20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Vector Control Product Manufacturer

Part 1	**General information**
Manufacturers details	
Name of manufacturer	Kwizda Agro GmbH
Corporate address of manufacturer	Bayer S.A.S. 16 rue Jean-Marie Leclair, CS 90106 Lyon 69266, France
Inspected site	
Name & address of inspected manufacturing site(s)	Kwizda Agro GmbH Kwizdaallee 1, 2100 Leobendorf, Austria
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	20 – 22 April 2022
Type of inspection	Initial inspection. The criteria for the inspection were based on the ISO 9001:2015 standard.
Introduction	
Brief description of the manufacturing activities	Kwizda Agro GmbH manufacturers herbicides, fungicides, seed treatment products and insecticides among others. The activities involved in the manufacture of K-Othrine included mixing of different ingredients, milling, granulation, labelling and packaging.
General information about the company and site	This was the first WHO audit. The site was ISO 9001:2015 certified. The site was certified by Bureau Veritas. ISO Certificate number AT002510-002. Issued 20/5/2021. Expiry: 24/5/2024. Scope: ‘‘Development, manufacturing and filling/packing of chemical and biological plant protection products, biocides, plant growth promotors, fertilizers, and repellents’’. The site also held an ISO 14001:2015 certificate number AT002513-002. Issued 20/5/2021. Expiry 24/5/2024. This certificate was issued by Bureau Veritas.

	Scope: ‘‘Development, manufacturing and filling/packing of chemical and biological plant protection products, biocides, plant growth promotors, fertilizers, and repellents’’.
History	This was the first WHO site audit.
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 herbicides, fungicides and other products not submitted to prequalification were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	K-Othrine WG 250 - 008-002
Abbreviations	**Meaning**
CoA	Certificate of analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
QMS	Quality Management System

Part 2	Brief summary of the findings and comments (where applicable)

1. Organizational roles, responsibilities and authorities

The organizational chart showing the reporting structure was in place. The Head of Quality Management and Compliance and the Plant head (production) reported independently to the Head of operations. The responsibilities of the Plant head (production) and Quality Assurance Manager were reviewed.

2. Quality policy and quality objectives

Documented quality objectives and policy were in place. The policy included a commitment to satisfy applicable requirements. The policy provided a framework for the set quality objectives. Key performance indicators had been defined to measure and monitor the quality objectives. The quality objectives took into account both requirements of the ISO 9001:2015 and the ISO 14001:2015 standards. The quality objectives were discussed in management review meetings.

3. Management review

Management review minutes dated 10th February 2021 were reviewed. Management reviews took into consideration process performance, audit results, related corrections, and corrective actions, quality objectives, customer's complaints, key performance indicators, service providers etc. Management review meetings were held once a year. In addition, top management held quarterly quality and compliance meetings. The quality and compliance meetings took into consideration budgeting, planning, waste disposal, raw materials consumption, energy consumption etc.

4. Leadership

The responsibilities of the key personnel were defined. The established quality objectives and policy were compatible with the context of the organization. Top management promoted improvement through trainings, internal audits, and management reviews. Top leadership demonstrated their commitment to customer focus by establishing a policy to satisfy the needs of customers.

5. Control of documented information

The relevant documented procedure was reviewed. Documents were maintained in both electronic and paper forms. The procedure described the creation, review, and approval documents. Documents were approved by the Head of Quality Management and Compliance. The documents under the site's quality management system included guidelines, procedures, Instructions, job descriptions, checklists etc. The document type determined the frequency of review of the document e.g., procedures, guidelines, job descriptions were reviewed every two years while general documents such workplace evaluation form were reviewed annually.

6. Personnel competence and training

The procedure for training management was reviewed. The procedure described the different types of training given to employees. According to the procedure trainings were assigned according to a qualification matrix (Q-Matrix) and tailored based on the needs of each employee. Trainees took a test to assess the effectiveness of trainings. Training records were maintained. This was found satisfactory.

