World Health Organization

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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	S.T.I Solfotecnica Italiana S.p.A
Applicant/ Corporate address of manufacturer	Syngenta Crop Protection AG Rosentalstrasse 67 4058 Basel, Switzerland Section 4: Inspection scheme,
Inspected site	
Name & address of inspected manufacturing site(s)	S.T.I Solfotecnica Italiana S.p.A Via Torricelli, 22 Cotignola, 48033, Italy
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	23-25 June 2025
Type of inspection	Initial Inspection The inspection was to establish that the applicable requirements to ISO 9001:2015 as well as WHO specific requirements continue to be met.
Introduction	
Brief description of the manufacturing activities	S.T.I Solfotecnica Italiana S.p.A is a private family company that was established in 1961. S.T.I Solfotecnica Italiana S.p.A manufactured Wettable powders, solution concentrates, and wettable granules. No herbicides were manufactured at this facility. The manufacture of Sovrenta 15WP involved preparation of the spray solution, preparation of the powder mixture (feedstock), milling, labelling and packaging.
General information about the company and site	The manufacturer held the following ISO certificates: **ISO 9001: 2015: Quality Management System** Certificate number: 944 Scope: Development, production, through formulation, blending, grinding, granulation, and packaging operations of crop protection products and other agricultural products for third parties. Production by mixing and milling, and marketing of sulfur on its own and for third parties. Production, through fermentation, drying, milling, mixing, and packaging processes of biological microorganisms for agricultural products for third parties. Procedures for weighing activities for the

	determination of the Verified Gross Mass of the container (VGM) according to Method 2 envisaged by the amendments to Chapter VI Rule 2 of the SOLAS Convention 74 as amended. Issue date: 21/01/2025 Expiry Date: 21/11/2027 The certificate was issued by IQNET. **ISO 14001:2015 Environmental Management System** Certificate number: 7118 Scope: ‘‘Development, production, through formulation, blending, grinding, granulation and packaging operations of crop protection products and other agricultural products for third parties. Production by mixing and milling, and marketing of sulfur on its own and for third parties. Production, through fermentation, drying, milling, mixing, and packaging processes of biological microorganisms for agricultural products for third parties. Issue date: 01/12/2022 Expiry Date: 07/01/2026 The certificate was issued by IQNET. **ISO 45001:2018 Safety Management System** Certificate Number: 30020 Scope: ‘‘Development, production, through formulation, blending, grinding, granulation and packaging operations of crop protection products and other agricultural products for third parties. Production by mixing and milling, and marketing of sulfur on its own and for third parties. Production, through fermentation, drying, milling, mixing, and packaging processes of biological microorganisms for agricultural products for third parties.’’ Issue date: 12/01/2024 Expiry date: 10/1/2027 The certificate was issued by IQNET.
History	This was the first WHO inspection of the site.

Brief report of inspection activities undertaken – Scope and limitation	
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	Sovrenta 15WP was not designed and developed by S.T.I Solfotecnica Italiana S.p.A. Design and development was therefore not audited.
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	• Sovrenta 15WP – (15% w/w Isocycloseram) - P-11568

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

Part 2	Summary of the findings and comments

1. Management Review

Management reviews were described in the Quality, Environment, and Safety manual. Management reviews were held once a year or more frequently if there were changes in the organization's structure or issues that required particular attention. All responsible personnel were to attend the meeting. The minutes of the management review were reviewed. The management review meeting agenda (inputs) was as defined by the ISO 9001 standard. Management review outcomes were also documented. The management review included the opportunities for improvement.

2. Organizational roles, responsibilities, and authorities

The organizational chart and job descriptions were reviewed. The Head of Quality Assurance reported directly to management. The Deputy Head of the Quality Control Laboratory also served as a production assistant. The responsibilities of the inline quality control operator and laboratory technicians were defined.

3. Personnel competence and training

The relevant procedure for training defined the training requirements for each job function. Induction training was conducted by a section tutor and included mandatory quality and safety topics. Operators were evaluated by their tutor and the general manager. On-the-job training was provided. Training plans were developed by the safety manager and approved by the general manager. Reviews were conducted annually, and missed sessions were tracked. A customised electronic system was used to monitor training records and completion.

4. Risk Management

The procedure for risk assessment was reviewed. The procedure described risk identification (SWOT) and actions to address risks and opportunities. The procedure described areas where the risk assessment was to be applied across the facility, including production areas.

The procedure for contamination assessment and risk management was also reviewed. The procedure described the approaches to the assessment of risk related to product contamination and production activities. The risk assessment was approved by the general manager. The criteria for prioritization of risks based on the determined risk priority number were defined.

5. Internal Audits

The procedure for internal audits was in place. Audits were categorized into internal audits and external audits. The procedure covered internal audits, external audits, safety and environmental audits. Quality assurance was responsible for handling audits. Internal audits were performed once every year. The audit covered the following areas: suppliers, management, production, shipment, human resources, equipment and instruments, design, communication, and product integrity. The quality management system was audited against ISO 9001, 14001:2015, and ISO 45001. The annual audit program was in place. Checklists were used for internal audits. Internal auditors had been trained on the internal audit - 19011 standard. Internal audit training certificates were provided. The corrections and corrective actions taken to address the nonconformities raised in the internal audits were verified.

