



**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.-Bazhou
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.-Bazhou Shiyou South Road, Kuoda Village, Nanmeng Township, Bazhou City, Hebei, China
Unit/Block/Workshop	Not applicable
Inspection details	
Dates of inspection	12 -14 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	The activities related to the manufacture of Yorkool LN and Yorkool G3 LN at the site included warehousing, cutting, sewing, labelling and packaging. The treated fabric was received from other processing sites at Cangzhou and Lixian.
General information about the company and site	Since the last inspection there was a change in the ownership and top management 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.
History	The site by WHO was last inspected in May 2019. The site was ISO 9001 certified as indicated below:



	<p>ISO 9001: 2015: Quality Management System Certificate Number: 30722Q20579R1M Reissue Date: 20 October 2022 Expiry Date: 23 September 2025</p> <p>Scope: Manufacture of Long Lasting Insecticidal Net. The certificate was issued by BAC</p>
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	<p>Document review including but 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	Yorkool LN (Deltamethrin -55mg/m ² ±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



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. The quality policy and quality objectives had been approved and signed by the General Manager. The quality objectives were measurable and monitored. Key performance indicators to monitor the extent to which the quality objectives had been met was defined. Monthly performance evaluations to assessment extent to which of quality objectives had been met for each department were in place. The performance of the following departments was monitored: Management department, Sales department, production department, Equipment department and quality department. These were discussed in management review.

2. Management review

The procedure for management review was discussed. Management review meetings were held at least once a year. The General Manager was responsible for chairing the meetings. Management review minutes were reviewed. The agenda included the following Internal audits, corrective and preventive measures, adequacy of resources, customer satisfaction, quality objectives and results of monitoring and measurement, performance of external suppliers etc. This was found to meet the requirements of the standard.

3. Organizational roles, responsibilities, and authorities

An organogram reflecting the changes in the management structure was in place. The in-charge of the Bazhou sub-factory reported to the Management Representative. The Management representative reported to the General Manager. The job descriptions of the Process inspectors, Management representative and QC manager were reviewed. The QC Manager was responsible for product release. The commitment of the top management to establish a quality policy and quality objectives for the quality management system, to promote improvement and support management roles in their areas of responsibility was documented in the quality manual.

4. Control of documented information

The procedures for document control and record control were reviewed. The document control procedure described the preparation, approval, identification, issuance, use, alteration, recovery, destruction and archiving of the company documents as well as the effectiveness evaluation and improvement to ensure that the latest and effective version of the corresponding documents are available in each department to prevent unintended use of invalid documents. The procedure was applicable to the management of the company quality system and product related management documents, technical documents, and external documents. Documents were categorized into Quality Manual, Procedures, Management Files and Technical Documents.

5. Personnel competence and training

The relevant procedure for training of staff was reviewed. The procedure applied to all employees of the company. The management department was responsible for compiling training needs and formulating a training plan. The departments were responsible for identifying training needs. Trainings were categorized into:

- i) Pre-job training
- ii) On-job training



iii) Expatriate training

Trainings were assessed by use of questionnaires. The pass mark was 85%. The annual training plan for 2023 was in place. The training plan included fire drill training, Site management, operation instructions for fabric inspection process, operation instructions for spreading process, safety, operation instructions for packaging process etc. Training records for training on operation instructions for the sewing process were reviewed. Effectiveness of the training was assessed, and evaluation record maintained.

6. Risks Management

The procedure for Risk Management was reviewed. 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 and that affect the ability to achieve the expected results of the QMS. The Quality department was responsible for development of a plan to deal with the identified risks. The General Manager was responsible for identification and evaluation of internal and external environmental factors and approval of the risk and opportunity planning. A risk register was in place. Risks related to the following had been identified and mitigation measures defined: 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 etc.

7. Control of changes

The procedure for Change management was reviewed. The procedure was applicable to changes related to the production process and quality specifically: to the operators of key processes, organizational environment, raw material, equipment, technology, quality standards, operation instructions etc. The Production Department was responsible for the management and control of site operation instructions and production equipment changes. Technical department was responsible for the management and control of changes related to the documents and technical documents. The Quality Department was responsible for the management and control of the changes related to the inspection process and inspection work instructions. Changes were documented. The impact of changes was assessed prior to implementation of any change. Records related a change in cloth laying process and equipment were reviewed.

