poblet, València 46930 Spain
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	23-25 October 2024
Type of inspection	Routine Inspection The inspection was to establish that the applicable requirements to ISO 9001:2015 as well as WHO specific requirements were met.
Introduction	
Brief description of the manufacturing activities	This site, formerly Bayer Crop Science, S.L had been recently acquired in June 2024. The site name and management had changed; however, the quality management system of the site remained the same. Envu had a contract with Bayer AG. Bayer AG then subcontracted Industrias Químicas del Vallés S.A.U. (IQV) to manufacture the WHO prequalified products. IQV released products to Bayer AG.

General information about the company and site	The manufacturer held the following ISO certificates: **ISO 9001: 2015** Scope: ‘‘Manufacture and packaging of products used as phytosanitary, fertilizers and biocidal products.’’ Certificate Number: ES139874-2 Effective date: 20-09-2024 Expiration date: 19-09-2027 The certificate was issued by Bureau Veritas Iberia S.L. **ISO 14001:2015** Scope: ‘‘Manufacture and packaging of products used as phytosanitary, fertilizers and biocidal products.’’ Certificate Number: ES144869-1 Effective date: 04-06-2024 Expiration date: 03-06-2027 The certificate was issued by Bureau Veritas Iberia S.L **ISO 45001:2018** Scope: ‘‘Manufacture and packaging of products used as phytosanitary, fertilizers and biocidal products.’’ Certificate Number: ES139854-1 Effective date: 25-09-2023 Expiration date: 27-12-2024 The certificate was issued by Bureau Veritas Iberia S.L
History	This site was last inspected by WHO in October 2021.
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	Design and development activities of the WHO prequalified products under the scope of this inspection were not undertaken at this site.
Out of scope	The manufacture of other products not submitted to PQ were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	• Ficam - WP– (Bendiocarb 800g/Kg) - 00162 • K-Othrine WG 250 (Deltamethrin 250 g/kg) - P-00159
Abbreviations	**Meaning**
CoA	Certificate of analysis
FMEA	Failure Modes and Effects Analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
MR	Management Review
MRM	Management Review Meeting
QMS	Quality Management System
RPN	Risk Priority Number

Part 2	**Summary of the findings and comments**

1. Management Review, Quality Policy and Quality objectives

Management reviews were held once annually. The latest management review minutes were reviewed. The established process for management reviews met the requirements of the standard. The review included a review of the policies on quality, environment, safety and health, follow-up on actions from previous management reviews, changes, objectives and goals etc. The quality objectives and KPIs had been defined.

2. Organizational roles, responsibilities, and authorities

The manufacturer had an organogram in place. The organogram showed independent reporting of the QHSE manager and Head of production to the Plant Manager. Responsibilities were communicated to the employees by human resources and emphasized during the onboarding training. The job descriptions of the Plant Manager and QHSE (Quality, Health, Safety and Environment) manager were reviewed.

3. Document control

The relevant procedure for document control was reviewed. The procedure was applicable to both internal and external documents. The procedure described the coding system assigned to procedures, and control of instructions, forms, process sheets, and quality control management documents. Procedures, manuals, and process sheets were reviewed every 3 years.

Obsolete documents were marked 'Obsolete' in gray and kept for 3 years. Documents could be archived as either hard or soft copies. A document distribution list was available. The validity of the documents was tracked.

4. Personnel competence and training

The relevant procedure for training and competence was reviewed. The procedure applied to both internal and external training activities. Training needs were identified by the managers and communicated to the Human resources department. The criteria for identifying training needs were defined. The training matrix and attendance control form were in place. Training records were retained for defined periods. The effectiveness of the training was evaluated at the end of the year (performance evaluation). The performance of the employees was monitored throughout the year.

5. Risk Management

A risk matrix was in place. The Failure mode effects analysis (FMEA) approach was adopted for analysis and evaluation of risks. The risk assessment included determination of the severity, likelihood, and detectability.

6. Internal Audits

The latest internal audit was conducted on 23-24 Sept 2024. The scope of the audit was defined. The report was issued to the QHSE manager. Internal audits were conducted at least once every year. The manufacturer had a database for tracking the actions taken to address observations and nonconformities raised in the internal audit.

7. Control of nonconforming products

The relevant procedure for handling of nonconformities was reviewed. This procedure applied to raw materials, packaging materials, cleaning solvents, semifinished products, and finished products. The procedure applied to both processes and products. The procedure provided for investigations. Nonconforming materials were to be identified and segregated. The nonconformities are documented on the nonconformity report. The documented nonconformities were reviewed.

