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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	Yorkool Chemicals (Cangzhou) Co., Ltd. - Gaotang
Corporate address of manufacturer	Tianjin Yorkool International Trading Co., Ltd F-721, Hi-Tech Information Plaza, #8, Huatian Avenue Huayuan Industrial Park, Tianjin China
Inspected site	
Name & address of inspected manufacturing site(s)	Yorkool Chemicals (Cangzhou) Co., Ltd. – Gaotang The Wind Road South Middle, Gaotang County Economic Development Zone Liaocheng City, Shandong, China
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	16, 19 and 20 June 2023
Type of inspection	Re-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	Yorkool LN and Yorkool G3 LN were manufactured at this site. The processing activities involved in the manufacture of these nets included warehousing, cutting, sewing, labelling and packaging. The treated fabric was received from other processing sites at Cangzhou and Lixian sub-factories.
General information about the company and site	Since the last inspection there was a change in the ownership of the site in 2021. Under the new management, Tianjin Yorkool International Trading Co., Ltd and Yorkool Chemicals (Cangzhou) Co., Ltd were both subsidiaries of Yorkool Group. The ownership of all the manufacturing sites under the management of Tianjin Yorkool International Trading Co., Ltd was transferred to Yorkool Chemicals. An additional product, Yorkool G3 LN that had been recently prequalified was manufactured this site.
History	The site by WHO was last inspected in May 2019. The site was ISO 9001 certified as indicated below:

	ISO 9001: 2015: Quality Management System Certificate Number: 30722Q20579R1M Reissue Date: 20 October 2022 Expiry Date: 23 September 2025 **Scope:** Manufacture of Long Lasting Insecticidal Net The certificate was issued by BAC.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	**Document review included but was 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 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	Yorkool LN (Deltamethrin -55mg/m2±25%) - 021-001 Yorkool G3 LN – (Deltamethrin - 120 mg/m^2 ±25%, Piperonyl Butoxide - 440 mg/m^2±25%) -021-003.
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

Part 2	Brief summary of the findings and comments (where applicable)

1. Quality policy and quality objectives

The quality policy and quality objectives had been established. The quality policy included a commitment to meet requirements and continuously improve the effectiveness of the QMS. The quality policy and quality objectives had been approved and signed by the General Manager. The quality objectives were measured and monitored. Key performance indicators used to monitor the level and extent to which the quality objectives had been met were defined. The quality objectives were discussed in management review.

2. Management review

The procedure for management review was reviewed. The General Manager was responsible for chairing the management review meetings. The management review representative was responsible for presenting the QMS operation status report. Management review meetings were held at least once a year. The management review meetings were also held in case of:

- Significant changes to the company's organizational structure, product scope and resource allocation.
- Major quality incidents or customer complaints on product quality
- When laws, regulations or other requirements change
- Significant changes in market demand
- Serious nonconformities raised from external audits

Management review minutes were reviewed. The agenda included the following: Measures taken in previous management review meetings, changes, process performance and qualification of products and services, nonconformities and corrective measures, monitoring and measurements, audit results, performance of external suppliers, adequacy of resources etc. This was found to meet the requirements of the standard.

3. Organizational roles, responsibilities, and authorities

An organogram was in place. The organogram reflected the changes in the management structure. The job descriptions of the Production Manager and Process Inspectors were reviewed. The responsibilities of the Production Manager included organizing the production workshop and execution of the production plan and training of production personnel. The Process Inspectors were responsible for the timely inspection of products during production. The production Manager reported to the Director of the Gaotang subsidiary while the Process inspectors reported to the Head of the quality department.

4. Control of documented information

Document control Procedure was reviewed. The procedure described the preparation, approval, identification, issuance, alteration, recovery, destruction and archiving of the company documents. It was applicable to the management of the company quality system and product related management documents, technical documents, and external documents. The quality department was responsible for the preparation of the quality system documents. The Record Control Procedure was also reviewed. Ink was to be used for making records. Errors were only allowed to be corrected by striking out and signing.