8. Internal Audits

The Internal Audit Control Procedure 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 and to verify whether the QMS was effectively implemented and maintained to ensure continuous improvement of the system. Management representative was responsible for the planning and organizing internal audits. The audit plan for 2023 was in place. The areas to be audited included: Management Department, Sales Department, Technology Department, Production Department, Planning and Purchasing Department, Quality Department, and Equipment Department. It was verified that the internal auditors were not auditing their own areas of work. The audit team was responsible for verifying the effectiveness of the implemented corrections and corrective actions.

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. Nonconforming products were categorized into 3:

- Minor
- General
- Major

The nonconforming products could be reworked, rejected, and returned, recalled, or used as scrap. Nonconforming products could also be accepted under concession with the client. Records of nonconforming products were reviewed and found satisfactory.

10. Performance evaluation

The pass rate and acceptance of the inspection results of the finished products was evaluated and assessed. The performance evaluation report for finished products (January – December 2022) was in place. The following are some of the inspection results and defects data that was collected and evaluated:

- Greasy dirt
- Oils and stains
- Trimming defects
- Holes
- Uneven width

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 surveys were conducted every quarter. Customer satisfaction survey form was in place. The customer satisfaction survey assessed the following parameters:

- Product quality
- Timeliness of delivery
- Product packaging
- Service Attitude
- Overall satisfaction

Customer satisfaction reports were reviewed. The customer was very satisfied with the services of the manufacturer.

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 issues and improve quality



of products. The quality department was responsible for coordinating with the respective department to analyse, investigate, propose, and verify corrective measures. Records on complaints were maintained. Complaints were reviewed.

14. Support

Infrastructure and work environment

The facility was generally well maintained. There were two warehouses one for fabric and the other for accessories such as packaging materials, labels hooks etc. Additionally, there was a separate warehouse for storage of finished goods. The other buildings housed the processing and packaging operations.

Monitoring and measuring resources

The equipment maintenance plan for 2023 was in place. The calibration schedule was also in place. The calibration certificate for the balances and measuring tape were reviewed. Maintenance records for the sewing machines were in place.

15. Production and service provisions

Control of Production

The manufacturing activities at this site included the cutting, sewing, labelling, and packaging of Yorkool LN and Yorkool G3 LN. The Yorkool LN treated fabric was received from the Cangzhou and Lixian sub-factories, Yorkool G3 LN treated fabric was received from Lixian sub-factory. The fabric was inspected for defects such as holes and stains. All the received fabric (100%) was inspected for defects. The inspected fabric is then cut, sewed labelled and packed according to customer requirements. Label issuance and control was found adequate. Label issuance and relevant records were in place. The sewed nets were sampled and inspected for defects. The inspection standard defined the sampling plans for the sewed, packaged, and warehoused nets. Defects were categorized into minor, major and critical. The sewed nets were inspected for tears, stains, holes, and workmanship. Inspection records were maintained. The packaged nets were again sampled after packaging prior to warehousing. The packaged nets were inspected for workmanship defects such as open seams, uneven width etc. There were separate lines for sewing and packaging of Yorkool LN and Yorkool G3 LN.

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 net were then released to the client.

Batch records for Yorkool Yorkool G3 LN were reviewed.

Waste management

The relevant procedure for production waste management were reviewed. Waste collected by a third-party company. The third-party company was responsible for the treatment of the waste. A contract between third-party company and Yorkool Chemicals (Cangzhou) Co., Ltd. – Bazhou was in place. The contract was drawn in accordance with the relevant national laws, regulations, and provisions on Environment protection in China. The roles of their party were clearly defined.



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

16. Post-delivery Activities

Retention samples for each batch were collected from the warehouse were sent to the Cangzhou sub-factory for storage. The samples were stored for 6 years. The sample management system procedure was reviewed. The number of retention samples to be retained were defined.

17. Preservation

The procedure for warehouse management was reviewed. Inventory in the warehouse was managed by use of stock cards. Material safety data sheets were available. There were dedicated areas for the storage of rejected material. The treated Yorkool LN and Yorkool G3 LN fabric was stored in separate area within the fabric warehouse.

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

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 procedure described the selection and evaluation of suppliers. Supplier evaluation forms of the different suppliers were reviewed

Part 3	Conclusion – Inspection outcome
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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.-Bazhou** located at **Shiyou South Road, Kuoda Village, Nanmeng Township, Bazhou City, Hebei, 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
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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/>