



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

Part 1	General information
Manufacturers details	
Name of manufacturer	Bayer S.A.S, Division Crop Science, Industrial Operations
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)	Bayer S.A.S, Division Crop Science, Industrial Operations 1 Avenue Edouard Herriot, 69400 Villefranche-Limas, France
Unit/Block/Workshop	Not applicable
Inspection details	
Dates of inspection	19-23 May 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	Bayer S.A.S has 8 R & D sites and 6 productions sites. Bayer S.A.S, Division Crop Science, Industrial Operations is one of the Bayer production sites. The site manufactured herbicides, insecticides, and fungicides among others. The activities involved in the manufacture of Aqua Reslin Super included preparation of the organic and aqueous phases, mixing of the two phases, filling, labelling and bulk packaging.



<p>General information about the company and site</p>	<p>This was the first WHO audit.</p> <p>Bayer S.A.S, Division Crop Science, Industrial Operations had the following certifications:</p> <ul style="list-style-type: none"> i) ISO 9001:2015 certificate number 2012/51141.4. Validity: 21st January 2022 to 20th January 2025. Scope: ‘Formulation, Packaging, Storage and Shipping of Plant Protection Products.’ The certificate was issued by AFNOR certification. ii) ISO 14001:2015 certificate number 2012/51140.4. Validity: 21st January 2022 to 20th January 2025. Scope: ‘Formulation, Packaging, Storage and Shipping of Plant Protection Products.’ The certificate was issued by AFNOR certification. iii) ISO 45001:2018 certificate number 2012/51143.6. Validity: 21st January 2022 to 30th December 2023. Scope: ‘Formulation, Packaging, Storage and Shipping of Plant Protection Products.’ The certificate was issued by AFNOR certification. iv) ISO 50001:2018 certificate number 2012/68095.5. Validity: 21st January 2022 to 20th January 2025. Scope: ‘Formulation, Packaging, Storage and Shipping of Plant Protection Products.’ The certificate was issued by AFNOR certification.
<p>History</p>	<p>This was the first WHO audit of the site</p>
<p>Brief report of inspection activities undertaken – Scope and limitations</p>	
<p>Areas inspected</p>	<p>Document review including but not limited to:</p> <ul style="list-style-type: none"> • 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



	<p>Physical areas:</p> <ul style="list-style-type: none"> • 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 for prequalification were not included in the scope of this inspection.
Restrictions	None
WHO products covered by the inspection	<ul style="list-style-type: none"> • K-Othrine WG250 – (Deltamethrin, 250 g/kg) - 008-002 • Aqua Reslin Super – (1.42 g/L S-Bioallethrin, 102.7 g/L Permethrin, 98.4 g/L Piperonyl butoxide)- 008-003 • Ficam – (Bendiocarb, 800 g/kg) - 008-005 • Fludora Fusion (Clothianidin 500g/Kg and Deltamethrin 62.5g/Kg WP) -008-006 • Fludora Co-Max (Transfluthrin 52.5 g/l and Flupyradifurone 26.3 g/l) - 008-007 <p>Bayer S.A.S, Division Crop Science, Industrial Operations only manufactured Aqua Reslin Super (008-003).</p> <p>K-Othrine, Ficam, Fludora Fusion and Fludora Co-Max were only stored at this site for distribution. These products were not manufactured at this site.</p>
Abbreviations	Meaning
CoA	Certificate of analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
QMS	Quality Management System
PBO	Piperonyl butoxide



Part 2

Brief summary of the findings and comments

1. Organizational roles, responsibilities and authorities

An organogram was in place. The Quality, Health, Safety and Environment (QHSE) Manager and Head of Industrial Operations reported independently to the Site Manager. The job description of the Quality Manager was reviewed. The responsibilities of the Quality Manager included ensuring that the quality management system of the site complies with ISO 9001:2015 standard requirements and QHSE guidelines, manage complaints in a timely manner, lead process interactions with various stakeholders, report on the performance and progress of Key performance indicators (KPI) to the leadership team.

2. Quality policy and quality objectives

A documented policy and quality objectives were in place. The policy covered four aspects namely:

- a) Quality,
- b) Health, Safety, and Hygiene,
- c) Environment and
- d) Energy

Key performance indicators (KPIs) had been defined for each quality objectives. The leadership team met every month to discuss and review the performance and progress of the key performance indicators. The quality objectives were also discussed in the management review

3. Management review

Management reviews were held once every year. Management review minutes for the year 2021 were reviewed. The following were discussed in the management review among others:

- Status of actions from previous management reviews
- Operational excellence - packaging, process, formulation and industrialization, information system, continuous improvement and training academy, management of change
- Human resource
- Industrial Operations - Production, sampling, supply management, incoming goods, shipping
- Technical services – Management of Energy, Maintenance plan, projects, and investments,
- QHSE – Safety, risks, environment, security (transport), quality, Integrated management systems
- Complaints
- SWOT analysis
- Internal and external audits

Opportunities for improvement had been identified. This was found satisfactory.



4. Leadership

The leadership team took accountability for the effectiveness of the quality management system by holding management reviews and monthly meetings on progress of KPIs. The quality policy and quality objectives were displayed throughout the facility. Customer surveys were also conducted to determine whether customer requirements had been met.

5. Control of documented information

The document control procedure was reviewed. The procedure described the creation, management, distribution and archiving of documents. Documents were categorized as follows: Quality Manual, Process documents, Procedures, Instructions and records, Mode of Operation, and specific guidelines. A process map was in place. Records were archived for 3 years. Documents were in both paper and softcopy forms. The process owner was responsible for approval of the procedures. Documents that are required by regulations are signed by the director. The Site Manager approved documents as required and mandated by regulatory requirements. The documentation system and product release were managed using a customized software system. The system linked with SAP and other programs.

