

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

Part 1	General information
Company information	
Name of manufacturer	MC Crop & Life Manufacturing Co Ltd
Corporate address of manufacturer	Mitsui Chemicals Crop & Life Solutions, Inc. Nihonbashi Dia Building, 1-19-1, Nihonbashi, Chuo-ku Tokyo, 103-0027, Japan
Manufacturing site(s) under assessment	
Address of manufacturing site if different from that given above	Funaoka Factory: 1-6 Takizawa, Funaoka, Shibata-machi, Shibata-gun, Miyagi, Japan Utsunomiya Factory: 1215 Iwazo-machi, Utsunomiya-shi, Tochigi, Japan Shinshiro Factory 11-4 Ihara, Oomi, Shinshiro-shi, Aichi
Desk assessment details	
Date of review	22-30 July 2025
Inspection record number	INSP-VCP-2023-0032 (I-04234) INSP-VCP-2023-0033 (I-04237) INSP-VCP-2023-0035 (I-04272)
List of documents submitted	<ul style="list-style-type: none"> • Site Master File • Site floor plans • Full address including latitude and longitude • Cover letter • Quality Manual • Staff Organogram • List of current quality management procedures • Complaint handling guidelines • Deviation control guidelines • Guidelines for quality change control • Risk Management • Regulations for purchasing management • List of ISO 9001 certification and surveillance audits • Audit planning • ISO 9001 management system certificate 2025 • Current full inspection report – Funaoka and Utsunomiya factories • Current full inspection report – Shinshiro factory

	<ul style="list-style-type: none"> • Product list • Cross contamination list • Name and contact details of the responsible person at manufacturing facility • Process Flow Chart • Recent Management review report • Completed batch records for the most recently released batch • Master batch records for Vectron 10EW • Master batch records for Vectron 10EW and Vectron 20WP • List of any recalls and returns
Last WHO inspection	The sites listed above have never been inspected by WHO. A desk assessment of the sites was conducted in March 2023 and were all found compliant.
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</i>	Japan Quality Assurance Organization (JQA)
<i>Dates of inspection</i>	2-4 June 2025
<i>Type of inspection</i>	Renewal audit (Routine inspection)
<i>Products(s) covered:</i>	Broflanilide 5 SC
<i>Inspected areas</i>	<p>The scope of the audit was stated as: “sampling of processes/departments/sites from the scope of registered activities”.</p> <p>The areas inspected included: Management review, corrective actions, complaints, quality objectives, laboratory, document management, operational management, quality manual, and deviations etc.</p>
<i>A summary of major areas of deficiency observed</i>	No deficiencies were raised in the report. However, a number of opportunities for improvement related to the handling of complaints, handling of results of the equipment inspection records and procedures for setting objectives and managing activity results were reported.
<i>Description of CAPAs</i>	A CAPA for implemented of the raised opportunities for improvement was provided.
<i>Final conclusion of the inspection report</i>	The conclusion on maintenance of registration was stated in part as follows:

