

Conformity of Production Processes of Field Sprayers

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Introduction

Conformity of Production (CoP) is a means of evidencing the ability to produce a series of products that exactly match the specification, performance and marking requirements outlined in the in the technical construction files, or type approval.

The sprayer manufactures are using industrial standards, conducting risk assessments, internal and third-party testing to ensure they meet CE mark self-certification requirements given by the Machinery Directive 2006/42/EC for the machinery use for pesticide application. The results from these activities are documented in the technical construction files for each product/model which are available for the market surveillance and other control authorities.

The sprayer producers also must demonstrate that their manufacturing organization (facilities) have fully functioning manufacturing quality control systems (incl. quality audits, certification of incoming components, run-off specifications, etc.) that assure products are compliant.

To help SPISE community to build up a correct picture of the sprayer industry and increase the trust in the self-certification of field sprayers we want to share some information about quality control systems and methods which sprayer manufacturers are using to control their products.

Requirements and Responsibilities of the Manufacturers

There are certain obligations which implies to every sprayer manufacturer. The most important one is the self-certification according to the Machinery Directive, which is usually based on fulfilling the requirements of EN ISO 16119. The self-certification is part of the declaration of conformity and is shown on the machine by the CE mark.

This certification is usually related to the type of equipment; due to the required measures for ensuring the quality, the Declaration of Conformity states the conformity of each individual machine. The self-certification is the formal and legal statement addressed to authorities that the machine complies with the Machinery Directive.

By the inclusion of the sprayers into Annex 1 (not Annex 4) EC has rightly concluded that mandatory third party inspection was not part of the compliance requirements for sprayers.

Related to the Conformity of Production there are following paragraphs specified in the Machinery Directive 2006/42/EC:

Article 12 - Procedures for assessing the conformity of machinery

Sub §2.: Where the machinery is not referred to in Annex IV, the manufacturer or his authorized representative shall apply the procedure for assessment of conformity with **internal checks on the manufacture** of machinery provided for in Annex VIII.

Annex VIII - Assessment of conformity with internal checks on the manufacture of machinery

*Sub §3.: The manufacturer must take all measures necessary in order that the **manufacturing process** ensures compliance of the manufactured machinery with the technical file referred to in Annex VII, part A, and with the requirements of this Directive*

Annex VII A 1 (b)

A. Technical file for machinery

...The technical file must demonstrate that the machinery complies with the requirements of this Directive. It must cover the design, **manufacture** and operation of the machinery...

1. The technical file shall comprise the following:

(b) for series manufacture, the internal measures that will be implemented to ensure that the machinery remains in conformity with the provisions of this Directive.

The internal measures, mentioned in Annex VII A 1b, may include the monitoring of supplies of materials, components and sub-systems.

Next, it may include the inspections and tests to be carried out at various stages of production and on finished products, but also measures to ensure that the manufacturer's specifications are correctly executed by subcontractors.

These measures can be implemented by applying quality management systems.

Conformity of Production (CoP)

The Conformity of Production CoP is a means of evidencing the ability to produce a series of products that exactly match the specification, performance and marking requirements outlined in the in the technical construction files, or type approval.

The CoP is a part of the complete Quality Management System which shall be integrated into each department of the production organization which needs to demonstrate its ability to consistently provide product that meets the customer requirements, applicable statutory and regulatory requirements.

The Quality Management System is normally documented by a Quality Manual which describes the processes, procedures, control plans and working documents used in the organization. (For example as a process can be seen the Compliance Audit process which defines the information and material flows, departments' responsibilities and what are the appropriate actions when an audited machine will not pass the criteria set up by the product specification).

The Quality Management System is not new for many of sprayer manufacturers and its principles and requirements are specified by several standards:

- ISO 9004:2009 - Guidance to organizations to support the achievement of sustained success by a quality management approach
- ISO 14001:2004 - Environmental Management System
- OHSAS 18001- Safety Management System
- ISO 19011:2011- Guidelines for Auditing Management Systems
- ISO 9001:2008- Quality Management Systems

The last mentioned is a popular Quality Standard which specifies a quality management system, but it is not a mandatory requirement to obtain CoP clearance. An internal quality management system can ensure CoP clearance too.

