



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

Part 1	General information
Manufacturers details	
Name of manufacturer	Fujian Yahe Industry & Trade Co., Ltd
Corporate address of manufacturer	Fujian Yamei Industry & Trade Co. Ltd No. 83, 5th Floor Hongxing Business Building, No. 56 Changle South Road, Fuzhou, Fujian, Taijiang District, China
Inspected site	
Name & address of inspected manufacturing site(s)	Fujian Yahe Industry & Trade Co., Ltd No. 31, Longyan East Third Road, Xinlu Village, Yanshi Town, Xinluo District, Longyan City, Fujian China
Unit/Block/Workshop	Not applicable
Inspection details	
Dates of inspection	10 -12 May 2023
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	The site only manufactured treated bed nets - Yahe LN. The activities related to the manufacture of Yahe LN included warehousing, coating, cutting, labelling, packaging, and quality control testing.
General information about the company and site	This was the first WHO inspection. The site was certified as indicated below: ISO 9001: 2015: Quality Management System Certificate Number: NOA2112042 Issue Date: 27 September 2021 Expiry Date: 26 September 2024 Scope: Production and sales of textiles (Mosquito nets, Long Lasting mosquito Nets) The certificate was issued by NOA Testing and Certification Group Ltd.



	<p>ISO 14001: 2015: Environmental Management System Certificate Number: NOA211041 Issue Date: 27 September 2021 Expiry Date: 26 September 2024 Scope: Production and sales of textiles (Mosquito nets, Long Lasting mosquito Nets) The certificate was issued by NOA Testing and Certification Group Ltd.</p> <p>ISO 45001: 2018: Occupational Health and Safety Management System Certificate Number: NOA211040 Issue Date: 27 September 2021 Expiry Date: 26 September 2024 Scope: Production and sales of textiles (Mosquito nets, Long Lasting mosquito Nets) The certificate was issued by NOA Testing and Certification Group Ltd.</p>
History	This was the first WHO inspection of the site.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	<p>Document review included but was not limited to:</p> <ul style="list-style-type: none"> • 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 <p>Physical areas:</p> <ul style="list-style-type: none"> • Raw material and finished goods • Production areas • Quality control laboratory
Exclusions and Non-applications of requirements in the QMS	Design and development activities were not undertaken at this site.



Out of scope	The manufacture of other products not submitted to WHO Prequalification were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	Yahe LN (Deltamethrin -55mg/m ² ±25%) - 015-001
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	Brief summary of the findings and comments (where applicable)
---------------	--

1. Quality policy and quality objectives

A quality policy and quality objectives were in place. Measurable key performance indicators (KPIs) had been defined for each quality objective. The KPIs were monitored. The review of the KPIs was conducted yearly. Some of the defined KPIs were related to quality of the product, qualified rate of product quality, customer’s satisfaction survey, and timely delivery of products among others.

2. Management review

The relevant procedure for management review was reviewed. The General Manager was responsible for presiding over the management review meeting, approving the management review agenda and report. Management review meetings were held at least once a year. The minutes of the management review meeting held in 2022 were reviewed. The agenda included among others: complaints, customer feedback, changes, corrective and preventive actions, safety and environmental factors, risks, and opportunities etc. No serious quality issues were reported. No complaints had been received. Customer satisfaction was reported to be 98%. The quality policy and quality objectives were also reviewed. Opportunities for improvement were also discussed. Management review was found satisfactory.

3. Organizational roles, responsibilities, and authorities

Leadership commitment with respect to the quality management system was demonstrated by establishing quality policy and quality objectives, promoting improvement, and supporting management roles in their areas of responsibility. The leadership commitment was described in the quality manual. An organizational structure indicating the hierarchical and reporting lines is in place. The job descriptions of the Quality Control in-charge, Quality Assurance Manager and Production Manager described in the quality manual were reviewed. The Quality Assurance Manager was responsible for product release.



4. Control of documented information

The procedure for document control was reviewed. Documented information included the quality manual, procedures, work instructions, production records etc. Documents were identified, issued, retrieved, and approved in accordance with the established procedure. Documents were approved by the General Manager. Records were maintained in hard copy formats. A document distribution list was in place.

5. Personnel competence and training

A training plan for 2023 was in place. Training records were maintained. Training records for the training of trainers on several procedures were reviewed. The effectiveness of the trainings was assessed. Pictures were also maintained as evidence of training.

6. Risks Management

The procedure for risk management was reviewed. The scope included among others process of business, change control, supplier and procurement control, equipment and tool maintenance, nonconforming products, corrective action implementation and verification etc. The procedure also described the risk assessment process. The approach for determination and evaluation of the occurrence and severity of the risks was described. A risk matrix was in place. The manufacturer had also performed a SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis. The SWOT analysis took in account external factors such economic factors, market environment etc.

7. Control of changes

The change control procedure was reviewed. Changes were reviewed by the management representative and approved by the General Manager. Changes were initiated made using a change request form. A change related to the template of the Fabric record was reviewed. The reviewed change was handled in accordance with the procedure.

