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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	Syngenta Seneffe BV
Corporate address of manufacturer	Syngenta Crop Protection AG Rosentalstrasse 67, 4058 Basel, Switzerland
Inspected site	
Name & address of inspected manufacturing site(s)	Syngenta Seneffe BV Rue de Tyberchamps 37, B-7180 Seneffe Belgium
Unit/Block/ Workshop	Not applicable.
Inspection details	
Dates of inspection	11-14 October 2021
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	Syngenta Seneffe BV started in 1976 and manufactures insecticides, herbicides, and fungicides. The activities involved in the manufacture of Icon® CS and Actellic® 300 CS included preparations of the formulation, filling, packaging, and labelling.
General information about the company and site	This was the first WHO inspection. The site was not ISO certified yet. The process for certification was ongoing.
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:** • Training • Risk management • Management review • Job descriptions and responsibilities of key personnel • Complaints

	• Non-conforming products • Data integrity • Product release • Batch processing records • Laboratory test reports • 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 were not applicable. The site was not involved in the design and development of the product.
Out of scope	Manufacture and testing of products not submitted to WHO for prequalification. The inspection was limited to the scope of products indicated in the section below (WHO products covered by the inspection).
Restrictions	None
WHO products covered by the inspection	• Icon® CS 25g/L - 012-004 • Icon® CS - 100g/L - 012-003 • Actellic® 300 CS - 012-001

Abbreviations	**Meaning**
CoA	Certificate of Analysis
KPI	Key Performance Indicators
PPE	Personal Protective Equipment
QMS	Quality Management System
WP	Wettable Powder
MSDS	Material Safety Data Sheets
GC	Gas Chromatography

Part 2	Brief summary of the findings and comments

1. Organizational roles, responsibilities, and authorities
An organogram showing the reporting structure was in place. The heads of Health, Safety, Environment and Quality (HSE&Q) and manufacturing were all reporting independently to the Site Manager. The job descriptions of the production manager (Insecticides) and Head of Health, Safety, Environment and Quality were reviewed. The head of Health, Safety, Environment and Quality was responsible for product release.

2. Quality policy and quality objectives
The site maintained a documented quality policy that included commitments to satisfy applicable requirements and continual improvement of the quality management system. The quality policy and quality objectives were displayed within the site and were communicated to staff through trainings. The quality objectives were monitored and measured by using key performance indicators and targets. The quality policy and quality objectives were discussed in management review.

3. Management review
The relevant procedure was reviewed. Management reviews were held at least once a year. The site manager was responsible for ensuring that management reviews were conducted as per the procedure. The management review minutes for the meeting held in February 2021 were reviewed. The management review took into consideration risks, internal audits, quality performance, customer satisfaction, nonconformities and corrective actions, legal requirements, complaints, opportunities for improvement, quality policy, quality objectives etc.

4. Leadership and Commitment
The quality policy was approved and signed by top management. The quality policy and quality objectives were appropriate to the context and purpose of the organization. Top management demonstrated commitment to improvement of the quality management system by promoting improvement through internal audits, monitoring and measurement and analysis of process and product attributes.

5. Control of documented information
The document management procedure describing the creation, identification, distribution, and access was reviewed. Documents were categorized into process procedures, operation procedures, formulas, document specific procedures, quality management system documents and quality systems manual. Documents were maintained in both electronic and paper forms. Electronic documents were maintained in a customized company software system. Access to the software was controlled with unique passwords for the users. Electronic data was backed up daily. There was an ongoing cybersecurity project involving creation of firewalls that was to be completed by the end of the year.

6. Personnel competence and training

Trainings were identified by the line managers and training plans developed. The training schedule and competency matrix were in place. Induction training was categorized into two parts i.e., theory and practical. Trainings records related to quality, cross contamination, risk assessment, chemical risks etc. had been conducted. It was the responsibility of line managers to ensure that the staff in their jurisdiction were trained. Trainings were evaluated and records were maintained.

7. Risks and opportunities

The relevant risk management procedure was reviewed. The procedure described the identification, analysis, assessment, and review of risks. The failure modes and effects analysis (FMEA) risk identification and analysis tool was used to assess risks. The risk register was in place. Effects of the COVID-19 pandemic had been assessed and documented.

8. Control of changes

The change control procedure was in place. It described the initiation, review and approval of changes. The procedure provided for impact assessment of changes. The impact assessment of changes was performed by the area manager in consultation with quality department. Records were maintained. There were no changes related to Icon CS or Actellic CS. Change records were reviewed and found satisfactory.

9. Internal Audits

The relevant procedure for internal audits was reviewed. The procedure described the planning, reporting and implementation of corrections and corrective actions. Internal audits were conducted at least once a year. Internal auditors were trained. A list of all the trained internal auditors was in place. The internal auditors were trained by an external company. The internal audit plan was reviewed. Internal auditors did not audit their own areas of work. The internal audit reports were communicated to the line manager and site manager within 10 days following the audit. The internal audit report for the year 2021 was reviewed.

