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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	PT Syngenta Indonesia
Corporate address of manufacturer/ Applicant	Syngenta Crop Protection AG Rosentalstrasse 67 4058 Basel, Switzerland
Inspected site	
Name & address of inspected manufacturing site(s)	PT Syngenta Indonesia Raya Tlajung Udik Km 62.8, Gunung Putri Bogor, Jawa Barat, 16962, Indonesia
Unit/Block/ Workshop	Not applicable
Inspection details	
Dates of inspection	29 April - 01 May 2024
Type of inspection	1st inspection. The inspection was to establish that the applicable requirements to ISO 9001:2015 as well as WHO specific requirements were met.
Introduction	
Brief description of the manufacturing activities	PT Syngenta Indonesia. – Gunung Putri site manufactured herbicides, insecticides, and fungicides without any product development activity. Only the manufacture, process, and quality controls, related the production of Icon 2.5 EC and Actellic EC were inspected.

General information about the company and site	This was the first WHO audit. The manufacturer held the following ISO certificates: **ISO 9001: 2015: Quality Management System** Scope: ‘‘Manufacturing of Pesticides’’ Certificate Number: ID20/05509 Issue Date: 25 November 2023 Valid until: 25 November 2026 The certificate was issued by SGS. **ISO 45001: 2018** Scope: ‘‘Manufacturing of Agrochemical’’ Certificate Number: 1492O Issue Date: 12/06/2022. Valid until: 12/06/2025 The certificate was issued by MSC Global **ISO 14001: 2015** Scope: ‘‘Manufacturing of Agrochemical’’ Certificate Number: 1492E Issue Date: 12/06/2022. Valid until: 12/06/2025 The certificate was issued by MSC Global
History	This was the first WHO 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 warehouse • Production areas • Quality control laboratory
Exclusions and Non-applications of requirements in the QMS	Design and development activities were not undertaken at this site.
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	• Icon 2.5 EC (Lambda-cyhalothrin 25g/l) – 012-005 • Actellic EC (Pirimiphos-methyl 500g/l) - 012-002

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
PQ	Prequalification

Part 2	**Brief summary of the findings and comments**

1. Quality policy and quality objectives

Top management had established an adequate quality policy which included a commitment to comply with regulatory requirements and to maintain the effectiveness of the QMS. The quality policy was displayed in various areas within the facility. The facility had established quality objectives. Key performance indicators had been defined for each of the quality objectives and the level and extent to which the quality objectives were achieved was monitored and measured. The quality policy and quality objectives were also communicated to staff through trainings.

2. Management review

The relevant procedure for management review was checked. Management reviews were held every quarter. The minutes of the latest management review meeting held were reviewed. The management reviews were conducted in accordance with the requirements of the ISO 9001 standard including review of customer complaints, internal audits, and changes. It was evident from the review that top management was committed to the development and implementation of the QMS.

3. Organizational roles, responsibilities, and authorities
The manufacturer had an established the organizational structure and defined designated responsibilities and authorities for staff undertaking or verifying work affecting quality. Reporting lines for quality and production were independent of the other. Job descriptions were available addressing inter alia responsibility, qualification, and experience.

4. Control of documented information
Documents were prepared, reviewed, approved, and distributed according to the procedure for control of documented information and records. Records were readily available. The issuance, revision and withdrawal of document was controlled. Revision histories were maintained. Procedures were reviewed every 3 years. The quality manual was reviewed annually. The structure of the documentation system was described in the quality manual.

5. Personnel competence and training
Procedure for training and the 2024 training plan were reviewed. Training records were maintained. Training records on the quality objectives and the revised working instructions for Filling and Packaging were also reviewed.

6. Risks Management
The procedure for Quality Risk Assessment was reviewed. The area manager of the affected section or area was responsible for conducting quality risk assessment. The FMEA approach was used for assessment of risks. The procedure defined the criteria for determination of severity, occurrence, and detectability. The procedure also defined the criteria for determination of the RPN and categorization of risks were defined. The quality risk assessment reports were reviewed.

7. Control of changes
The change control procedure reviewed. Changes were categorized into level 1 and level 2. Impact assessment of the changes performed prior to implementation of changes. Records describing the results of the review of changes were maintained.

8. Internal Audits
The internal audit procedure was reviewed. Nonconformities were categorized into 3 namely: Low, Medium, and High. The internal audit schedule and plans were in place. There was evidence that audits were performed by appropriately qualified auditors independent of the areas being audited. The nonconformities raised were adequately addressed.