8. Control of Changes

The relevant procedure for control of changes was reviewed. Change management form for technical changes and Product change management form were in place. The forms provided for both permanent and temporary changes. The forms also provided for risk assessment/impact assessment of the change. Changes were approved by the Head QHSE. The effectiveness of changes was verified by the Management of Change (MOC) in-charge.

The site had created an oversight committee to manage and oversee the changes following acquisition of Bayer Crop Science, S.L and to ensure smooth transition to the new management. Changes were reviewed.

9. Complaints

The relevant procedure for handling of complaints was reviewed. Complaints were communicated to the QHSE manager. The complaints were registered using the product nonconformity report form. The QSHE manager was informed of any nonconformities and maintained the relevant records of nonconformities and actions in an excel sheet. Investigations were conducted depending on the gravity, potential risk of repetition, and request from client/management. Once the investigation was completed and a report was provided to the QHSE manager for review and closure. Registered complaints were reviewed.

10. Design and development of products

Design and development activities of the WHO prequalified products under the scope of this inspection were not undertaken at this site.

11. Support

Infrastructure and work environment

The facility was well maintained. The warehouse was equipped with fire extinguishers, and water sprinklers. Spill kits were in place. Material safety data sheets were also in place. Personnel in production and laboratory were appropriately gowned.

Monitoring and measuring resources

The maintenance plan for 2024 was in place. The plan provided information on the planned maintenance and equipment break down. The maintenance plan for equipment was checked. Information on actions taken was maintained. The maintenance reports for selected HPLCs were checked. The calibration certificates of selected balances were also checked.

12. Production and service provisions

Control of Production

The manufacture of Ficam – WP involved mixing of the different ingredients in a mixture, milling, and post-mixing for homogenization and packaging. A software was used to determine the quantities of the different ingredients for a production order based on the master/standard recipe. The software had been validated. The cleaning instructions were in place. A cross contamination matrix for line was in place. The batch records for Ficam WP were reviewed.

K-Othrine 250 WG was not formulated at this facility. K-Othrine WG 250 was received in bulk and packaged into sachets. The powder was filled into sachets, sealed, labelled, and packaged into cartons. The fill weight was monitored, and records were maintained. The online check weigher was calibrated. The seal integrity was verified every hour. Production records for K-Othrine 250 WG were reviewed.

The laboratory carried out both physical and chemical tests. The sampling procedure was reviewed. The sampling plan was defined. The procedure for handling of out-of-specifications and the Sample retention procedure were reviewed. Test reports of some selected batches of Ficam WP were reviewed. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Cross contamination prevention

The procedure for prevention of cross-contamination was reviewed. The procedure applied to all products packaged and formulated at IQV. The cross-contamination limits for formulated products were defined.

The production lines were cleaned following defined instructions. Each equipment on the powder production line was cleaned separately. Production was halted until cross-contamination results were obtained from the laboratory. Cross contamination test results were maintained in a database. These were verified and found within the acceptable limits.

Waste management.

Waste was collected and stored in accordance with the Spanish regulations. The manufacturer had an authorization certificate allowing them to segregate and store the waste. The waste was stored in a dedicated area. The waste was then collected by an authorized and licensed third-party company for treatment and incineration.

13. Preservation

Upon receipt of the raw materials the quantity, physical condition batch number and names of the materials were verified. The Inventory records and movement were managed by ERP. Raw materials were sampled and tested for identification upon receipt. A dedicated area for sampling of toxic materials was in place. The ERP system assigned appropriate locations in which materials were to be stored. The materials were issued to production following the FIFO principle. Any discrepancies would be documented and communicated accordingly.

14. Retention samples

Retention samples were stored in a new storage area. The temperature of the storage area was monitored, and records were maintained. The retention samples were appropriately labelled. Retention samples were maintained for 4 years.

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

Bayer AG was responsible for selection and monitoring of the performance of suppliers. Bayer provided all the raw materials including the packaging materials. Any issues or nonconformities identified are communicated accordingly. Industrias Químicas del Vallés S.A.U was not responsible for the selection and monitoring of the performance of suppliers of the raw materials. The manufacturer also had an incident tracking database where any issues/nonconformities related to the raw materials were monitored.

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 by **Industrias Químicas del Vallés S.A.U.** located at **Av. Comarques del Pais Valencia, 267, Quart de Poblet, València 46930, Spain** 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/