World Health Organization

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Prequalification Unit Inspection Services
WHO INSPECTION REPORT
(WHOPIR)
Vector Control Product Manufacturer

Part 1	**General information**
Company information	
Name of manufacturer	Saerfu (Henan) Agrochemical Co. Ltd
Corporate address of manufacturer	High and New Technology Industrial Area, Mengzhou, Henan 454750 People's Republic of China
Manufacturing site(s) under assessment	
Address of manufacturing site if different from that given above	As above
Desk assessment details	
Date of review	1-7 April 2026
Type of inspection	Desk Assessment
Last WHO inspection	Onsite inspection: • I-03487 – 7-9 June 2023. Compliant.
Introduction	
History of the site	Saerfu (Henan) Agrochemical CO., LTD. is situated in Mengzhou City, Henan Province, China. The site is approximately 53,300 square meters with a production area of 15,000 square meters. The site contains dormitories, quality control area, three production workshops: synthesis workshop, solid preparation workshop, and liquid preparation workshop. There is one finished products warehouse, two raw materials warehouses, one turnover warehouse, a hazardous waste warehouse, distribution power station, freezing station, maintenance workshop, sewage treatment station, MVR salt-containing wastewater treatment and other equipment and facilities.
WHO Product(s) to be covered by this desk assessment	• 035-001 – FastM – Prequalified – Vector Control Product • P-00100 – Bendiocarb – Acceptable – Vector Control Active Ingredient

Abbreviations	**Meaning**	
NC	Non-conformity	
NCR	Non conformity Report	
OOS	Out-of-specification	
QC	Quality control	
QMS	Quality management system	
SCAR	Supplier Corrective Action Request/Report	
Part 2	**Summary of the assessment of ISO evidence submitted**	
Inspection Report 1		
Competent authority names	Henan Provincial Department of Agricultural and Rural Affairs – Henan Provincial Pesticide Production License Review Team	
Dates of inspection	11-12 September 2023	
Type of inspection	Renewal – first issued September 29, 2018	
	Products	Included.
	Scope:	The scope was listed as: The production license scope including: 98% methomyl, 98% insecticide, granules, wettable powders, water dispersible granules, emulsifiable concentrates, emulsions in water, microemulsions, soluble powders, aqueous solutions.
Final conclusion of the inspection report	At the time of the audit, the report stated that "the applicant holds 20 pesticide registration certificates issued by the Ministry of Agriculture and Rural Affairs, including: 9 emulsifiable concentrates (insecticides), 1 granule (fungicide), 3 wettable powders (insecticides/fungicides), 1 soluble powder (insecticide), 1 water-dispersible granule (insecticide), 2 aqueous solutions (1 fungicide and 1 plant growth regulator), 1 98% insecticide technical material, 1 95% dual insecticide technical material, 1 98% methomyl technical material. Currently, there are no pesticide registration certificates for emulsions in water and microemulsions."	
Comments / observations on the scope and comprehensiveness of the report and appropriateness of the CAPAs	It was noted that this was a production renewal license only.	

Part 3	Review of additional documents

1. Certification and audit reports:
The manufacturer provided a copy of the Pesticide Production License audit and the report on the rectification of deficiencies.

A copy of the ISO 9001:2015 certificate issued by Tuorong Certification (Jiangsu) Co. Ltd (expiry 2028-05-12) was provided.

The scope of certification was as follows:
Production, formulation, and sales of the products within the scope of qualification and permission: Bendiocarb 98%TC, Wettable powder (WP), Water soluble powder (SP), soluble concentrate (SL), Water dispersible granule (WDG) and Emulsifiable concentrate (EC).

2. Quality Manual:
The manufacturer provided a copy of the Quality Manual. The quality manual was approved by the general manager. A revision or update to the manual; was not evident since the implementation in 2018. The management representative roles and responsibilities were listed within the manual. Top management was committed to the development and continual improvement of the quality management system. The manual was set out as per the requirements of ISO 9001:2015 and was applicable to the manufacturing of Bendiocarb Tech and 80% WP and 20% WP. There were no exclusions or non-applicable clauses stated.

Top management was responsible for implementing the Quality Policy and that the policy was understood, implemented, and maintained at all levels of the organizations. The Quality Objectives were available within the manual.

The manufacturer provided a copy of the organizational chart with clear separation of roles and reporting responsibilities between production and the QC department.

Relevant national and international standards as well as regulations were available.