6. Personnel competence and training

The manufacturer had a training academy. The training academy has both classroom and E-learning platforms. The training academy had creativity area, e-learning center, collaborative, and modular meeting room. Training records were maintained. Training records on the following were reviewed: Training on operations on new production, Risks on production line, Quality, Health, Safety Security and Environment, communication, Cross Contamination, Documentation requirements, internal audits etc. The training of internal auditors covered the following topics: internal audit principles, types of audits, impartiality, errors to avoid in audits etc. The effectiveness of the trainings was assessed.

7. Risks Management

A guide on identification, assessment and evaluation of risks was in place. The risk assessment considered the impact and probability of occurrence of the risk. A risk register dated March 2022 was in place. Risks related to quality, health, safety, environment, energy were reviewed. This was found satisfactory.

8. Control of changes

The relevant procedure for management of change was reviewed. A risk assessment was performed to evaluate the impact of the change. The impact of changes was assessed. Change related to reduction in the use of flammable solvents were reviewed. Changes were recorded and tracked in a customized software.



9. Internal Audits

Internal audit programs and plans for the year 2021 and 2022 were reviewed. Each area was audited at least once a year. The areas audited included Energy, operational excellence, human resource, industrial operations, financial management, storage, risks associated with transportation and legal requirements etc. The auditors did not audit their own areas of work. Following receipt of the internal audit report, corrective actions and preventive actions were proposed by the process owner. The proposed corrections and preventive actions were then reviewed and approved by QHSE manager, Quality Manager, and the Head Engineering department (where applicable). The effectiveness of the implemented corrections and preventive actions were verified during internal audits.

10. Control of nonconforming products and complaints

The procedure for handling of non-conforming products was in place. Quality, Health, Safety and Environment (QHSE) department was responsible for handling nonconforming products. Complaints were managed by the global procedure for complaints. Complaints were categorized into 3 namely: low, moderate, and severe. The procedure provided for investigation, determination and implementation of corrections and preventive actions. Market complaints were received by Bayer S.A.S (Corporate). The complaints were then communicated to Bayer S.A.S, Division Crop Science, Industrial Operations through global complaint monitoring system. No complaint related to Aqua Reslin Super had been received by the time of the audit.

11. Performance evaluation

The manufacturer evaluated the effectiveness of the quality management system through management reviews, monitoring the planning and execution of production plans, key performance indicators, customer surveys, customer complaints, internal audits among others. These parameters were monitored and analysed. They were summarized using graphs, tables, and other descriptive statistical tools. This information was discussed in management review.

12. Design and development of products

The design and development of the products was undertaken by Bayer S.A.S (R & D site). The product was not designed and developed at the inspected site, and this was therefore not inspected.

13. Support

Infrastructure and work environment

Material safety data sheets were in place. Personnel in production wore appropriately protective gear which included gloves, safety shoes and masks. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Monitoring and measuring resources

Calibration certificates for balances and temperature probes in the mixing tank used for manufacture of insecticides were reviewed. The calibration certificate of the standard masses was also reviewed. An equipment maintenance plan was maintained in SAP.



14. Production and service provisions

Control of Production

The manufacture of Aqua Reslin Super involved preparation of aqueous phases and organic phases. The phases were then mixed until the desired particle size of the emulsion is reached. The mixture is then packaged in IBCs as bulk and labelled. Granulometry was performed as an in-process test. A production software system was used to monitor and control the production activities. The materials added were scanned to confirm that the correct raw material is weighed and used for production. Parameters monitored in-line included temperature, mixing speed etc. The equipment were cleaned using an automated cleaning program. A cleaning matrix was in place. A sample of the final rinse was tested to verify the cleaning. Labels were adequately controlled.

Batch production records for Aqua Super Reslin were reviewed. Batch numbers of the raw materials used in production were recorded.

The laboratory was equipped with HPLCs, GC, balances, pH meters, granulometer, IR spectrophotometer etc. The equipment were uniquely identified. A sample receipt register was in place. The information retained in the sample receipt register included sample number, article number, status, date, name of the product etc. The quality control tests performed on Aqua Super Reslin included emulsion stability, granulometry, density, pH, active ingredient content etc. The analytical method validation for the determination of the active ingredients in Aqua Super Reslin was reviewed. The analytical test reports for Aqua Reslin Super were reviewed.

The certificates of analysis and storage conditions of the reference standards for S-Bioallethrin, Permethrin and Piperonyl Butoxide (PBO) were verified. All the issues raised related to this section were addressed satisfactorily by the manufacturer.

Identification and traceability

The SAP inventory software, production records and laboratory records and software allowed for adequate traceability of raw materials, samples, and products. Equipment were uniquely identified.

15. Preservation

Inventory in the both the raw material and finished goods warehouse was managed by the SAP software. The available information maintained by the software included material names, locations, quantities of received and issued. Raw materials were supplied by Bayer S.A.S (Corporate). There was a checklist in place to verify received materials. The product name, lot number, quantities, physical condition of the containers, shipping documents were verified upon receipt of the materials. Certificates of Analysis were provided along with the received materials. S-Bioallethrin and PBO raw materials were sampled upon receipt. All the issues raised related to this section were addressed satisfactorily by the manufacturer.



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

The raw materials used in the manufacturer of Aqua Super Reslin were supplied by Bayer S.A.S. (Corporate). The evaluation, selection and monitoring of performance of the suppliers of the materials used in the manufacture of Aqua Super Reslin was performed Bayer SAS (Corporate).

Part 3	Conclusion – Inspection outcome
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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 S.A.S, Division Crop Science, Industrial Operations* located at *1 Avenue Edouard Herriot, 69400 Villefranche-Limas, 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
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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/>