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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	Bayer CropScience, S. L
Corporate address of manufacturer	Bayer SAS 16, Rue Jean-Marie Leclair F-69009 Lyon, France
Inspected site	
Name & address of inspected manufacturing site(s)	Bayer CropScience, S. L Av. Comarques del País Valencià, 267 – 46930 – Quart de Poblet (Valencia), Spain
Unit/Block/ Workshop	Not applicable.
Inspection details	
Dates of inspection	19-21 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	Bayer CropScience, S.L was established in 1971 and manufactures rodenticides, herbicides and non-herbicides. Product categories manufactured on site included wettable powders, solids or liquids. Buildings used for the manufacture of powders, solids and liquids were dedicated. Ficam® and Fludora® (WP and WP-SB) were manufactured in the Wettable Powder (WP) building. The manufacture of Ficam® and Fludora® involved mixing, milling, homogenization, labelling and packaging.
General information about the company and site	The site was ISO 9001 certified. ISO certificate number 12 100 60325 TMS issued by TUV SUD. Valid from 11/01/2021 until 28/10/2022. Scope: ‘‘Manufacture, packaging and distribution of products used as phytosanitary, fertilizers and biocidal 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:** • Quality Manual • 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. Ficam® (Bendiocarb 800g/Kg) WP, WP-SB Product number- 008-005 2. Fludora® Fusion (Clothianidin 50%, Deltamethrin 6.25%) WP, WP-SB Product number - 008-006

Abbreviations	Meaning
CoA	Certificate of analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
QMS	Quality Management System
LLIN	Long Lasting Insecticide treated Nets
WP	Wettable Powder
WP-SB	Wettable Powder in water soluble bags

Part 2	Brief summary of the findings and comments

1. Organizational roles, responsibilities and authorities

The roles and responsibilities of the Production Manager and Head of QA/QC were reviewed. An organogram was in place. The organogram illustrated the relationship and reporting structure between the departments and managers. The production department and Quality control were independent of each other. The Head of Production reported to the Site Manager.

2. Quality policy and quality objectives

The documented quality objectives were reviewed. The quality objectives were measured and monitored using defined key performance indicators. The quality policy included commitments to continual improvement of the quality management system and to satisfy applicable requirements. The quality objectives and quality policy were communicated to staff in meetings and were displayed within the facility. Management review took into consideration quality policy and quality objectives. An updated Quality Policy was adopted in 2020, due to social distancing measures because of the pandemic, the Quality Policy was communicated to staff by placing posters at the entrance of the facilities and in public areas.

3. Management review

Management reviews were conducted once a year. The site manager was responsible for initiating management reviews. Management review minutes for the year 2020 were reviewed. The management review meetings took into consideration the quality objectives, quality policy, complaints, non-conformities and corrective actions, audit results etc. This was found satisfactory. Further to management review meetings there were monthly senior management reviews monitoring KPIs and pending quality related issues.

4. Leadership

The quality policy had been signed by the Site Manager as commitment from top management. The importance of the effective quality management system was communicated in staff meetings. Top management demonstrated their commitment to promoting improvement through internal audits, management reviews and performance evaluation.

5. Control of documented information

The relevant procedure for document control was reviewed. The procedure described the creation, review, issuance, and distribution of documents. Documents were maintained in both electronic and paper form. The manufacturer had a software for maintenance of electronic documents. The users had unique passwords for access to the software. Procedures were reviewed every three years. Access to obsolete documents was restricted.

6. Personnel competence and training

The procedure for training and competence was reviewed. A training schedule and plan were in place. Training needs were identified by the line managers. Training records were reviewed.

7. Risks and opportunities

The relevant procedure for risk management was reviewed. The procedure described risk identification, risk evaluation and assessment. A risk register was also in place. The probability of occurrence of risks, impact and mitigation measures were clearly outlined. The impact of the COVID-19 pandemic had also been assessed. A risk assessment on major operations was performed at least once per year or whenever was considered necessary.