	<p>“In this periodic audit no improvement points were found in the applicable standard (ISO 9001:2015) standard. It is judged that the system is maintained for the registered management system.”</p> <p>The conclusion on Certificate of registration was as follows: “As a result, it is determined that the registration certificate continues to be appropriate for the scope of this audit.”</p> <p>It was therefore concluded that the system was maintained in compliance with the ISO 9001:2015 standard and that it was appropriate for the scope of the audit.</p>
<p><i>Comments/observations on the scope and comprehensiveness of the report and appropriateness of the CAPAs</i></p>	<p>It was noted that on 1st April the company changed its name from Utsunomiya Chemical Industry Co., Ltd. to MC Crop and Life Manufacturing Co., Ltd. The Quality management system was maintained. There were no changes to the scope of the QMS.</p> <p>The QMS was exempted from the requirement of Clause 8.3 - Design and development as the site was not involved in such activities but only manufactured products in according with the customer requirements.</p> <p>The audit covered several key areas of the quality management system. No nonconformities (improvement issues) were raised in the report. However, a number of opportunities for improvement related to the handling of complaints, handling of results of the equipment inspection records and procedures for setting objectives and managing activity results.</p>
<p>Part 3</p>	<p>Summary of the last WHO inspection</p>
<p>Date and conclusion of most recent WHO inspection</p>	<p>The sites listed above have never been inspected by WHO. A desk assessment of the sites was conducted between 6-9 March 2023.</p>
<p>Brief description of manufacturing activities</p>	<p>Funaoka Factory has a manufacturing area of 9,580m². With approximately 34 employees. The following activities occur at the site:</p> <ul style="list-style-type: none"> • Fabrication, packaging, labelling, testing and storage- <ul style="list-style-type: none"> • Etofenprox 10EW (Vectron 10EW) <p>Utsunomiya Factory has a manufacturing area of 13,811m². With approximately 42 employees. The following activities occur at the site:</p> <ul style="list-style-type: none"> • Part fabrication and Packaging, labelling, testing and storage- <ul style="list-style-type: none"> • Etofenprox 20WP (Vectron 20WP) • Etofenprox 10EW (Vectron 10EW)

	<p>Shinshiro Factory has a manufacturing area of 8,856m². With approximately 31 employees. The following activities occur at the site:</p> <ul style="list-style-type: none"> • Fabrication, packaging, labelling, testing and storage – <ul style="list-style-type: none"> • Etofenprox 20WP (Vectron 20WP) • Etofenprox 10EW (Vectron 10EW) • Packaging, labelling, testing and storage – <ul style="list-style-type: none"> • Broflanilide 50WP (VECTRON T500) <p>The sites manufactured other products such as herbicides, fungicides, insecticides, agricultural spray adjuvant, fertilizer and snow melt agents.</p>
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.

Part 4	Summary of the assessment of supporting documentation
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1. Quality Manual:

The quality manual described the interaction between the processes of the Quality Management System (QMS), it defined the structure of the documentation system, its scope, processes, and procedures used to ensure quality. The quality manual applied to all three sites of MC Crop & Life Manufacturing Co., Ltd. listed above.

2. List of current quality management procedures:

The list of the current QMS procedures at MC Crop & Life Manufacturing Co., Ltd. was provided.

3. Standard operating procedures for:

i. Complaint handling and vigilance:

The procedure for complaint handling was provided. The Review & Implementation Department was responsible for investigating the cause of complaints and examining corrective actions. The results of the investigation were reported to the General Manager for review and to the factory manager for approval.

The report was required to include the following:

- 1) Investigation results
- 2) Cause of occurrence
- 3) Measures for prevention of occurrence
- 4) Method of confirmation of effectiveness of corrective actions.

Any returned materials were to be handled in accordance with instructions for disposition that were received from the Japan Crop Sales Administration Department or the Sales Administration Department.

ii. Control of nonconforming goods/processes:

The procedure for deviation control (01_00_01 revised 1 April 2024) was reviewed. The procedure applied to the handling of nonconformities related to products, intermediate products, and raw materials. Nonconforming materials were to be identified and isolated. The procedure provided for investigation, correction and corrective actions.

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

The procedure for quality change control was reviewed. The Manager of the change initiator department was responsible for assessing the impact of the change and presenting high-impact cases to the confirmation meeting (planning) for review and evaluation of the change plan. The change plans were approved by the General Manager and Factory Manager.

iv. Risk management:

Top management was responsible for drawing up action plans to address quality risks and opportunities. A copy of the risk assessment (financial and non-financial) was provided.

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

A copy of the Regulations for procurement and purchasing management was reviewed. The regulations for procurement and purchasing management described the roles of the supply chain department (SCM department).

SCM department at Mitsui Chemicals Crop & Life Solutions, Inc. was responsible for the selection, evaluation and assessment of the performance of the suppliers of raw materials used in the manufacture of Vectron 10EW and Vectron 20WP.

