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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) Zürich Branch Im Tiergarten 7 8055 Switzerland
Inspected site	
Name & address of inspected manufacturing site(s)	BASF Agriproduction SAS Rue Jacquard, Genay, Z.I. Lyon-Nord, Auvergne-Rhône-Alpes 69727, France
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	09 – 11 December 2024
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 at this site included the formulation and packaging of insecticides, fungicides, seed treatment products etc. There was no manufacture of herbicides at this site. There were four formulation lines. One of the lines was dedicated to formulation of insecticides. Fendona 6 SC and 10 SC were formulated on the insecticide formulation line.

General information about the company and site	The manufacturer held the following ISO certificate: **ISO 9001: 2015/ISO 14001:2015** Scope: ‘‘Formulation, Filling, Storage and Distribution of Plant Protection Products.’’ Certificate Number ISO 9001:2015 - No 8435 Certificate number ISO 14001:2015 – No 23868 Validity 11/4/2022 until 26/3/2025 The certificate was issued by Afnor Certification
History	The site was last inspected by WHO in October 2021. There were no major changes related to the production activities since that last inspection. The nonconformities raised in the previous inspection had been adequately addressed.
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	None
Out of scope	The manufacture of other products not submitted to PQ were not included in the scope of this inspection.
Restrictions	None

WHO products covered by the inspection	• 002-006 - Fendona 6 SC (Alpha-cypermethrin 5.80%) • 002-005 - Fendona 10 SC (Alphacypermethrin 9.6%)

Abbreviations	**Meaning**
CoA	Certificate of analysis
FMEA	Failure Modes and Effects Analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
LLIN	Long Lasting Insecticide Nets
MR	Management Review
MRM	Management Review Meeting
QMS	Quality Management System
RPN	Risk Priority Number

Part 2	**Brief summary of the findings and comments**

1. Quality policy and quality objectives

The quality policy and quality objectives were defined in the Quality Manual. The quality policy and objectives were reviewed annually during the management review. The manufacturer had established, implemented, and maintained a documented quality policy as part of its commitment to the requirements of ISO 9001:2015. The integrated policy reflected the core principles of Quality, Health, Environment, and Safety and aligned with the strategic priorities of the site.

The policy was appropriate to the organization's context, supported its strategic direction, and provided a framework for setting quality objectives. It included a strong commitment to:

- Meeting applicable requirements.
- Continual improvement of the quality management system (QMS).

The Quality Policy and Objectives were effectively communicated within the through trainings. Regular training sessions and stakeholder engagement ensured that the policy is understood, applied, and accessible to all relevant parties.

2. Management review

The procedure for management review was reviewed. Management reviews were conducted annually. Minutes of the latest management review meeting were in place.

This process was in line with the requirements of ISO 9001:2015 ensuring that the quality management system components were reviewed for continued suitability, adequacy, and effectiveness.

3. Organizational roles, responsibilities, and authorities

The job descriptions of the production manager and Manager of the Performance and Methods Department (Quality Control) were defined in the relevant procedures respectively. The responsibilities were clearly defined and found satisfactory.

The reviewed organogram clarified the roles and responsibilities within the organization with a clear depiction of the hierarchy, reporting arrangements, and communication within the manufacturing site. The reporting arrangements for the QMS, QA, and QC were clearly defined. The structure provided a well-defined hierarchy, with responsibilities for monitoring QMS performance, reporting improvement opportunities, and overseeing QA and QC functions clearly defined and assigned.

4. Control of documented information

The relevant document control procedures were reviewed.
Documents were managed and controlled using a customized software system. All stages of the document lifecycle were digitally managed using the software. The software effectively supported the creation, updating, review, approval, and control of documented information, ensuring its availability and protection.

5. Personnel competence and training

The relevant procedure for Hiring procedure, reception, and integration was reviewed. The training process was well-structured and tailored to ensure that employees were competent to perform their tasks effectively. The manufacturer has an established structured training process that included induction training and ongoing and specialized trainings among others. The organization's training system was well-aligned with the requirements of ISO 9001:2015 clause 7.2 which ensures that employees are competent based on appropriate education, training, and experience, and it includes mechanisms to evaluate the effectiveness of training actions. The process's structured approach, regular retraining, and emphasis on critical skills demonstrate a robust commitment to competence management.

6. Risks Management

The relevant procedure for quality risk assessment was reviewed. Quality risk assessment was carried out to ensure that risks related to product nonconformities, such as cross-contamination, bacterial contamination, release of noncompliant product, and loss of traceability, are controlled. The procedure defined the methodology to be used in the identification and assessment of risks by the different departments throughout the facility. The Failure Modes and Effects Analysis (FMEA) approach was used for the identification of risks. The calculation for Risk Priority Number (RPN) and the risk rating to be assigned to the identified risks was defined. The RPN was based on severity, occurrence, and detection.

