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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	SBM Formulation S.A.
Applicant/ 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)	Z.I. AV. Jean Foucault, CS 621 Béziers Cedex, 3453 France
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	17 – 19 February 2025
Type of inspection	Re-Inspection The inspection was to establish that the applicable requirements to ISO 9001:2015 as well as WHO specific requirements continue to be met.
Introduction	
Brief description of the manufacturing activities	SBM formulation S.A is a contract manufacturer for Envu. SBM Formulation S.A is a family-owned company that was created in 1994. The facility manufactures fungicides and insecticides. There are no herbicides manufactured at this facility.
General information about the company and site	The manufacturer held the following ISO certificates: **ISO 9001: 2015** **Scope: "**Formulation, Packaging, Storage, Custom Shipping of Plant Protection Products, and related development activities.'' Certificate number: 2019/84449.3 Valid from: 02 December 2022 Valid until: 01 December 2025 The certificate was issued by AFNOR Certification. **ISO 14001:2015** **Scope:** ''Formulation, Packaging, Storage, Custom Shipping of Plant Protection Products, and related development activities.'' Certificate number: 2019/84448.3

	Valid from: 02 December 2022 Valid until: 01 December 2025 The certificate was issued by AFNOR Certification. **ISO 45001:2018** **Scope:** ‘‘Formulation, Packaging, Storage, Custom Shipping of Plant Protection Products, and related development activities.’’ Certificate number: 2019/84450.3 Valid from: 02 December 2022 Valid until: 01 December 2025 The certificate was issued by AFNOR Certification. **ISO 50001:2018** **Scope:** ‘‘Formulation, Packaging, Storage, Custom Shipping of Plant Protection Products, and related development activities.’’ Certificate number: 2019/83509.2 Valid from: 10 November 2022 Valid until: 21 July 2025 The certificate was issued by AFNOR Certification.
History	The site was last inspected by WHO in May 2022.
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 other products not submitted to PQ were not included in the scope of this inspection.

Restrictions	None
WHO products covered by the inspection	• Aqua K-Othrine (EW) – (Deltamethrin 2%) - P-00158

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

The manufacturer held management reviews twice a year. Management review minutes for the year 2024 were reviewed. The management review minutes were checked. The first management review focused on risks and opportunities. The challenges, risks, impact on QSE opportunities and actions to be taken etc. were discussed. Actions to be taken following different resolutions were defined and documented.

2. Leadership, responsibilities, and authorities

The roles and responsibilities of selected key staff were reviewed. The job description of the Production Manager and Quality Control manager were reviewed. The respective job descriptions were signed by the job holders.

An organogram depicting the structure of the facility and reporting arrangements was in place. The production manager, QC manager and QHSE manager all reported independently to the Site manager.

3. Quality policy and Quality objectives

An integrated quality, health, safety, and environment policy for 2024-2025 was in place. The quality policy was signed by the factory manager. The quality policy included a commitment to continual improvement of the quality management system and a commitment to satisfy applicable requirements as well as regulatory requirements. The objectives and key performance indicators (KPIs) were defined. The quality policy was displayed in various areas throughout the factory. Meetings were held to discuss the progress and extent to which the KPIs were met on a monthly basis. KPIs not met were reported as nonconformities, and corrective actions were proposed.

4. Document control

The procedure for management and documentation and registration was reviewed. The scope of the procedure included the documentation and records related to quality, safety, and environment. Documents were reviewed every 3 years. Documents were structured as follows: manual,

procedures, instructions, registration forms, and records. The procedure described the format of the different documents. The in-charge or person responsible for a process was responsible for editing procedures. Procedures were approved by the site manager. The QHSE manager was responsible for ensuring that the newly created and edited procedures aligned with other procedures and ISO requirements. The procedure also described the control of documents of external origin. Production documents were retained for 5 years. Information on any updates was communicated by email.

5. Personnel competence and training

The relevant procedure for Human Resource was reviewed. The procedure defined the interaction of Human Resource (HR) process with other processes.

The training plan for 2024/2025 was checked. The training plan included both the mandatory and identified trainings. The trainings were categorized into trainings related to safety, quality, and work of the personnel. Trainings were tracked (trainings conducted, personnel attendance, etc.). Key Performance Indicators (KPI) for training were defined and monitored.

Training needs were determined each year depending on the roles and responsibilities of the personnel in addition to the mandatory trainings. Trainees were evaluated following the training and records were maintained.

6. Risk Management

Risk identification was carried out by a multidisciplinary team using the FMEA tool, primarily for production. Risks were evaluated by the responsible person, and action plans were documented for annual review to assess the effectiveness of mitigation measures. The Global Risk Register for the formulation workshop was reviewed. Risks were reassessed whenever changes occurred, such as the introduction of a new product. The contamination risk register for production of Aqua K-Othrine was also in place.

7. Internal Audits

The internal audit procedure documented in the Quality Manual was reviewed. There were no significant changes noted since the last audit. Audit reports were reviewed by each process manager for further action.

