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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 Thai Co., Ltd.
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)	Bayer Thai Co., Ltd. Bangpoo, 239 Moo 4, Bangpoo Industrial Estate Soi 3, Samutprakarn, Samut Prakan 10280, Thailand.
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	8 – 10 May 2024
Type of inspection	Initial 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	Bayer Thai Co., Ltd. manufactures insecticides, fungicides, and herbicides among others. The production line used for the manufacture of herbicides was separate from that used for the manufacture of insecticides/fungicides.
General information about the company and site	The manufacturer held the following ISO & GMP certificates: **ISO 9001: 2015** Scope: ‘‘Formulation, Repackaging and Storage of Crop Science and Environmental Science Products.’’ Registration Number: 44 100 20 80 0100 Valid from: 21 November 2023 Valid until: 17 November 2026

	The certificate was issued by TUV Nord. The inspected address and activities were covered by this certification. **ISO 14001:2015** Scope: ‘‘Formulation, Repackaging and Storage of Crop Science and Environmental Science Products.’’ Registration Number: 04 104 01436 Valid from: 21 November 2023 Valid until: 17 November 2026 The certificate was issued by TUV Nord. **ISO 45001:2018** Scope: ‘‘Formulation, Repackaging and Storage of Crop Science and Environmental Science Products.’’ Registration Number: 44 126 20 80 0100 Valid from: 21 November 2023 Valid until: 17 November 2026 The certificate was issued by TUV Nord. **Good Manufacturing Practice (GMP)** Scope: “Manufacturing of Pesticide Products” Ref. No. 1-6-04-90-22-00011 Valid From: 16 September 2022 Valid Until: 15 September 2025 The certificate was issued by Food and Drug Administration – Ministry of Public Health
History	This was the first WHO inspection 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	Design and development of products were not applicable as the site was not involved in the design and development activities.
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	• P-00159 – K-Othrine (WG) - 250 g/kg Deltamethrin • P-00158 - Aqua K-Othrine (EW) – 20 g/L Deltamethrin

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. Quality policy and quality objectives

Established quality objectives and a quality policy were in place. The integrated quality policy included commitments to satisfy applicable requirements and continual improvement of the quality management system. The quality policy had been signed by the Site Lead. Key performance indicators had been defined to measure and monitor the quality objectives. The key performance indicators and quality objectives were discussed in Management Review.

2. Management review

The relevant procedure for Management review was in place. The management review took into consideration the requirements of ISO 9001, 14001 and 45001 & GMP standards. Management review meetings were held at least once every year. The latest management review meeting minutes were reviewed and met the requirements of the ISO 9001 standard. Opportunities for improvement and resources needed had been identified.

3. Organizational roles, responsibilities, and authorities

An organogram was in place. The QC Supervisor and the Production Manager reported independently to the Site Lead. The job descriptions and responsibilities of the Packaging Development Executive, Quality Assurance and QC supervisor were reviewed.

4. Document control

The relevant procedure for document control was reviewed. It described the interaction between the different QMS processes and defined the structure of the documentation system. The issuance, revision, superseding and withdrawal of all documents were controlled as defined in the procedure. Records were readily available. Documents were retained for 5 years. Electronic data was backed up on an online server. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

5. Personnel competence and training

The training procedure was in place. The manufacturer had both internal and external trainings for staff. The 2024 annual training plan was also in place. Training needs were determined and reviewed annually. Training and assessment records for selected staff were checked.

6. Risk Management

The risk register was reviewed. The risks were registered and monitored in SAP. Risks were categorized as low, medium, and high based of the assigned Risk Priority number (RPN). The criteria for deriving the RPN were defined. The risk assessment covered the products in the scope of the inspection. The risk assessment took into consideration risks related to the production processes including liquid formulation, powder filling, and quality control laboratory.

7. Internal Audits

The relevant procedure for internal audit was in place. Internal audits were conducted once a year by qualified auditors independent of the areas being audited. An internal audit schedule was in place. The schedule considered the status and importance of the areas to be audited. Internal audit reports were also available. The identified nonconformities had been appropriately addressed.