8. Control of changes

Change control procedure was reviewed. The procedure provided for impact assessment. A team selected by the Head, QHSE was selected to manage the change. Changes related to equipment were reviewed. The impact of changes was evaluated and documented. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

9. Internal Audits

The relevant procedure for internal audits was reviewed. Internal audits were conducted at least once a year. Internal audit schedule and plan for 2021 was also reviewed. Internal audits were contracted to a qualified external auditor. The competences of the external auditor were documented. The Audit reports were sent to the Head, QA/QC and Head, QHSE. Effectiveness of the implemented corrections and corrective actions was verified by the external auditor. Internal audit plans, reports, corrections and corrective actions were maintained in the company software. The progress of the corrections and corrective actions was monitored using the company software. The site was also subject to external audits performed by Bayer Corporate (Global).

10. Control of nonconforming products

The relevant procedure for handling non-conformities was reviewed. The procedure allowed for root cause analysis, corrections and corrective actions. Non-conformities identified during production were maintained in the company software. Complaints were received by Bayer country offices and communicated to Bayer CropScience, S.L, Spain. The relevant complaint handling procedure was also reviewed. No complaint related to Fludora® or Ficam® had been registered. However, other registered complaints were reviewed. Investigations were conducted and corrections and corrective actions taken. A complaint related mix-up of was reviewed.

11. Performance evaluation

Parameters monitored and analysed included KPIs, contamination, product release etc. These were discussed in management review. In the event that some of the parameters do not meet the target then the process improvement steps are discussed and initiated.

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 manufacturer had different and separate buildings for the manufacture of wettable powders and liquids. The infrastructure was generally well maintained and clean. Waste was collected and kept at a central location (waste warehouse). This was then collected and treated by a third party.

Monitoring and measuring resources

The calibration and maintenance schedule was in place. Calibration records for balances were reviewed. The qualification report for the HPLC were reviewed. Some of the test performed included pump flow, injector precision, flow rate, detector accuracy etc. These were found satisfactory.

14. Production and service provisions

Control of Production

The manufacture of Ficam® and Fludora® involved involved mixing, milling, homogenization, labelling and packaging. The pallets were scanned to ensure that the correct raw materials are mixed. The scan provided information on the name and batch number of the raw material. Mixing times were monitored. Milling was performed using a jet mill and then homogenized. Cleaning was performed whenever there was a product change. A cleaning and contamination matrix was available. Cleaning instructions for the different types of cleaning were described. The powder was filled in sachets and soluble bags. The filling lines were equipped with an online weigh checker. The calibration status labels on the online weigh checkers for Ficam® and Fludora® was verified. In-process checks included seal integrity check and label verification. Batch records for Ficam® and Fludora® were reviewed.

The laboratory was equipped with the following instruments: laser particle analyser, rheometer, titrator, pH meter, densimeter, moisture analyser, balances, HPLCs, GCs, FTIR. A receipt sample register was in place. The laboratory equipment were uniquely identified with calibration status labels available. The date and time on the laboratory computers were locked. Data was backed up on external hard drives. Standard testing procedures and reports for Ficam® and Fludora® were reviewed. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Identification and traceability

Batch numbers of raw materials used during production were recorded. Identification number of the equipment used were also recorded. An equipment use register was maintained in the laboratory.

Release of products and services

The Head of QA/QC was responsible for release of products. Batches were released following review of production and laboratory data.

15. Preservation

Upon receipt of raw materials, the quantity, certificate of analysis, container integrity were verified. Raw materials were supplied by Bayer SAS (Global). Raw materials not sourced from Bayer sources were sampled for identification testing. Inventory was controlled by SAP. SAP provided details on the name of the materials, the status, quantities, locations etc. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

16. Post-delivery Activities

One sample per batch of Ficam® and Fludora®. A register for all the samples retained was in place. Only one sample was retained, and this was enough for one full analysis. Samples were retained for 4 years. Retention samples were stored at ambient temperatures. Stability studies had been conducted by Bayer SAS and were not available at the site for review at the time of the inspection.

17. Control of externally provided processes, products and services

The selection, approval and monitoring of suppliers was managed by Bayer SAS (Global). This was not managed by Bayer CropScience, S.L, Spain.

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 ***Bayer CropScience, S. L*** *located at* ***Av. Comarques del País Valencià, 267 – 46930 – Quart de Poblet (Valencia), Spain*** 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/