9. Control of nonconforming products
The procedure for nonconforming products, corrective, and preventive action was reviewed. The procedure applied to bulk, intermediate, incoming materials, and finished goods. Investigations were to be completed within 30 days and corrections and corrective actions were implemented within 30 days from the date of approval of the implementation plan. A customized software was used for the management and record keeping of nonconforming products. Selected nonconformities were reviewed.

The procedure for product recalls was also reviewed. The criteria for initiation of a recall were defined. An emergency team created by the country office would be responsible for handling the recall. The procedure provided for investigations and root cause analysis. There had been no product recall by the time of the audit.

10. Design and development of products
This site was not involved in design and development activities.

11. Performance Evaluation
The manufacturer analyzed and evaluated the following among others monthly:

- Customer complaints
- Cross contamination
- Nonconformities
- Changes
- Near misses
- Internal audits
- Quality observations
- Right the first time

These were discussed in management review meetings.

12. Customer Satisfaction and Complaints
The procedure for customer complaints was in place. The investigation of complaints and root cause determination were described in the procedure. Complaints were received by the supply chain team. Complaints were logged into and managed using the customized software. Information describing the complaint, investigation, and root cause analysis was retained customized software. Feedback to complaints was to be provided within 14 working days. Registered complaints were reviewed.

Customer satisfaction surveys were conducted by Syngenta Country Corporate office. The site was not responsible for this activity.

13. Support
Infrastructure and work environment
Herbicides and insecticides/fungicides were produced on separate and dedicated lines. The warehouse for storage of herbicides was also separate from that of the insecticide/fungicide raw materials. The infrastructure was well maintained. The 2024 maintenance schedule was in place. The maintenance records were also maintained.

Monitoring and measuring resources
The calibration certificates for the load cells in formulation tanks were reviewed. The calibration certificates of the selected weighing balances were reviewed.

14. Production and service provisions

Control of Production

The inspection team visited the warehouse, production areas and quality control laboratory. Icon 2.5 EC and Actellic EC were manufactured following documented and approved recipes. The manufacturing process included mixing, filling, capping labelling, and packaging. The mixing speed and time were monitored. Prior to filling a sample of Icon 2.5 EC and Actellic EC was collected and tested for active ingredient content. The insecticide filling line (MFA Line) was equipped with an online checkweigher The line was also equipped with a sensor to detect capping defects. The fill weight and torque were also checked every 15 minutes. The working instructions for cleaning were reviewed. Production batch records were reviewed. Batch records were reviewed and released by the Quality Assurance supervisor.

Waste management.

The facility had an Effluent Treatment Plant for treatment of water-based waste collected from the herbicide production area. The waste was sampled, and relevant tests conducted by a government approved third party laboratory. Certificates of analysis for treated waste were available.

The rest of the solid and liquid waste was collected in drums. This was then collected by a government approved third party waste treatment company for disposal. Records of issuance of waste to the third-party companies were reviewed.

Quality control laboratory

The Quality Control Laboratory was separate from production areas. The laboratory was designed and equipped with facilities for chemical and instrumental testing. The laboratory had adequate space for the orderly placement of equipment and materials and to perform tests. Appropriate specifications were established. Access to lab premises was restricted to authorized personnel. A test sample receipt and allocation form were in place.

Retention samples

Retention samples were stored separately according to relevant retention sample procedure. Enough retention samples for at least 2 full analyses were retained.

15. Preservation

Inventory was managed by an ERP system. Details of the batch numbers of the raw materials, quantities received, date of receipt, quantities issued, stock at hand etc., were maintained in an ERP system. The procedure for receipt and handling of materials (Active Ingredients, co-formulants, bulk materials, labels, and packaging materials) was reviewed. The raw materials were received along with certificates of analysis. There were segregated areas for storage of rejected materials. The storage areas were of sufficient capacity to allow orderly storage of various categories of materials.

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

The selection and evaluation of suppliers of active ingredients was performed by Syngenta - Global office and not by the inspected site. An approved vendor list was in place. The site only selected the suppliers of co-formulants and packaging materials. The procedure for purchasing controls and supplier management was reviewed. The procedure described the criteria for selection, evaluation, approval, ongoing monitoring, and re-evaluation of suppliers. Supplier evaluations was conducted monthly. Records of supplier evaluations were reviewed and found satisfactory.

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 **PT Syngenta Indonesia** located at: **Jl. Raya Tlajung Udik, Km 62.8 Desa Tlajung Udik Kecamatan Gunung Putri Kabupaten Bogor, West Java Province Indonesia** 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/