8. Control of nonconforming products and complaint handling

The procedure for handling of nonconformities was reviewed. The nonconformities were categorized into:

- Internal nonconformities/product hold
- External customer complaints
- Product recall
- Adverse events
- Product returns
- Laws and regulations review

The product recall criteria into class I and Class II were defined. The procedure provided for investigations, root cause analysis, corrections, and corrective actions. The criteria for classification of adverse events into emergency, severe, moderate, and low categories were also defined. The relevant actions to be taken depending on the classification of the adverse event were also outlined. There had been no product recall by the time of the audit.

9. Control of Changes

Changes were controlled and implemented in accordance with the procedure for management of Changes. The list of changes implemented in 2023 was provided. Changes were reviewed. A risk assessment had been performed prior to the implementation of the change. This was found satisfactory.

10. Performance Evaluation

The following were evaluated and analyzed by the manufacturer:

- Packaging and labels
- Customer satisfaction and feedback
- IT security management
- External and internal regulations
- Internal audits
- Conformity of formulations

11. Design and development of products

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

12. Support

Infrastructure and work environment

The facility was well maintained. The warehouse and production areas were equipped with sprinklers. Material safety data sheets were in place. The personnel were gowned in appropriate personal protective equipment. The calibration and maintenance schedule was maintained in SAP. Notifications of any upcoming maintenance were generated by SAP to the engineering department. The maintenance records of selected equipment were checked.

Monitoring and measuring resources

The 2023 calibration plan for laboratory equipment was in place. The calibration records of selected equipment were reviewed.

13. Production and service provisions

Control of Production

The manufacture of Aqua K-Othrine involved the preparation of the organic phase and aqueous phases was performed as per the following documented recipes. Batch production records for Aqua K-Othrine were reviewed. The mixing speed was monitored on PLC. Access to the PLC was password controlled. Following the mixing of the aqueous and organic phase, a sample was collected and tested for active ingredient content. The integrity of the capping was monitored by an

online sensor. The fill volume was also monitored. The packaging of the filled and labelled bottles into cartons was done manually. The procedure for cleaning the liquid formulation and filling line (used for production of Aqua K-Othrine) was reviewed.

K-Othrine was received in bulk and packaged in aluminium sachets. The bulk K-Othrine was unloaded into a hopper, and under gravity, the granules flowed to the filling machine. The powder was filled into sachets, sealed, labelled, and packaged into cartons. The work instructions for cleaning the powder filling machine were reviewed. The seal integrity and fill weight were monitored. The filling and packaging line was equipped with a bar code reader. Batch records for K-Othrine were reviewed.

The QC laboratory was separate from production areas. The laboratory has been designed and equipped with facilities for chemical and instrumental testing. The laboratory had adequate space for the orderly placement of equipment and materials and to perform tests. Appropriate specifications were established. Microbiological analysis was performed in the same laboratory. The procedure for microbiological examination of water and aqueous materials using Dip Slides was reviewed.

Waste management

The procedure for waste management was in place. The procedure provided guidance on the handling and sorting of waste. The waste was collected at a centrally designated location. The waste was then collected by Government approved companies for disposal. Reports on the waste disposal by the third-party companies are submitted to Bayer Thai Co., Ltd.

All the issues raised related to this section were addressed satisfactorily by the manufacturer.

14. Preservation

Inventory records were managed by SAP. SAP provided details on the product names, batch number, quantities, locations etc. The materials to be issued from the warehouse were selected by SAP following the FEFO principle. Upon receipt, the physical appearance, quantity, batch number were verified. The materials were received with a certificate of analysis together with other documents such as the invoice, packing list, etc. A checklist was maintained. All the chemical raw materials were received from Envu.

15. Retention samples

Retention samples were maintained for 5 years. The retention samples were appropriately labelled with information on the date of sampling, product name, batch number etc. Adequate quantities of the retention samples were maintained.

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

The selection and evaluation of the suppliers of the chemical raw materials used in the manufacture of the WHO prequalified products was performed by Envu. The manufacturer only selected and evaluated the suppliers of other materials such as packaging materials.

The relevant procedure for the selection of suppliers was reviewed. The selection of suppliers was limited to suppliers of leaflets, accessories, and packaging materials. The suppliers were evaluated

annually. The criteria for evaluation of suppliers were defined. An approved supplier list was available in SAP. The supplier evaluation reports for selected suppliers were 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 **Bayer Thai Co., Ltd.** located at **Bangpoo, 239 Moo 4, Bangpoo Industrial Estate Soi 3, Samutprakarn, Samut Prakan 10280, Thailand** 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/