7. Internal Audits

The procedure for internal audits was reviewed. The manufacturer conducted six internal audits per year. The internal audit program was established by the QA supervisor considering the results of previous audits and the importance of processes. The manufacturer ensured that all site processes were audited at least once every three years, ensuring systematic approach to maintaining a comprehensive coverage of the quality management system. Internal auditors received either internal or external training, ensuring they are competent to conduct audits effectively. The organization had a robust internal audit process with strong planning, competent auditors, and a structured audit approach.

8. Control of nonconforming products

The relevant procedure for handling of nonconformities was reviewed. Identified nonconforming products were managed using SAP software. The procedure specified that nonconforming products must be affixed with a "Non-Conforming" sticker or quarantine sticker to ensure clear identification. In the event of an Out of Specifications (OOS), and investigation was conducted by defined and responsible personnel. Depending on the investigation the product is either corrected, destroyed, reworked etc.

The relevant procedure for rework/reprocessing was also reviewed. The technology and process supervisor or/and quality control supervisor or performance and methods manager authorized reprocessing of batches. The procedure allowed for investigation and documentation of actions to be taken.

9. Customer satisfaction and complaints

The procedure for Handling complaints from customers, interested parties and suppliers was reviewed. The procedure applied to quality of products, transportation, and distribution. Complaints were registered and managed using a customised software system. The manufacturer's complaint handling process was reviewed. Customer satisfaction surveys were conducted by BASF Marketing Team. The manufacturer did not perform customer satisfaction surveys.

10. Change Control

The procedure for management of changes was reviewed. The procedure applied to the entire BASF Agri-production site in Genay. It was not applicable to document management and human resource processes (organization management). Any employee could propose changes. The proposals for change were communicated to their superiors by email or telephone. The procedure provided for impact assessment. The impact assessment was performed by the change management committee. The change management committee comprised of department managers or their representatives. Changes were classified as permanent, temporary, urgent modification, or replacement. Changes were requested using the Change request form. Selected changes were reviewed.

11. Performance evaluation

The manufacturer evaluated the following: Production, Supply chain, Environment, Maintenance, QHSE (quality, hygiene, security and environment), and Human Resources. These were discussed in management review.

12. Design and development of products

This site was not involved in design and development of Fendona SC. This was therefore not inspected.

13. Support

Infrastructure and work environment

The facility was in good state of repair. The warehouse was equipped with sprinklers and spill kits were in place. The laboratory had eyewash stations. Personnel in the laboratory were appropriately gowned. Material safety data sheets were in place.

Monitoring and measuring resources.

Calibration records of selected equipment were reviewed. A calibration schedule was in place.

14. Production and service provisions

Control of Production

The manufacture of Fendona 6 SC and 10SC involved two main steps. The preparation of the premix and then dilution of the premix containing Alphacypermethrin to the desired concentration, packaging, and labelling. There was no production of Fendona SC ongoing at the time of the inspection. Selected production records for the preparation for the Fendona 10SC and Fendona 6 SC were reviewed.

The procedure for cleaning was reviewed. A cross-contamination matrix (with acceptable contamination limits) and cleaning records were in place. Cleaning records were also in place.

The laboratory carried out both physical and chemical tests. The analytical test report was reviewed. The procedure for conducting the sieve test and relevant test records were reviewed. The excel sheet used for calculation of the production recipe was locked. The manufacturer had different access levels and right to the HPLC software. The audit trails were activated. Laboratory data was automatically backed up on the server.

Retention samples

A sample of every batch was retained in a dedicated retention sample storage area. The retention samples were appropriately labelled. The retention samples were kept for 5 years. The samples were stored at ambient conditions.

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

15. Preservation

The relevant procedure for receipt of materials and procedure for storage were reviewed. The manufacturer had in place a checklist. The quantities were verified upon receipt. Inventory and material management was managed by SAP. The Certificates of Analysis (CoA) received along with the raw materials were verified by the laboratory. The materials were issued to production following the FEFO principle.

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

The facility was not responsible for selection and evaluation of suppliers. The selection and evaluation of suppliers was performed by BASF – Technology and Supply chain department. The manufacturer only sources materials from suppliers approved by the BASF Technology and Supply chain department.

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: **Rue Jacquard, Genay, Z.I. Lyon-Nord, Auvergne-Rhône-Alpes 69727, France** 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/