

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

Part 1	General information
Company information	
Name of manufacturer	Kwizda Agro GmbH
Corporate address of manufacturer	Envu, 2022 Environmental Science FR S.A.S Lyon Vaise Business Center, 1 Place Giovanni Da Verrazzano 69009 Lyon, France
Manufacturing site(s) under assessment	
Address of manufacturing site if different from that given above	Laaer Bundesstrasse Kwizda Allee 1; A 2100 Leobendorf Austria
Desk assessment details	
Date of review	9-11 December 2025
Inspection record number	INSP-VCP-2023-0011 (I-04033)
Last WHO inspection	Compliant onsite inspection between 20-22 April 2022. The site was compliant with the requirements of the ISO 9001:2015 standard.
Abbreviations	Meaning
NC	Non-Conformity
NCR	Non-Conformity Report
OOS	Out-of-specification
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
Part 2	Summary of the assessment of ISO evidence submitted (most recent to oldest)
<i>Inspection Report 1</i>	
<i>Competent authority names</i>	Bureau Veritas Certification Austria
<i>Dates of inspection</i>	03-09 April 2025
<i>Type of inspection</i>	Surveillance audit
<i>Products covered:</i>	Acetamipride, Pendimethalin
<i>Inspected areas</i>	The three Kwizda sites including the site at Leobendorf were inspected against ISO 9001:2015. The scope of the audit included: product development, manufacturing, filling/packing of chemical and biological plant protection products,

	<p>biocides, plant growth promotors, fertilizers and repellents. The inspection took into consideration all the clauses of the ISO 9001:2015 standard and those of the other standards.</p> <p>The areas audited at Leobendorf included: changes, internal audits, training, safety, quality assurance, job descriptions, KPIs, Planning, document control, etc.</p>
<i>Final conclusion of the inspection report</i>	It was determined that the all the requirements were adequately met and effectively implemented.
<i>Comments/observations on the scope and comprehensiveness of the report and appropriateness of the CAPAs</i>	The report was comprehensive.
Inspection Report 2	
<i>Competent authority name</i>	Bureau Veritas Certification Austria
<i>Dates of inspection</i>	04-12 April 2024
<i>Type of inspection</i>	Recertification audit
<i>Products covered:</i>	OS-222 Nichino, Zosteric
<i>Inspected areas</i>	<p>The site was inspected against three ISO standards namely: ISO 9001:2015, ISO 14001:2015 and 45001:2018. Two Kwizda sites were audited i.e. Kwizda Agro GmbH located at Kwizda Allee 1, 2100 Leobendorf, Austria and Leonard-Bernstein-Straße 10, 1220 Wien, Austria.</p> <p>The scope of the audit included: product development, manufacturing, filling/packing of chemical and biological plant protection products, biocides, plant growth promotors, fertilizers and repellents. The inspection took into consideration all the clauses of the ISO 9001:2015 standard and those of the other standards.</p> <p>The areas audited at Leobendorf included: Organizational chart, KPIs, product life cycle, sales, price lists, terms and conditions of business, biological development/regulatory, process development, safety and health protection, warehouse, production areas, SAP, procurement and purchasing, customer service, etc.</p>
<i>Final conclusion of the inspection report</i>	It was determined that the all the requirements are adequately met and effectively implemented.
<i>Comments/observations on the scope and comprehensiveness of the</i>	The audit was comprehensively covered all the clauses of the ISO 9001:2015 standard. The CAPA was reviewed by Bureau Veritas Certification and found appropriate.

<i>report and appropriateness of the CAPAs</i>	
Part 3	Summary of the last WHO inspection
Date and conclusion of most recent WHO inspection	The site was last inspected by WHO in April 2022. The site was found compliant and met the requirements of the ISO 9001:2015 standard.
Brief description of manufacturing activities	The site manufactured herbicides, fungicides, seed treatment products and insecticides among others. The activities involved in the manufacture of K-Othrine included mixing of different ingredients, milling, fluid bed granulation, labelling and packaging.
General information about the company and manufacturing site	The site had several ISO certifications including the ISO 9001:2015 certification. Kwizda is a contract manufacturer for Envu.
Focus of the last WHO inspection	The criteria of the last WHO inspection were represented by the ISO 9001:2015 standard with a focus on the quality management system of the site.
Areas inspected	<ul style="list-style-type: none"> • Organizational roles, responsibilities, and authorities • Quality policy and quality objectives • Leadership • Management review • Control of documented information • Training • Risk Management • Internal Audits • Production control • Nonconforming products • Complaints • Control of Changes • Monitoring and measuring resources • Infrastructure and work environment • Identification and traceability • Preservation • Control of externally provided processes, products and services
Out of scope and restrictions (last WHO inspection)	The manufacture of herbicides, fungicides and other products not submitted to PQ were not included in the scope of this inspection.
WHO products covered by the last WHO inspection	K-Othrine WG 250

Part 4

Summary of the assessment of supporting documentation

1. Quality Manual:

A copy of the Quality manual was not provided. Instead, the site master file provided adequate information to assess the QMS and activities of the site.