7. Risks Management

Actions to address risks and opportunities had been planned and integrated into the quality management system processes. A risk register was in place. The risk register identified risks and mitigation measures among others. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

8. Control of changes

The relevant procedures i.e., Management of Change procedure (Products and packaging); and Management of Change – (Equipment) were reviewed. The procedures described the scope, roles and responsibilities and the overall process to follow when initiating and implementing a change. Whenever a change was initiated; a formal change request was drafted, and a workflow entered in the customized QMS Software. An assessment was performed to evaluate the impact of the risk associated with implementation of the change. The impact assessment of the changes was performed in consultation with the relevant stakeholders. Changes were electronically tracked and followed up using the QMS software. The difference between the two procedures was that the closure of the change for equipment was supported by specific documented evidence such as a final function test under certain operating conditions. A change related to qualification of a new line was reviewed. This was found satisfactory.

9. Internal Audits

The procedure for internal audits was reviewed. The procedure described the preparation of the internal audit including description of with roles and responsibilities and how to conduct the audit. The goal being to ensure that processes are performed according to the regulations and to identify areas of continuous improvement. The audit program was created by the Quality Management and Compliance department and planned for a period of 3 years. Each process was audited at least once every 3 years. Records were maintained. Nonconformities, corrections, and corrective actions were electronically tracked and followed up using the IMS software. The process for managing internal audits was found satisfactory.

10. Control of nonconforming products

The relevant procedure for Control of Defective products was discussed. The procedure described the steps to follow for products that were not meeting the specifications and how to handle the materials in the logistic management software. The procedure also described the handling, labelling and storage of non-conforming products. Bayer SAS was responsible for the recall of the product from the market.

11. Performance evaluation

The site had defined parameter to monitor and evaluate the effectiveness of the quality management system. Some of the defined parameters included customer's complaints and status of the related corrections and corrective actions, First pass yield, Out of Specification results (OOS) etc. These were analyzed, evaluated, and discussed in management review.

12. Design and development of products

The product was designed and developed by Bayer S.A.S. Therefore, this was not included in the scope of this audit.

13. Support

Infrastructure and work environment

The infrastructure was in a good state of repair and well maintained. The facility had in place both safety and environmental protection measures. The facility had personnel responsible for ensuring compliance with the relevant environmental and safety regulations.

Monitoring and measuring resources

The calibration certificate for the balances were reviewed. The maintenance records and calibration records of the water flow meter were also reviewed.

14. Production and service provisions

Control of Production

K-Othrine was manufactured on the insecticide lines. There were two insecticides lines. The manufacture of K-Othrine included mixing of different ingredients, milling, fluid bed granulation, labelling and packaging. The in-process controls included water content and particle size. In-process test records were maintained. The fluid bed granulator was linked to an in-line monitoring software system that monitored critical parameters such as temperature, pressure, air flow rate. Software systems were protected. In addition to having encrypted laptops the manufacturer had in place spam filters, firewalls, antiviruses.

The cleaning procedure was in place. Cleaning records were maintained. Cleaning was verified by testing of the final rinse from each equipment used during production. Batch production records for K-Othrine WG were reviewed. Products were released by the Quality Assurance Manager.

The laboratory was well equipped. Some of the equipment included HPLCs, GCs, UV / VIS & FT-IR, pH meters, particle size analyzers etc. The laboratory equipment was uniquely identified and calibrated. The standard testing procedure for the determination of Deltamethrin in K-Othrine WG and laboratory test records were reviewed. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Identification and traceability

Equipment were identified. The SAP software allowed for traceability of the lot numbers and quantities of the raw materials received in the warehouse, quantities and lot numbers of materials received and issued to production.

15. Preservation

The inventory management in the warehouse was controlled a software. The warehouse had an incoming goods zone where the quantities, batch numbers, label information, certificate of analysis, etc. were verified. Materials were assigned a quarantine or release status by Quality Control personnel. Rejected materials were blocked in the inventory software and it was not possible to use them for production activities. Retention samples were stored in a dedicated area in the warehouse under lock and key.

16. Post-delivery Activities

A sample of every batch was retained. The samples were labelled and retained for 7 years.

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

The raw materials used in the manufacturer of K-Othrine WG were supplied by Bayer S.A.S. The evaluation, selection and monitoring of performance of the suppliers of the materials used in the manufacture of K-Othrine was performed Bayer SAS.

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 ***Kwizda Agro GmbH*** located at ***Kwizdaallee 1, 2100 Leobendorf, Austria*** 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/