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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	BASF Agriproduction SAS
Corporate address of manufacturer	BASF AGRO B.V. Arnhem (NL) Zuerich Branch Im Tiergarten 7 8055 Switzerland
Inspected site	
Name & address of inspected manufacturing site(s)	BASF Agriproduction SAS France FR 69727 Genay ZI Lyon Nord Rue Jacquard
Unit/Block/ Workshop	Not applicable.
Inspection details	
Dates of inspection	25-28 October 2021
Type of inspection	Initial inspection. The criteria for the inspection was based on the ISO 9001:2015 standard.
Introduction	
Brief description of the manufacturing activities	The site was constructed in 1977 and is currently engaged in the formulation and packaging of insecticides, fungicides and see treatment products. The process of manufacture of Fendona® 10 SC and Fendona® 6 SC involved preparation of the premix, mixing, filling, packaging and labelling.
General information about the company and site	The site had received both ISO 14001:2015 and ISO 9001:2015 certification. ISO 9001: 2015 certificate number 8435 and ISO 14001:2015 certificate number 23868 issued by Afnor. Valid from 23/05/2019 to 26/03/2022 was provided. Scope: ‘‘Formulation, filling, storage and distribution of plant protection products.’’
History	This was the first WHO audit of the site

Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	**Document review including but not limited to:** • Training • Risk management • Management review • Job descriptions and responsibilities of key personnel • Complaints • Non-conforming products • Data integrity • Product release • Batch processing records • Laboratory test reports • Control of changes • Internal audits • Calibration and equipment maintenance **Physical areas:** • Raw material and finished goods warehouse • Production areas • Quality control laboratory
Exclusions and Non-applications of requirements in the QMS	Design and development were not applicable. The site was not involved in the design and development of the product.
Out of scope	Manufacture and testing of products not submitted to WHO for prequalification. The inspection was limited to the scope of products indicated in the section below (WHO products covered by the inspection).
Restrictions	None
WHO products covered by the inspection	1. Fendona® 10 SC, Product number- 002-005 2. Fendona® 6 SC, Product number - 002-006
Abbreviations	**Meaning**
CoA	Certificate of Analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
QMS	Quality Management System
SC	Suspension Concentrate

Part 2	Brief summary of the findings and comments

1. Organizational roles, responsibilities and authorities
An organogram was in place. The Production Supervisor, Quality Control Laboratory Supervisor and Filling Supervisor all reported independently to the Operations Manager. The job descriptions, job requirements and qualifications of the position of the site manager and Quality control supervisor were reviewed. The Quality Control Supervisor was responsible for release of products. Job descriptions were reviewed every 3 years.

2. Quality policy and quality objectives
Documented quality policy and quality objectives were available. The quality policy and quality objectives were displayed within the facility and was discussed with employees in meetings. The quality policy met the requirements of the standard. KPIs had been defined to measure and monitor the quality objectives. The quality objectives and quality policy were discussed in management review.

3. Management review
Management reviews were held once every year. The management review minutes of meeting held in March 2021 were reviewed. The review took into consideration the following: quality objectives, quality policy, risks, processes performance, safety, environment, changes, nonconformities etc. This was found to meet the requirements of the standard.

4. Leadership and Commitment
As a commitment the quality policy had been signed by the Director of Industries (BASF). Leadership promoted improvement of the quality management system. Opportunities for improvement had been identified and documented following the Management review. Commitment to improving the quality management system was further demonstrated through internal audits, performance evaluations etc.

5. Control of documented information
The relevant document control procedure was reviewed. Documented were categorized into: Manual process documents, reference documents, operation documents and instructions. Documents were maintained in both electronic and paper forms. Documents were reviewed every 3 years. Electronic documents were maintained in a company software system. Access to the software was controlled by use of unique passwords. More so, the software has access rights to create, review and approve documents. Documents of external origin were incorporated into the system following approval from the responsible persons.

6. Personnel competence and training
The relevant procedure for training was reviewed. The training program and schedule for 2021/2022 was in place. Trainings were monitored. Trainings were categorized into induction training and continuous training. Trainings on cross contamination and use of the forklift were reviewed. The trainings were evaluated, and records were maintained.

7. Risks and opportunities

The relevant procedure for risk management was reviewed. Risk assessment was performed every 3 years or whenever there was a change. A risk matrix was in place. A pandemic continuity plan that considered the related risks related to COVID-19 pandemic was also in place.

8. Control of changes

The change control procedure was reviewed. Changes were reviewed to ensure that all the requirements including risks and impacts have been considered prior to implementation of the change. A change regarding the nitrogen generator was reviewed. Records were maintained.