2. List of current quality management procedures:

The manufacturer provided a list of current procedures.

3. Standard operating procedures for:

i. Complaint handling and vigilance:

The procedure for complaint management was provided. Complaints were received by the Customer Service and purchasing or the Head Quality Management and Compliance. Complaints were managed using the ‘Consense’ software. The procedure for investigations and root cause analysis was provided and found acceptable. Recalled products were handled in accordance with the procedure for nonconforming products.

ii. Control of nonconforming goods/processes:

The procedure for handling of defective products described the process and activities undertaken for dealing with products reported to be defective. According to the procedure provided the nonconforming products were blocked to prevent their use. Depending on the issue at hand, the defective products could be reworked.

iii. Change control/change notifications (product and processes):

The manufacturer had established processes for handling changes including provisions for the assessment and management of the impact of changes.

iv. Risk management:

It was described in the site master file that the risk management process involved identification of risks / opportunities for critical processes, prioritization, evaluation, quantification, determination of actions and actions monitoring.

v. Supplier evaluation and control, verification of purchased product:

The procedure for Logistics and Material Preparation was reviewed. The purpose of the procedure was to ensure legally compliant storage of externally procured materials and their timely provision for production, filling and packaging. Incoming goods were inspected. The list of documents to be verified upon receipt of incoming goods was defined. Any defect identified during receipt of the incoming goods was documented in the checklist for deviation.

The procedure for Purchasing of Kwizda materials was reviewed. Supplier evaluation was conducted once every year. The criteria for supplier evaluation were defined. Suppliers were categorized into one of two categories (i.e., A or B) based on total order value and other criteria.

4. Site Master File (SMF) and site floor plan:

The site master file was reviewed and found satisfactory. Site floor plans, organograms and process flow charts were also provided.

5. Quality management system certificate(s) and scope of certification: (e.g. ISO 13485/ISO 9001):

ISO 9001 Certificate Number: AT002921

Scope: “Development, manufacturing, filling/packing of chemical and biological plant protection products, biocides, plant growth promoters, fertilizers and repellents. Sales of chemical and biological plant protection products and Biocides”.

Issue date: 24-04-2024

Expiry date: 24-05-2027

The certificate was issued by Bureau Veritas Certification Holding SAS – UK Branch.

6. List of notifications of upcoming inspections by the regulatory authorities or ISO 9001:2015 certification bodies in the next 6 months:

The list of the inspections conducted in the last 5 years was provided. The site undergoes an annual inspection by the state government of Lower Austria in compliance with the Seveso III Directive.

7. Process flowchart including in-process control points:

The flow charts for the different QMS processes were provided and found acceptable.

8. List of all the products and formulation types manufactured at this site:

The list of all product categories manufactured on site was provided.

9. Most recent management review report/minutes:

The agenda for the 2024/2025 management review minutes was provided. The agenda included organizational changes, policy, changes in the external and internal issues affecting the integrated management system, status of the previous management reviews, performance, and effectiveness of the QMS, adequacy of resources, effectiveness of actions taken to manage risks and opportunities, and opportunities for improvement.

10. Master batch manufacturing, and/or packaging records of the WHO product of interest:

A screenshot of the electronic batch record was provided.

11. Completed batch manufacturing and/or packaging records:

Batch records for K-Othrine WG25 batch number 100301773 were provided.

12. List of any recalls/returns:

The manufacturer declared that there were no recalls or returns within the last three years.

13. Control of cross contamination and/or contamination matrix:

The procedure for contamination control was reviewed. The procedure described the different contamination control strategies including plant design, decontamination protocols, and management of changes, among others.

14. Name and address of sites to which any related activities are outsourced:

Not applicable

Part 5	Desk assessment conclusion
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Based on the previous WHO inspection and on the QMS evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***Kwizda Agro GmbH*** corporate address located ***Laaer Bundesstrasse Kwizda Allee 1; A 2100 Leobendorf Austria*** is considered to be operating at an acceptable level of compliance with ISO 9001:2015 standard and WHO compliance guidelines as per *Overview of the WHO Prequalification Assessment of Vector Control Products, June 2021*.

This WHOPIR will remain valid until May 2027, provided the outcome of any WHO pre-qualification inspection or other audit from regulatory authorities that WHO relies on conducted during this period provides evidence of current compliance with the audit criteria.

Part 6	List of guidelines referenced in this inspection report
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1. WHO Information for Manufacturers on Prequalification Inspection Procedures for the Sites of Manufacture of Diagnostics (PQDx_014).
(https://www.who.int/diagnostics_laboratory/evaluations/en/)
2. ISO 9001:2015 Quality management systems - Requirements
3. Manual on development and use of FAO and WHO specifications for pesticides
First edition - third revision ISSN 0259-2517