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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	Saerfu (Henan) Agrochemical Co. Ltd
Corporate address of manufacturer	Saerfu (Henan) Agrochemical Co. Ltd High and New Technology Industrial Area, Mengzhou, Henan 454750, China
Inspected site	
Name & address of inspected manufacturing site(s)	Same as above
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	07 -09 June 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	There were 3 workshops: Technical Workshop, Dry Powder workshop, Liquid Workshop. These were in separate buildings. There were 5 dry powder production lines. One line was dedicated to the production of Bendiocarb 80% WP-SB. The other four lines were used to produce Methomyl products. Only Dry powder workshop (Bendiocarb production line) was inspected.
General information about the company and site	This was the first WHO inspection of the site. The site was ISO 9001 certified as indicated below: **ISO 9001: 2015: Quality Management System** Certificate Number: 06921Q17152R0 Issue Date: 15 December 2021 Expiry Date: 14 December 2024 **Scope:** Production, formulation and sales of products within the scope of qualification and permission: Bendicard 98% TC, Wettable powder

	(WP), water soluble (SP), Soluble Concentrate (SL), Water Dispersible Granule (WDG), and Emulsifiable Concentrate (EC), (Limited to the manufacture of insecticides and fungicides).
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 activities were not undertaken at this site.
Out of scope	The manufacture of herbicides, fungicides, fertilizers, rodenticides, and other products not submitted to PQ were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	FastM (Bendiocarb – 800g/Kg, WP-SB) - 035-001
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

The manufacturer had established quality policy and quality objectives. These were documented in the Management Manual. The Quality policy included a commitment to continuously improve the quality management system. The quality objectives were related to delivery and inspection pass rate, and customer satisfaction, among others. Key performance indicators to monitor the extent to which the quality objectives had been met were defined and discussed in the management review meetings.

2. Management review

Top management held management review meetings every quarter. The minutes of the management review meeting were checked. The agenda included the following: training, indicators and objectives, improvements, preventive and corrective measures, nonconforming products, and new technologies etc. This was found to meet the requirements of the standard.

3. Organizational roles, responsibilities, and authorities

An organogram was in place. The site was headed by the General Manager. The Technology director and Factory manager reported independently to the General Manager. The factory manager headed the production departments including the technical production line, powder production line and liquid production line. The Technology Director headed the quality department, 'Analysis room' (laboratory). The job description of the Production Manager and Quality Control Supervisor were reviewed. The Production Manager reported to the Factory Manager while the Quality Control Supervisor reported to the Technology Director. The Factory manager was responsible for organizing production operations and organizing the production schedule. The factory manager was also responsible for the effective implementation of the quality management system. The Quality Control supervisor was responsible for organizing the quality control plan according to the company's overall quality status and monitoring the quality of the products. The quality control supervisor was also responsible for summarizing product quality issues and providing feedback.

4. Control of documented information

The relevant procedure for Quality, Environment, and Occupational Health was reviewed. The purpose of the procedure was to manage the documents related to quality and environmental management systems to ensure that the documentation was appropriate, adequate, and effective. The purpose of the procedure was also to ensure that all documents related to the management system were under control to prevent misuse. The document structure of the management system was divided into 3 levels.

Level 1: Management Manual including quality, environmental policies, and objectives
Level 2: Procedural Documents
Level 3: Management standards, work standards, technical documents, process procedures, inspection specifications, external documents from suppliers, national laws and regulations.

Procedures were prepared by the concerned department. The management representative was responsible for organizing and compiling the Quality and Environmental management Manual and the General Manager was responsible for approving and issuing it. The Enterprise Management

and Human Resource department was responsible for the management, and control of issuance, and archiving of documents. The Technical Quality Control department was responsible for the preparation, modification, management, and control of product technical documents. The operators accessed both hard and soft copies of the procedures. Only read access to documentation was provided.

5. Personnel competence and training

A competence form was in place. The competences of the different positions within the company were reviewed:

a) Production Monitor
b) Operators
c) Maintenance Worker
d) Operator training requirements.

Operator Technical Training records were also reviewed. The company conducted training in classroom and on the job training (OTJT). The following trainings had been conducted, records and assessments were in place: Occupational Safety, MSDS training, Laboratory Management System Training, Hazardous Chemical Substances Training, Method of use for Laboratory Instruments, Awareness of labor Laws and Cross Contamination Training, Preparation of equipment, Technical Process training, Onsite Safety training, 5S (Housekeeping) training and Quality Management Training.

6. Risks Management

The procedure for risk management was reviewed. Each department was responsible for identifying and evaluating hazards in its own department. The procedure described the identification and evaluation of risks. A risk matrix was in place. The risk matrix took the following into consideration: Main hazardous substances, hazardous and human factors in the production process, distribution of main hazardous and harmful factors, and sources of hazardous chemicals~~,~~ etc.

7. Control of changes

The relevant procedure for change control was reviewed. The purpose of the procedure was to control and plan possible changes to ensure that all changes were managed. The change control form and was in place. Changes related process documents were reviewed.