10. Control of nonconforming products

Market complaints were received by Syngenta Crop Protection AG (Global group) and communicated to the Syngenta Seneffe BV, Belgium. The relevant customer complaints procedure was reviewed. Complaints were categorized into two i.e., Major and Minor. The procedure allowed for investigations, root cause analysis, corrections, and corrective actions. It was required to provide feedback to the complainant within 30 days. Complaints were reviewed. Syngenta Crop Protection AG (Global group) was responsible for handling recalls. The relevant procedures for Management of Returns and Rework, and the relevant procedure for nonconformity management were also reviewed. Nonconforming products identified, quarantined, blocked in the inventory control software.

11. Performance evaluation

Nonconformities, complaints, production performance (Right first time), number of corrections were some of the parameters monitored. These were analyzed and the results of analysis were included in management review. Customer satisfaction surveys were conducted once a year in different markets by Syngenta Crop Protection AG (Global group). This was used to evaluate the degree of customer satisfaction and conformity of products to specifications and customer requirements.

12. Design and development of products

Design and development were not applicable. The site was not involved in design and development activities.

13. Support

Infrastructure and work environment

The site had dedicated buildings for the formulation of insecticides, herbicides, and fungicides. MSDS were in place. Safety measures and procedures were also in place. At the facility, waste was collected in bulk containers. This was then collected and treated by a certified third party.

Monitoring and measuring resources

The equipment calibration and maintenance schedule was available. Maintenance and re-qualification records of the GCs were reviewed. Calibration certificates for balances were in place.

14. Production and service provisions

Control of Production

The activities involved in the manufacture of Icon® CS and Actellic® 300 included mixing of the different ingredients in a heated mixer to prepare a surfactant solution, an aqueous and organic phase. These solutions were then mixed to make the final formulation. The formulation was then filled, labelled, and packaged. The mixing speed, flow rate, heating temperature and pH were monitored, and records were maintained. The filling lines were color coded. The filling lines were equipped with cameras and calibrated weigh checkers. The filled bottles were sampled, and the integrity of the capping and labelling was verified. A sampling plan was in place. The recipes for Actellic and Icon were reviewed. The production records for Actellic® and Icon® CS were reviewed. Cleaning instructions and a contamination matrix were available. Cleaning was verified both visually and by testing the last rinse. Cleaning was performed whenever there was a change from one product to another. Cleaning records were reviewed. Dispensing scoops were dedicated.

The laboratory equipment was uniquely identified and calibrated. Test records for determination of the active ingredient in Actellic® CS (*Pirimiphos*) and Icon® CS (*Lambda cyhalothrin*) were reviewed. The analytical method validation reports for determination of active ingredient content in Actellic® CS and Icon® CS were reviewed.

Products were released by the Head of Health, Safety, Environment and Quality (HSE&Q) (with delegation to QC department) following review of production and laboratory data.

Identification and traceability

Production records were reviewed, and these were found sufficient to allow for traceability of batch numbers and equipment used for production and testing of Icon® CS and Actellic® 300. Equipment were uniquely identified. The information on the status labels was also found adequate.

15. Preservation

Raw materials were supplied by Syngenta Crop Protection AG (Global Group). The suppliers of raw materials were approved by Syngenta Crop Protection AG (Global Group). A risk assessment was used to determine whether raw materials were to be sampled or not. The quantity, integrity of containers, Certificate of Analysis, delivery note etc. were verified upon receipt of the raw materials. Inventory was controlled by SAP.

Raw materials were also stored at Interlogistics Houdeng located at Boulevard Millenium, 17, 7110 Houdeng Gaeguis, Belgium. Interlogistics Houdeng is a logistics company located about 7 Km from the site. Raw materials were transported to interlogistics following verification of the raw materials by Syngenta Seneffe BV. Inventory control at Interlogistics Houdeng was managed by SAP. There was an interface between both SAP systems at Syngenta Seneffe BV and Interlogistics Houdeng. Raw materials were placed in the different locations following a documented risk assessment log.

16. Post-delivery Activities

One sample per batch of Icon® CS and Actellic® 300 CS was retained. A sample register was in place. The samples were stored at ambient temperatures. The samples were retained for 5 years. Reports for the determination of the shelf life of Icon® CS and Actellic® 300 CS were provided. The studies were conducted at 54ºC for two weeks. The tests results complied with the WHO Specifications and Evaluations for Public Health Pesticides requirements.

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

The selection and evaluation of performance of the suppliers of raw materials was controlled by Syngenta Crop Protection AG (Global Group) in accordance with the relevant procedure.
The criteria for selection of suppliers included capability, sustainability, innovation and technology, cost, mutual benefits etc. Suppliers were categorized into strategic and tactical suppliers. Strategic suppliers were audited yearly. Tactical suppliers were audited periodically. Some of the parameters used in evaluating the performance of suppliers included quality, complaints among others.

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, ***Syngenta Seneffe BV*** located at ***Rue de Tyberchamps 37, B-7180 Seneffe Belgium*** 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. Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange, Final Document, Global Harmonization Task Force, November 2, 2012, GHTF/SG3/N19:2012
   https://www.imdrf.org

3. 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/