Production Quality Control Measures

The following production quality control measures are the typical outcome from a sprayer manufacturer which has to ensure that his products meet the regulatory requirements specified in the Machinery Directive 2006/42/EC (Annex VII A1b):

- Goods Receiving Inspection
- Production Quality Warrant
- Production Part Approval Process (+ Control plan)
- Quality center verifications
- Serial number registration
- Run- Off specification
- Pre-delivery Instructions
- Product Audit
- Tooling Calibration

The first four measures, mentioned above, describe the controlling of single components which are critical to quality, the machine assembly, testing and delivery of the machine to the customer. These measures will be described more in details.

Good receiving inspections and other actions taken at supplier's level

Many organizations have a program to designate “certified suppliers”. They receive products from these suppliers directly into stock. If they qualify suppliers by auditing their quality system, by inspecting trial orders, or by other means they can determine what kind of sampling plan they need to monitor the quality of their product. (E.g. there can be requested 100 % checks and calibration of the digital pressure sensors at the supplier location, before their delivery. It includes also decisions about the proper packaging of the component with an aim to avoid their damage during the transport from the supplier to the production line)

Some products come with certain certifications or standards already met for the product. These come with a Certificate of Analysis or other evidence that control is exercised at the supplier's location. If this is the case, the inspection may be checking for a Certificate.

Incoming inspection can be as simple as reviewing the packing slips and verifying that the correct item and quantity are received. It is up to the organizations to determine how the quality of the supplies affects their product quality and how you will measure and monitor.

An inspection can be performed on shipments of goods arriving at a manufacturer's location it may include: functionality testing, drawing check (+ measurements), material analysis and surface inspection of shipping containers.



Fig. 1. Example of component which are certified by suppliers (Quality checks are done at supplier facility)

Production Quality Warrant

The quality warrant composes from the production part approval process (PPAP), control plan, serial number registration, run-off specification and quality notes.

The PPAP is a process which is used mostly in the road and off-road vehicle supply chain for establishing confidence in component suppliers and their production processes, by means of demonstrating that supplier can meet the manufacturability and quality requirements of the supplied parts to the customer.

It must be ensured that the customer engineering design record and specification requirements are clearly understood and fulfilled by the supplier. Next, it has to demonstrate that the established manufacturing process has the potential to produce the part that consistently meets the all requirements during the actual production run at the quoted production rate.

There should be the defined who is the process owner, how is the process documented, monitored, analyzed and improved. The records shall be maintained.

The control plan describes the ongoing tests conducted throughout the production process and their frequency. The plan is set up for an individual component or a machine function, if it is defined by PPAP and by the quality part level (QPL) which is specified during the design process. The QPL is based mostly on the complexity of the part or its impact on the final function of the machine. (E.g. a simple screw can be rated as QPL =1, a control unit QPL=4).

The control plan includes also the frequency of the checks. For example for the nozzle manufacturing includes the control plan the frequency of the test bench testing of the nozzle batches, the time of the testing am/pm for the 24/7 production process, a plan for machine and tooling calibration, etc..).

Serial number registration is used for some critical parts for the tracking purposes (engine, axles, braking systems, pumps, etc...)

Run-Off Specification defines the machine run off requirements for each model/version of the sprayer manufactured by the production facility. It is applicable to each single sprayer produced. The run-off specification includes for example directions for programming, factory adjustments, checking various systems for appropriate function, adding the appropriate fluids to the machine and the general machine auditing.

4.3.4 Validation dead band setting
 To ensure the regulation is working as expected later in the field, it is essential that the regulation dead band in the factory settings is set correct as long as EOL programming is not implemented.
 Check in "Factory Settings", Tab "Regulation 3":
 R900: Reg. Dead Band set to 1.5
 M900(i): Reg. Dead Band set to 3.

4.3.5 Flushing of the spray-lines
 Close all sections (also Master will be off).
 Ensure no end stops are mounted on the spray lines so water can flush through.
 Open 1 section and flush it with 9 bar on the spray line for 10 seconds.
 Close section and flush next section.
 Continue until all sections are flushed.

4.3.6 Calibration of Flow Sensor (<KC>)
 Go to Machine Settings, Calibrations and select "flow". Then press "AUTO"
 Follow the instructions on the display.
 Alternative calibrations are allowed using the pattermator to determine the correct value.
 Value shall be between 140 and 170 pulses/ltr.

4.3.7 Calibration of the Liquid Pressure sensor (<KC>)
 Connect a pressure gauge (electronic or mechanic) to the spray line, in the middle of the spray boom.
 Go to Machine Settings, Calibrations and select "Liquid Pressure".
 Follow the instructions on the display.
 The pressure to use for calibration is the value as indicated by the connected pressure gauge.
 Zero calibration shall be between 0 and 20 ADC
 With reference pressure of 5 bar on the spray line, sensor ADC value shall be between 180 and 230 ADC.