8. Internal Audits

The internal audit procedure was reviewed. The procedure was applicable to all areas covered by the company's quality, environmental, occupational health, and safety management systems. Internal audits were conducted at least once a year. Internal audits could also be conducted in special circumstances such as a major changes, major quality, occupational health, and safety incidents, change in laws and regulations etc. An internal audit schedule for 2022 was reviewed. Internal audits were conducted using a checklist. To ensure objectivity of the internal audit process the auditors did not audit their own areas of work.

9. Control of nonconforming products

The procedure for control of unqualified products was reviewed. The manufacturer inspected bed nets to ensure that defective bed nets were identified and controlled. The fabric was sampled and inspected at receipt. The bed nets were also sampled and inspected for defects such as holes, tears, stains following the cutting, sewing, and coating processes. Repairable defects such as holes were repaired by stitching. Records of identified defects during the manufacturing process were maintained. Fujian Yamei Industry & Trade Co. Ltd was responsible for receipt of market complaints and recalls. The procedure provided for investigations. Any returned products would be identified and segregated. The procedure provided for investigations. No complaints had been received by the time of the inspection.

10. Performance evaluation

The manufacturer monitored and measured the following parameters among others: Complaints, degree of customer satisfaction, performance of external providers. These were discussed in management review assessing the effectiveness of the quality management system.

11. Design and development of products

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

12. Customer satisfaction

Customer surveys were conducted every year. The 2022 customer satisfaction survey was reviewed. The target was to have over 95% of the customers satisfied. The customer survey report indicated that the customers were satisfied with the products of the manufacturer.

13. Support

Infrastructure and work environment

Manufacturing activities were carried out in two buildings. Building 1 housed the warehouse (greige fabric) and cutting and sewing activities. The warehouse (greige fabric) was housed on the first floor while the cutting and sewing activities were carried out on the second and third floor. The warehouse (Chemical), coating, packaging, baling, and warehousing of the finished bed nets were carried out in Building 2. The administrative offices and quality control laboratory were housed in another building.

Personnel had appropriate PPE. The personnel in the chemical mixing section were donned in overall coat, gloves, mask and boots.

Monitoring and measuring resources

The procedure for Infrastructure control was reviewed. The infrastructure was categorized as:

- a) Buildings
- b) Workshop facilities such as power and water supply
- c) Monitoring and Measuring facilities
- d) Support services such as computers

The maintenance schedule for 2022 was in place. Maintenance records for the chemical bath and HPLC were reviewed. Calibration certificate for the weighing balances were in place.

14. Production and service provisions

Control of Production

The manufacture Yahe LN involved cutting, sewing, labelling, coating, heat setting, and baling. Only Yahe LN was manufactured at the site. The greige fabric was cut and sewed according to customer specifications. Cutting and sewing records were maintained. The cut and sewed fabric was inspected for defects such as holes, stains, open seams etc. Inspection records were maintained. The sewed nets were then coated and passed through a stenter. The temperatures of the drying chambers were monitored and controlled. The coating solution was prepared following a documented recipe. The mixing time was monitored and documented. The batch numbers of the raw materials were



recorded in the mixing record. The weighing balances were uniquely identified and calibrated. Cleaning of the mixing tanks and water bath was performed once a week. Cleaning records were available. Label issuance records were also in place.

Batch production records for Yahe LN were reviewed. Batches were released by QA following review of QC test results and production records. Production batches were released to Fujian Yamei Industry & Trade Co. Ltd.

Quality control lab

Both physical and chemical test were carried out in the lab. The test carried out in the lab included: GSM, bursting strength, mesh count, and Active ingredient content among others. Analytical test report for reports for Yahe LN were reviewed. Raw data was available. The CIPAC method was used for determination of Active Ingredient content in the coated nets. The analytical test reports were reviewed by the QC director/supervisor.

Waste management

Waste generated during production was collected at a central point and collected by a third-party company for treatment. A list of chemical waste collected by the third party was available.

Retention samples

The samples were stored at ambient temperatures. A sample of every batch was retained. The retention samples were kept for 3 years.

Stability studies

Stability study report for Yahe LN was available.

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

15. Preservation

Inventory was managed by use of stock cards. The raw materials were received along with the certificates of analysis. The greige fabric received at the fabric warehouse was sampled and inspected on receipt. The sampling criteria was defined in the product inspection standard. The greige fabric was inspected for GSM, appearance, hole. size etc. The raw material inspection records were maintained. The artwork and label information on the label was verified upon receipt of the labels.

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

The relevant procedure for procurement control was reviewed. The procedure described the criteria for selection and evaluation of suppliers. Supplier evaluations were performed every year. An approved supplier list was available and evaluation reports available.

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 **Fujian Yahe Industry & Trade Co., Ltd** located at: **No. 31,**



Longyan East Third Road, Xinlu Village, Yanshi Town, Xinluo District, Longyan City, Fujian China 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/>