8. Internal Audits

The relevant procedure for internal audits was reviewed. The purpose of the procedure was to verify the effectiveness and conformity of the Quality, Environmental, Occupational Health, and Security Management System to the relevant standards and identify area for improvement. The audit plan for the year 2022 was reviewed. The scope of the audits was as follows: Production and Sales of Bendiocarb WP soluble powder and granules, company's management systems documents, applicable laws, products and related standard customer and related requirements. The areas audited in the January 2022 included Human Resource, Technical Production, Production Workshop, Supplier Department, Financial Department and Security and the Management Department. The team issued a written report next day after the closeout meeting. Timeline to address the nonconformities were defined. The effectiveness of the implemented corrections and corrective actions were verified. All observations raised, were closed out. The auditors did not audit their own areas of work.

9. Control of nonconforming products

The procedure for control of nonconforming products was reviewed. The procedure was applicable to the process of delivery of raw materials, auxiliary materials, outsourced parts and finished products including the production process and inspection of finished products. The substandard products could be reworked, disposed, or accepted with concession. Reworking and acceptance with concession was approved by the management representative. The procedure provided for investigations, root cause analysis, corrections, and corrective actions. The procedure required that the nonconforming product be identified and isolated. The template for nonconforming product was in place.

The procedure for product recall was also reviewed. The purpose of the procedure was to ensure a complete recall of a product in a timely manner after delivery to reduce harm to customers. The general manager was responsible for approving the recall of a product. A recall could be initiated in the following instances:

- If the product has serious safety hazards or violates requirements of laws and regulations or fails sampling inspection and be recognized by relevant authorities.
- If certification or government agencies order product withdrawal from the market.

The quality department was responsible for investigations to determine the root cause, follow-up on the implemented corrective actions. No recalls had been initiated by the time of the inspection.

10. Performance evaluation

Laboratory analytical data was compiled and monitored. The manufacture compiled data related to active ingredient content, wettability, and other test parameters. Complied data for the period of January 2021 to December 2021 was in place. The data was compiled monthly. The data for January 2023 was also in place.

11. Design and development of products

Design and development of FastM was not undertaken at this facility. This area was therefore not inspected.

12. Customer satisfaction

The procedure for customer satisfaction was reviewed. Customer satisfaction survey was conducted by use of a questionnaire. The customer satisfaction survey forms were sent to the customer three months after purchase of the products. The customer feedback form was in place. The customer assessed the following: Product appearance, Package loading, Performance in use, Instructions for use, Service Attitude, Service timelines, and Service personnel technical knowledge. These were rated as Very Satisfied, Generally Satisfied, Basically Satisfied, Not Satisfied, Not satisfied at all. The reasons for the choice were also to be provided. The 2022 customer satisfaction report which included a data trend report was reviewed. The customers were very satisfied with the services of the manufacturer.

13. Complaints

The company had received no complaints since 2019. The procedure for customer complaint handling was also reviewed. Complaints from the market were received by the sales department. Quality assurance department was responsible for investigations, root cause determination and verifying that the implemented corrective measures were effective. The complaint registration form was in place.

14. Support

Infrastructure and work environment

The infrastructure was generally well maintained. The operators were equipped with protective gear. The weekly maintenance schedule was in place. The maintenance records for the premix tank, dust collector and jet mill were reviewed.

Monitoring and measuring resources

The calibration schedule and plan were place. The calibration records for the electronic balances were reviewed. Calibration certificates for the HPLCs respectively were also reviewed. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

15. Production and service provisions

Control of Production

The manufacture of Bendiocarb 80% WP (FastM) included premixing, jet milling, remixing, and packaging. The raw materials were weighed following a documented recipe. A sample was collected for analysis after remixing of the powder from the Jet mill. The tests performed included a~~A~~ctive ingredient content, wet sieve test, suspensibility, persistent foam, and wettability. Following the approval of the in-process analysis on the powder; it was then packaged in soluble bags and staged for 24 hours (aging) prior to secondary packaging into aluminium pouches. The weight of the bags was verified as part of the in-process control tests. The packaged bags were again sampled from the warehouse for finished product testing.

The laboratory was well equipped. The laboratory comprised of separate area namely, Instrument analysis room, chemical analysis room, weighing rom and the drying room. Samples were adequately labelled. A sample register was in place. The laboratory performed both physical and chemical tests. Analytical test reports for Bendiocarb 80% WP and Bendiocarb technical material were reviewed. Active ingredient content determination was performed using HPLC. Primary and secondary reference standards were in place. The test for solubility of the soluble bags was witnessed by the inspectors.

Production batch records for Bendiocarb 80% were reviewed.

Waste management

The waste generated from production activities was treated by the facility. The dust generated from the Bendiocarb production line was collected by use of a dust extractor and pumped to the incinerator.

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

16. Post-delivery Activities

A sample of each batch was retained. The retention samples were stored under ambient conditions. A register was in place.

17. Preservation

Raw materials were sampled at receipt. The materials in the warehouse were stored on pallets and metallic racks. Inventory management was by use of stock cards. Materials were stored at ambient conditions.

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

The procedure for supplier management was reviewed. The procedure was applicable to management of all suppliers that provided services and products to the company. The procedure described the selection and evaluation of suppliers. The Supply Chain Department was responsible for centralized management of suppliers while the Production Department, Technical Quality Control Department, Finance Department, Safety and Environment Department participated in the supplier evaluation. An approved supplier list was in place. The assessment reports 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 **Saerfu (Henan) Agrochemical Co. Ltd** located at: High and New Technology Industrial Area Mengzhou, Henan 454750, 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/