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

A copy of the site master file (Version 6) was provided. The site manufactured insecticides, fungicides, herbicides and a snow melting agent. The SMF provided an overview of the quality management system and processes. The processes flow charts for the material management, warehousing, quality control, and complaint handling were provided. The layout of the facility was also provided.

The organogram depicted independent reporting of the Production department and Management department to the Factory Manager. The Quality Assurance division reported to the Management department. Recent inspections by relevant regulatory/certification bodies were outlined.

**5. Quality management system certificate(s) and scope of certification: (e.g. ISO 13485/ISO 9001):
ISO 9001 Certificate Number: JQA-QMA15928**

Scope: “The manufacture and ancillary service for agrochemical, pharmaceutical chemicals (insecticides for prevention of epidemics), veterinary products, termiticides and wood preservatives”

Renewal date: July 10, 2025

Expiry date: July 9, 2028

The certificate was issued by Japan Quality Assurance Organization.

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

It was indicated that the sites were inspected by Japan Quality Assurance Organization in May 2020, May 2022 and May 2023. The manufacturer complied with requirements of the ISO 9001:2015 Standard.

“No information on upcoming inspections” was declared by the manufacturer.

It was also indicated in the site master file that the sites were last inspected by FAMIC (Incorporated Administrative Agency Food and Agricultural Materials Inspection Center) on 25 January 2023.

“No information on upcoming inspections” was declared by the manufacturer.

7. Process flowchart including in-process control points:

A process flow chart for Etofenprox 10EW with in-process controls was provided. The manufacturing process included preparation of an oil premix, mixing emulsification, filtration, filling, capping and sealing. The in-process controls included particle size measurement, pH, and viscosity.

The process flow chart for Etofenprox 20WP was reviewed. The manufacturing process involved mixing of Etofenprox technical material with other inert materials, milling and packaging. In process controls and process parameters were provided.

The process flow chart for packaging of VECTRON T500 was also provided. The packaging involved heat sealing and the line was equipped with a weigh checker.

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

The list of all products manufactured at the facility was provided. The facility manufactured pesticides, fungicides and herbicides.

9. Most recent management review report/minutes:

Minutes and agenda showing a meeting between members of top management held on 24th and 25th October 2024 were provided.

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

Templates of the batch manufacturing records (Revised January 6, 2025) for Vectron 10EW, and Vectron 20WP were provided.

11. Completed batch manufacturing and/or packaging records:

The manufacture declared that no batch of Vectron 10EW, Vectron 20WP and VECTRON T500 had been manufactured in the last 5 years.

12. List of any recalls/returns:

The manufacturer declared that there were recalls or returns last three years.

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

A contamination matrix with carry over limits was provided.

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

None.

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 **MC Crop & Life Manufacturing Co., Ltd.** located at the following addresses

- **Funaoka Factory: 1-6 Takizawa, Funaoka, Shibata-machi, Shibata-gun, Miyagi, Japan**
- **Utsunomiya Factory: 1215 Iwazo-machi, Utsunomiya-shi, Tochigi, Japan**
- **Shinshiro Factory 11-4 Ihara, Oomi, Shinshiro-shi, Aichi, Japan**

are 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 compliance status shall be valid until 9 July 2028 or when another inspection is conducted by WHO or by a reliable certification body.

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 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
3. ISO 9001:2015 Quality management systems - Requirements
4. WHO Post-market surveillance of in vitro diagnostics 2015 (ISBN 978 92 4 150921 3)
5. Medical devices - Application of risk management to medical devices - ISO14971:2007
6. GHTF/SG3/N19:2012 “Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange”

7. GHTF/SG4/(99)28 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements
8. GHTF/SG4/N30R20:2006 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy
9. GHTF/SG4(pd1)/N33R16:2007 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 3: Regulatory Audit Reports ISO 13485:2016, Commitments to WHO PQ
10. Manual on development and use of FAO and WHO specifications for pesticides
First edition - third revision ISSN 0259-2517