6. Control of Changes

The change control procedure was reviewed. It applied to all modifications related to production processes and new active ingredients. Changes originated from customer requests, internal improvements, or updates to equipment and methods. Each change was evaluated for impact, including validation and training needs, contamination control, and infrastructure. Selected examples of selected changes were reviewed.

7. Design and development of products

Sovrenta 15WP was not designed and developed by S.T.I Solfotecnica Italiana S.p.A and this was therefore not audited.

8. Control of documented information

The procedure for document management was reviewed. The procedure described the identification, modification, approval and archiving of documents. Documents were categorized into the manual, management procedures, operation procedures, records, and instructions. The Manual and management procedures were approved by the Director General. Operational procedures were approved by the Director General or the Technical Director. The instructions were approved by the Director General, the Technical Director, or the Quality Manager. The frequency for revision of different documents was defined depending on the criticality of the documents.

The procedure for the identification of documents was also reviewed. All procedures were to be identified with a number and titles, page number, revision number, etc. Document distribution lists were available.

9. Quality policy and quality objectives

The quality policy was documented in the Quality, Environment, and Safety manual. The manual described the integrated managed system including policies and approaches to quality, safety, environment, continuous improvement, risk prevention, compliance with legislation, customer satisfaction, product integrity, and other key elements that supported the main objective: ‘‘To ensure customer satisfaction, protect the health and safety of workers and other stakeholders, and comply with applicable legislation.’’

The quality policy was published on the company’s website and made available on the internal SharePoint platform, where all employees with access credentials could consult it.

Quality objectives were described in the Quality Objectives Procedure. This procedure outlined how customer satisfaction and the performance of the quality management system (QMS) were monitored. The objectives were measurable and monitored annually. A formal review of the quality objectives was conducted annually.

10. Non-conformities and complaints

The relevant procedure for handling nonconformities was reviewed. The procedure addressed nonconformities related to both products and processes. Product-related nonconformities were defined as any deviation from specifications at any stage of the supply chain. Process-related nonconformities referred to deviations from production targets.

Nonconformities were detected by the laboratory, production line personnel, or through customer feedback. Once identified, nonconformities were recorded.
The complaint investigation form was also reviewed. The procedure allowed for investigations to be conducted. Selected examples of complaints were reviewed

11. Support

Infrastructure and work environment

The facility was equipped with fire extinguishers, eye shower stations, and rodent traps. Personnel wore appropriate PPE. The materials safety data sheet for Isocycloseram was in place. The facility was in a good state of repair.

Monitoring and measuring resources

The procedure for preventive maintenance was reviewed. Regular maintenance was scheduled. The maintenance schedule plan was in place. Maintenance carried out was tracked. Maintenance records of selected equipment were checked.

12. Production and service provisions

The manufacture of Sovrenta 15WP involved the preparation of the spray solution, preparation of the powder mixture (feedstock), milling, labelling, and packaging. The mixing tank was equipped with load cells. The weight of materials added to the mixers recorded and process parameters were monitored and controlled using a Programmable Logic Controller (PLC).

At the time of the inspection, process validation was still ongoing. The process validation report was reviewed. The quality control laboratory was well equipped. The laboratory performed both physical and chemical tests. A sample receipt register was in place. The procedure for sampling was reviewed.

The analytical method procedure for the determination of active ingredient content was reviewed. Selected analytical test records and raw data for selected batches were reviewed. The procedure for analytical method validation for the determination of Isocycloseram and relevant validation report respectively, were also reviewed. The validation parameters included were defined. The time and date on the computers used for analysis were locked. The primary reference standard for Isocycloseram was kept in a fridge. The certificate of analysis for the primary reference standard was available.

Product release was performed by the QC manager. The transport arrangements for the product were made by Syngenta. Solfotechnica released products to Syngenta. Retention samples were adequately labelled. The retention samples were kept at ambient conditions.

Waste management

The relevant procedure for management of waste. The purpose of the procedure was to describe the activities of collection, movement, temporary storage, and transfer to a third party of the waste produced by the facility. Waste was categorized into solid and liquid waste. The solid waste was collected in bags. The solid waste containing sulfur was labelled and collected separately. The liquid waste was collected in IBCs. The liquid was segregated accordingly. The third-party companies that collected and treated the waste were licensed by the government. The manufacturer received a delivery report whenever the waste was delivered for waste treatment.

13. Preservation

The procedure for warehouse management was reviewed. The manufacturer used a FIFO/FEFO principle for the issuance of materials. The physical verification of the received materials was done by the warehouse personnel. A verification checklist was in place. The quantity, conditions of the packaging, labelling, quantity etc. were verified. The COA was verified by the quality control laboratory.
Any nonconformities were documented in SAP. The non-conforming materials were identified and isolated. The nonconforming materials were communicated to Syngenta, and a decision was taken.

The inspection team noted that the control of labels was appropriately managed. Labels were stored in a secure location, with access restricted and traceability maintained, ensuring that labelling operations were well controlled.

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

The procedure for supplier control applied to all suppliers of goods and services. Supplier evaluations were performed annually. The suppliers of the chemical raw materials used for the manufacture of Sovrenta 15 WP were selected by Syngenta.

Pest control services were provided by RADIS. Monthly controls were conducted, and target pests were identified based on an initial risk assessment. The service contract with RADIS was checked.

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 by **S.T.I Solfotecnica Italiana S.p.A** located at **Via Torricelli, 22 Cotignola, 48033, Italy** 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/