9. Internal Audits

The relevant procedure for internal audits was reviewed. The audit plan for 2021 was in place. The facility had 8 internal auditors. Training records of the internal auditors were available. The procedure provided for corrections and corrective actions. The different areas were audited every 3 years. Due dates for which a correction or corrective action had to be implemented was included in the report. The correction and corrective actions are verified by Internal auditors.

10. Control of nonconforming products

Market complaints were received by BASF (global) and communicated to BASF Agriproduction SAS, Genay. The complaints were communicated to BASF Agriproduction SAS, Genay via an Internal system. It was required to investigate complaints within 30 days. The progress of the investigation was monitored. Registered complaints were reviewed and found satisfactory. Records were maintained. Market recalls are carried out by BASF Global.

11. Performance evaluation

Customer satisfaction was measured by the number complaints and number of non-conforming products. Customer evaluation is performed on a quarterly basis. These were discussed in management review.

12. Design and development of products

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

13. Support

Infrastructure and work environment

The site had the following buildings: Bulk storage warehouse, formulation building, filling unit, finished product warehouse, raw materials warehouse, and packaging storage building.
There were four formulation, filling, and packaging lines namely, F12 (Insecticide line), F10 (Fungicide – solvent based line), F8 – (Fungicide – water-based line) and F 14 (pelliculants line). Fendona® was manufactured on line F-12. The site was generally in a good state of repair.
Material Safety Data Sheets were in place.

Monitoring and measuring resources

Equipment maintenance records were reviewed. Calibration certificate for the standards weights was in place. The calibration and maintenance records of the filling line (F-12) were also reviewed and found satisfactory.

14. Production and service provisions

Control of Production

The manufacture of Fendona® 10 SC and Fendona® 6 SC involved mixing of different ingredient to form a premix, this was then mixed with other ingredients to achieve the desired concentrations, filtration, filling labelling and packaging. The flow rate, mixing time and temperature were monitored. The master formulas were reviewed. Production records for Fendona® 10 SC batch number 24031971 was reviewed. The filling lines were equipped with cameras and calibrated weigh checkers. Bottles presenting weight or screw cap integrity issues were automatically rejected in the SERAC filling line. The rejected bottles underwent a second manual check and if appropriate were returned to production stock. The weight of the filled bottles was carried out every hour during filling. Cleaning was performed whenever there was a change of product active ingredient. A contamination matrix was available. Cleaning instructions were in place. Cleaning records were maintained. A sample (final rinse) was collected after cleaning and sent to the laboratory for analysis. Production was not allowed to proceed prior to receipt of cleaning results from the laboratory.

The calibration records of laboratory equipment were verified. The calibration records for the weighing balances were reviewed. Sampling plans were available. The standard testing procedure and test records for the determination of Alpha-cypermethrin (Fendona®) were reviewed. The laboratory data management system was verified. Date and time were locked.

Identification and traceability

Laboratory samples were adequately labelled. The information on the labels for the samples collected from production included: product name, batch number, equipment, production line, date, time etc. The batch numbers of the raw materials were recorded in the batch production records.

15. Preservation

Raw materials were supplied by BASF Global. The suppliers of the materials were approved and monitored by BASF Global. Raw materials manufactured by BASF were not sampled. The manufacturer relied on Certificates of analysis. An identification test was performed for all the excipients. Upon receipt of the raw material the following were verified: packing list, order number, name of the material, lot number, quantity etc. A certificate of analysis was provided for all batches of raw materials received. Inventory was controlled by SAP. Access to SAP was controlled by unique passwords. The locations of the different materials were indicated in SAP. Non-conforming products were blocked in SAP and labelled accordingly.

16. Post-delivery Activities

One sample per batch of Fendona® was retained. The retention samples were stored at ambient temperature. The retention samples were kept for 6 years. One batch per year was place on a stability study program. Stability chamber temperature probes were calibrated. Stability studies were conducted at elevated temperature (54±2°C) for two weeks. The storage stability results were reviewed, and these complied with the WHO Specifications and Evaluations for Public Health Pesticides requirements.

17. Control of externally provided processes, products and services

BASF Agriproduction SAS, France did not evaluate the performance of suppliers. Suppliers were selected and evaluated by BASF Global. The evaluation of the suppliers of the raw materials used in the production of Fendona® was performed by BASF Global. BASF Agriproduction SAS, France only provided information the nonconformities related to the raw materials supplied.

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 ***BASF Agriproduction SAS*** located at ***Genay ZI Lyon Nord Rue Jacquard, France FR 69727*** 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. Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange, Final Document, Global Harmonization Task Force, November 2, 2012, GHTF/SG3/N19:2012
   https://www.imdrf.org

3. 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/