5. Personnel competence and training

The relevant procedure for training of staff was reviewed. The objective of the procedure was to enhance the skills of the employees and build a management team that meets the requirements of the development enterprise. The procedure was applicable to all employees of the company. Management was responsible for preparing and revising the company's training management system, collecting training demand information, formulating and reviewing annual training plan, improving the training system and guiding the construction of the internal trainer team. Training categories included: Orientation training for new employees, Pre-job training for new employees, on the job training. New employees were trained on quality objectives and quality policies. Each department determined its training needs according to the company annual work plan, objective, standards, employees working ability and performance. Annual training demand forms were submitted by each department for approval. The Training Plan for 2023 was reviewed. Training content included trainings on working instructions for the inspection process, packing operation, sewing operation, laying operation, Sewing Process safety, and broken needle management system. Training records for packaging personnel, inspection of LLIN, and sewing instructions were in place. Effectiveness of the training was evaluated. 18 operators were trained with a pass-mark of 85% and they all scored above this requirement.

6. Risks Management

The procedure for Risk Management was reviewed. The procedure was applicable to the identification and evaluation of internal and external environmental factors, products, and service covered by the QMS and the planning and implementation of risk management. The purpose of the procedure was to effectively address risks and opportunities by identifying and evaluating various internal and external environmental factors related to the company's objectives and strategic direction that affect the ability to achieve the expected results of the QMS. The General Manager was responsible for the identification and evaluation of internal and external environmental factors and approval of the risk and opportunity planning. A risk register was in place. Risk and opportunity identification, response evaluation form was in place. Risks related to the following had been identified and mitigation measures defined: Traceability, allergies/reactions to the active ingredient, Organizational environment, Changes in local economic environment, Fire Safety, Resource Management, Production Floor, ability, awareness and communication, Quality Department, Operation and planning process, Active ingredients, Release of products and Services, Operation and planning process.

7. Control of changes

The "Change Management System'' procedure was reviewed. The purpose of the procedure was to standardize change management, control the impact of changes and ensure that the change processes are effectively controlled. The procedure was applicable to the changes related to the production process and quality specifically: the operators of key processes, organizational environment, raw material, equipment, technology, quality standards, operation instructions. The technical department was responsible for the management and control of changes of the process documents and technical documents. The management department was responsible for management and control of personnel and environment changes in key positions while the quality department was responsible for management and control of the changes to the inspection process and inspection work instructions. A Change request Verification Report Verification form related to changes in the packaging process was reviewed.

8. Internal Audits

Internal Audit Control Procedures was reviewed. The purpose of the procedure was to determine through internal audit whether the QMS of the company conforms with the standard requirements and with relevant laws and regulations. It was also to verify whether the QMS was effectively implemented and maintained to ensure continuous improvement of the system. The General Manager was responsible for approving the yearly plan and making decisions on major issues raised during the audits. Management representative was responsible for the planning, organization and leading the audits. The audit team was responsible for verifying the effectiveness of the implemented corrections and corrective actions. Internal audits involved the following activities:

- Audit planning
- Audit preparation
- Audit implementation
- Conducting of the audit, audit report, tracking and verification of corrective measures, audit program monitoring and review, audit effectiveness evaluation and improvement.

The audit plan for 2023 was reviewed and internal audit report were reviewed. The following departments were to be audited: Management Department, Sales Department, Technology Department, Production Department, Planning and Purchasing Department, Quality Department, Equipment Department, Bazhou sub-factory, Gaotang sub-factory, Lixian sub-factory. It was verified that the internal auditors were not auditing their own areas of work. Nonconformities were categorized as General or Serious nonconformities.

9. Control of nonconforming products

The procedure for control of nonconforming products was reviewed. The purpose of the procedure was to guide the identification, recording, isolation, review, and disposal of nonconforming products. The procedure was applicable to the nonconforming products after purchasing materials, identified during the production process, inspection, testing and delivery. The quality department was responsible for the recording, isolation, review, and disposal of the nonconforming products. The management representative was responsible for approval of the disposal of the nonconforming products. The nonconforming products could be reworked, rejected, and returned, recalled, or used as scrap. Nonconforming products were categorized into 3:

- Minor
- General
- Major

The procedure also provided for investigation, corrections, and corrective actions. Records of nonconforming products were reviewed and found satisfactory. No recall had been registered by the facility at the time of the audit.

10. Performance evaluation

Performance evaluation for the year 2022 was provided. The evaluation included the pass rate of the finished products and statistical evaluation of finished products inspection defects such as holes, oil stains, trimming defects, dirt etc. A comparison of performances between Gaotang and Bazhou sub-factories was also available. Suggestions for improvement had been identified and submitted to top management for consideration.