3. Site Master File:
A copy of the Site master file was provided. It was stated within the manual that the management team had reviewed the SMF in August 2025 and concluded that modifications were not required. The identified management representative listed in the SMF differed from that listed in the Quality manual.

4. List of current quality management procedures:
A list of the relevant Quality Documents was available. Document name and unique identifier were available.

5. Standard operating procedures for:

i. Complaint handling and vigilance:
The manufacturer provided a copy of the Customer Feedback and Complaint Handling Procedure. The manufacturer stated that there had been no complaints received in the past two years. A copy of the complaint handling form was provided. All complaints received were the responsibility of the sales department. Complaint handling timelines were available, and complaints were to be closed in 7 days (including the investigation). QA were responsible for investigation of a complaint, including comparison with retained samples.

ii. Control of nonconforming goods/processes:
The manufacturer provided a copy of the Control Procedure for Nonconforming Products. Nonconforming products were classified into three grades:

1) minor – no impact on product quality,
2) general - do not meet requirements but do not affect the performance and
3) serious - can affect function and performance.

The manufacturer had a number of disposal methods for nonconforming product to include rework, repairing, downgrading, concessional acceptance and scrapping.

All products that had undergone rework or repair were subjected to a re-inspection.

For serious nonconformities of semi-finished product, the quality department would report to the management representative who would organise a review and decide on the next step (rework / repair, or disposal) but concessional use and release were not permitted for such product.

For nonconforming product found after delivery, a corrective action would be raised by the quality control department.

iii. Change control/change notifications (product and processes):
The manufacturer provided a copy of the Change Control Procedure. Changes to product were in accordance with clause 4.4 of ISO 9001:2015 standard. Changes in product and service requirements would be communicated to top management via the management review process.

iv. Risk management:
The manufacturer provided a copy of the Nonconformity, Corrective and Preventive Actions Procedure. The document provided incorporated the identification and analysis of nonconformities which was performed by the Quality Control department. The procedure did not specifically identify that a risk analysis was performed for the full life cycle of the product, it did describe that corrective, and preventive actions were implemented to eliminate actual and

potential nonconformities, including the control of risk. The risk analysis process was reviewed at the last WHO inspection.

v. Supplier evaluation and control, verification of purchased product:
The manufacturer provided a copy of the Procurement Procedure. Suppliers were classified according to criticality with Class A being items that constitute the main or key component of the product and have a direct impact on the performance and safety. Re-evaluation of suppliers was to occur annually and was a review of performance over the past year. Class A and B suppliers were approved by the General Manager.

vi. Design and development:
The design and development procedure were reviewed at the previous WHO on-site inspection and was found to meet the requirements of the standard. The manufacturer stated that there had been no changes to the product.

vii. Internal Audits:
The manufacturer provided a copy of the 2025 Internal Audit Non-conformity items and rectification report. The report was provided in local language as well as a translated copy. There was reference within the Quality Manual to internal audits and in the SMF to internal checks that were to be conducted annually. The roles and responsibilities of the auditor were available including the prevention of auditing one's own work.

6. Changes to the product:
The manufacturer had declared that there had been no changes to the product since the last WHO inspection, including changes to production processes or changes in the quality assurance process. The production of the above listed products continues to adhere to the national pesticide production license requirements.

7. Complaints received:
The manufacturer stated that there have been no batch recalls or out of specification of final product in the last two years. Product quality was recorded as a 100% pass rate.

8. Management Review meeting:
The minutes from the 2025 Annual Quality Management Review Report were provided. The quality policy was discussed, and all objectives were met. Onsite training for all staff was available and included all areas.

9. Batch manufacturing Records:
The manufacturer provided a copy of the batch manufacturing records including the chromatograms and the analysis reports performed for release of product. The information provided was legible, with all forms and reports signed and dated by the analysis and checker.

10. Manufacturing flowchart including in-process control points:

The manufacturer provided a copy of the manufacturing flowchart that included QC points. Acceptance criteria were available.

Part 5	Desk assessment conclusion

Based on the QMS evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***Saerfu (Henan) Agrochemical CO., LTD*** located at ***High and New Technology Industrial Area Mengzhou City, Henan Province, People's Republic of China*** is considered to be operating at an acceptable level of compliance with ISO 9001:2015 and WHO requirements.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 5	List of guidelines referenced in this inspection report

1. ISO 9001:2015 Quality management systems – Requirements

2. WHO guideline for the prequalification assessment of insecticide-treated nets (ISBN 978-92-4-008647-0)

3. Inspection Services Procedures (https://extranet.who.int/prequal/inspection-services/inspection-services-procedures)