4.3.8 Nozzle calibration
 Calibrate each nozzle by collecting the amount sprayed out for 1 minute when the reference pressure as set in the nozzle presets is applied to the sprayline
 Measure 1 nozzle on each section.
 Go to Machine settings, Boom, Nozzle Presets to see the value for the specific nozzle.
 Determine the average volume for 1 minute and enter it into the display.
 Repeat for each nozzle present on the machine.

4.3.9 Membrane check
 Open all sections.
 Have the machine spray with 6 bar when using non-fertilizer nozzles, Spray with 3 bar when using fertilizer nozzles.
 Close the master.
 Close the section valves one by one.

| | | | | |
|-------|-----------|-------------|---------|----------|
| SIZE | CASE CODE | PART NUMBER | VERSION | REV. |
| A4 | | WZW13972 | JD90 | E |
| SCALE | | METRIC | | SHEET |
| | | | | 38 of 45 |

Fig. 2. Example of the Run-off specification for field sprayers used at final test area.

Pre Delivery Instruction

To meet the requirements for the conformity of production does not apply only to the quality checks at manufacturing location, but also at the dealer's location after delivery from the factory and just before delivery to customer. In the Fig. 3, are shown examples of the pre-delivery instructions for a self-propelled sprayer.

Predelivery

After the machine has been assembled, inspect to be sure that it is in good running order before delivering to the customer. The following checklist is a reminder of points to inspect. Check off each item as it is found satisfactory or after proper adjustment is made.

- Check pump oil level.
- Verify all moving parts move freely.
- Check machine for damage (electrical wiring, hoses, and decals).
- Check functions are all operating properly.
- Check nozzle output.
- Check spray pattern of nozzles.
- Check operation of lights.
- SMV emblem and reflectors installed.
- All fluid levels have been checked. All grease fittings have been lubricated.
- Tires and suspension are properly inflated. Tighten wheel nuts to specified torque.
- Solution system operates properly and does not leak.
- Hydraulic systems operate properly and do not leak.
- Verify that nozzles are drip free.

- Check brakes for proper operation.
- Check boom transport supports have been correctly adjusted.
- Verify that antifreeze has been removed, and all dismantled parts have been refitted (filters, hoses, pressure gauge, and end caps).
- Verify all the customer-ordered attachments have been installed.
- Verify that spraying control unit has been programmed and the sensors have been calibrated.
- Check any parts scratched in shipment have been touched up with paint.
- Factory made entries in GreenStar™ 3 2630 display monitor have been confirmed and/or reset to agree with calibration values.
- Test machine with clean water.
- This machine has been thoroughly checked and to the best of my knowledge is ready for delivery to the customer.

Signed: _____
Date: _____

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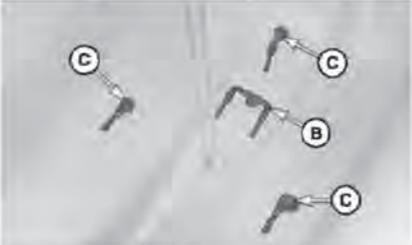
Agitation Check

1. Push agitation switch (A) to the ON position.
2. Check double agitation nozzle (B) and the single agitation nozzles (C) are all flowing water inside the tank.
3. Push agitation switch to the OFF position.

A—Agitation Switch

B—Double Agitation Nozzle

C—Single Agitation Nozzles

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Fig. 3. Example – Pre-delivery Instruction.

Conclusion

The Machinery Directive requests to implement internal measures to ensure that the machinery remains in conformity with the provisions of this Directive (CoP) and document these in the Technical Construction File. The Conformity of Production is mandatory for every manufacturer (large or small) who places CE mark on its sprayer.

There are different ways and provisions how to ensure the CoP during the whole production process. Each manufacturer can decide how will he establish the quality controls thorough the manufacturing process or at the end using e.g. final test area or dealers location equipped with proper instrumentation.

Some companies have already established Quality Management System which ensures the CoP and some are still developing it. However, there are some manufacturers which will be not able to reach the required level of quality it and will still place the CE mark on their non-compliance products. For this cases there shall be an appropriate action taken by the market surveillance authority.

The sprayers are included into Annex 1 of Machinery Directive which means that mandatory third party inspection, as the one used for the sprayers in use (specified in ENISO 16122) is not a part of the compliance requirements and it can be used only optionally.