8. Control of nonconforming products

The procedure “Non-Conformities Matrix and Feedback Management” was reviewed. The procedure specified the persons responsible for handling the corrective actions. The corrective actions were handled following the procedure for corrective actions. The procedure provided for investigations. Selected nonconformities were reviewed. There was no nonconformity or complaint related to Aqua K-Othrine since the last inspection.

9. Control of Changes

The relevant procedure titled ‘Continuous Improvement’ was documented in the Quality Manual. Two types of changes were defined: product-related and process-related changes. Changes could be initiated based on product non-conformities, supplier issues, KPIs, and feedback etc. Changes were also categorized as urgent or non-urgent based whether it was an immediate improvement or complex changes requiring project conversion. Non-urgent changes were reviewed monthly. All

changes were reviewed at least once annually during the management review. The change request system was managed through a customised software.

10. Recalls

Recalls were the responsibility of Envu. The relevant Envu global procedure for recall number was reviewed. The procedure applied to Envu manufacturing sites, tollers, vendors, and subcontractors. In the event of a complaint, a cross-functional team (CFT) comprising legal, marketing, commercial, R&D, regulatory product supply, quality, and the master data was responsible for handling recalls. The legal department was responsible for approving decisions from the CFT.
There were three levels of recalls:
Level 1: Recall linked to Customer complaints.
Level 2: Recall linked complaints from authorities.
Level 3: End of life of a product

The originator provided QHSE/regulatory all the relevant information. The procedure provided for investigation, impact assessment, and recall plan, including reconciliation of the recalled product. The depth of the recall depends on the impact and risk of the issue. The customer service/marketing/sales were responsible for communicating the recalls to the customers, including WHO.

11. Performance evaluation

Performance and the effectiveness of the quality management system was assessed by analyzing and evaluating the following:
• Customer satisfaction
• Complaints
• personnel absenteeism
• Training
• KPIs analysis - to determine which KPIs need more surveillance.
The evaluation and analysis were performed by use of graphs, pie charts and percentages etc. These were maintained as part of management review minutes.

12. Design and development of products

This site was not involved in design and development of Aqua K-Othrine. This area was therefore not inspected.

13. Support

Infrastructure and work environment

The procedure titled "Management of Equipment and Facilities" and a maintenance program were in place. The infrastructure was generally well maintained. The maintenance records for the HPLC were reviewed. Material safety data sheets and spill kits were in place. Personnel were appropriately gowned.

Monitoring and measuring resources

The calibration records for the load cells and temperature probes in selected equipment were verified.

14. Production and service provisions

Control of Production

The manufacture of Aqua K-Othrine involved preparation of the organic solvent and aqueous phase and mixing the two phases to make the final product. This was followed by labelling and packaging. A recipe for preparation of Aqua K-Othrine was in place. Batch records for preparation of Aqua K-Othrine were reviewed. Aqua K-Othrine was manufactured on insecticide line IF1 and IF2. The mixing tanks were equipped with calibrated load cells. Mixing times were monitored and recorded in the batch records. The sample sizes for the different in-process checks was defined in the batch records. The procedure for prevention of cross contamination and cleaning matrix were checked. Cleaning records were in place.

The laboratory was well equipped. Both physical and chemical tests were conducted at this laboratory. A sample receipt register was in place. The test records for Aqua K-Othrine were checked. Traceability of samples in the lab was managed by use of a customized software. Audit trails were activated. The laboratory manager was responsible for approving test results. The validation report for the in-house test method for determination of Deltamethrin in Aqua K-Othrine by HPLC was checked. The validation took into consideration the following parameters: LOD, LOQ, repeatability, robustness specificity and linearity. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

15. Preservation

The procedure for receipt and identification of materials was reviewed. Materials were verified upon receipt. Any discrepancies were reported to the purchase department and following the relevant procedure for nonconformities this was communicated to the supplier. Inventory was managed by use of an inventory software. The warehouse adhered to a First-In-First-Out (FIFO) system for stock management. The software provided information on the locations of the stock, stock movements and balances. The warehouse also employed the use bar code scanners. The bar code scanners provided information on the identity and status of the material.

16. Retention samples

A retention sample was retained for each batch. The retention samples for Aqua K-Othrine were retained for 3 years. The retention samples were kept in a dedicated area. The temperature was monitored, and records maintained.

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

The technical material used in the manufacture of Aqua K-Othrine was supplied by Envu. The manufacturer only selected and evaluated the suppliers of the inactive materials (co-formulants).
The procedure for purchasing and supply was reviewed. The procedure described the selection and evaluation of suppliers. A questionnaire was sent to prospective suppliers to provide information on QMS & environmental management system, prices, incoterms, certifications, etc. Other relevant information, price packaging on the product to be supplied, were requested from the supplier, and evaluated. The manufacturer also requested samples for validation or trial purposes. The criteria for evaluation of suppliers had been defined. The performance evaluation of selected supplier was reviewed.

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 **SBM Formulation S.A.** located at **Z.I. Avenue Jean Foucault, CS621, 34500 Béziers, 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/