11. Design and development of products

Design and development of Yorkool LN and Yorkool G3 LN was not undertaken at this facility. This area was therefore not inspected.

12. Customer satisfaction

Customer satisfaction survey form was in place. Customer satisfaction surveys were conducted every quarter. The customer satisfaction survey for the fourth quarter of 2022 were reviewed. The customer was very satisfied with the services of the manufacturer. The overall satisfaction was 95.8%. The following parameters were assessed: Product quality, Timeliness of delivery, Product packaging, Service Attitude, Overall satisfaction.

13. Complaints

The customer quality complaint management system procedure was reviewed. The purpose of the procedure was to ensure timely handling of customer feedback on quality problems, timely handling of customer feedback on quality issues and improve product quality. No complaint had been received in 2021, one complaint was received in 2022. No complaint had been received in 2023. The complaint was reviewed and found satisfactory.

14. Support

Infrastructure and work environment

The facility was generally well maintained. There were two warehouses, one for raw materials and the other for finished products. The two other buildings housed the administrative offices and processing and packaging activities.

Monitoring and measuring resources

An equipment list and equipment maintenance schedule were in place. Maintenance records (2023) for the sewing machines were reviewed. Calibration certificates for the rulers and tape measures were also in place. The annual calibration was performed by Shandong Hennguang Testing Technology Co Ltd.

15. Production and service provisions

Control of Production

Treated fabric from Cangzhou and Lixian sub-factories was cut, sewed, labelled, and packaged according to customer requirements. Both Yorkool LN and Yorkool G3 LN fabric was received at this site. The fabric was inspected for defects such as holes and stains. All the received fabric (100%) was inspected for defects. Label issuance records were in place. The fabric inspection record and inspection standard were reviewed. The inspection standard defined the sampling plans for the sewed, packaged, and warehoused nets. Defects were categorized into minor, major and critical. The fabric inspection record provided details on production batch number, inspection dates, denier, width, colour, length, defects etc. The sewed nets were inspected for tears, stains, holes, and workmanship. Inspection records were maintained.

The packaged nets were then transferred to the warehouse. The nets are sampled for inspection. The nets are inspected for workmanship and defects. A sample is also collected form the warehouse and sent to the Cangzhou sub-factory for physical and chemical testing. The nets are released by the Quality Control Manager.

The nets were then transferred to the warehouse. The warehoused nets are again sampled and inspected for workmanship and defects. A sample was also sent to Cangzhou for physical and chemical testing. Following the approval of the tests results by the Quality Control Manager the nets were then released to the client.

Batch records for Yorkool LN and Yorkool G3 LN were reviewed.

All the nonconformities raised under this section were satisfactorily addressed.

Waste management

The procedure for production waste management was reviewed. The technical department was responsible for the collection and classification of waste generated during production. Waste collected by a third-party company, Taicang Sanfeng Chemical Fiber Co. Ltd. The third-party company was responsible for the treatment of the waste. A contract between Taicang Sanfeng Chemical Fiber Co. Ltd and Yorkool Chemicals (Cangzhou) Co., Ltd was in place. The roles of either party were clearly defined.

16. Post-delivery Activities

A sample of each batch was retained. The retention sampled were stored at the Cangzhou sub-factory. The sample management system procedure was reviewed. The sampling plan was defined. The samples were retained for 6 years.

17. Preservation

The procedure for warehouse management system was reviewed. The inspection standard for accessories was reviewed. Inventory was managed by used of stock cards. The material safety data sheets were available. There were dedicated areas for the storage of rejected material.

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

The Purchasing Control Procedure was reviewed. The procedure applied to the control of the company's current procurement process, supplier control, procurement, information, and procurement product verification. The Planning and purchasing department was responsible for the centralized management of the procurement of raw materials and auxiliary materials. The Technical Department was responsible for providing technical information on material and participate in the selection of suppliers. The procedure described the selection and evaluation of suppliers. Suppliers were evaluated annually. An approved supplier list was in place. Supplier evaluated records 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 **Yorkool Chemicals (Cangzhou) Co., Ltd. - Gaotang** located at **The Wind Road South Middle, Gaotang County Economic Development Zone Liaocheng City, Shandong, 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/