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VALIDATION, A CHALLENGE IN CLEANING PROTOCOLS

Hein Timmerman[1,2*]

[1]Ghent University, Coupure Links 653, 9000 Gent, Belgium
[2]Sealed Air, 8215 Forest Point Boulevard, Charlotte, NC 28273, USA

[*]e-mail: hein.timmerman@sealedair.com

Abstract

The validation of process lines is more than the lineup of single equipment. Implementation of a new validation plan will require a holistic approach, and can absorb a huge amount of time of a dedicated team and will have an economic impact. Finding the balance between a theoretical and academic proven method and the practical realization of the validation plan will require good insights in current available technologies and their practicality on the plant floor.

The base of a good validation has several key elements starting with a line design with all European Hygienic Engineering and Design Group - EHEDG know-how and development for an effective program. As second step, the principles and calculations of residue limits for a wide variety of residue types, routes of administration, and dosage types the selection of available analytical methods, such as ATP, along with appropriate levels of analytical method validation should be investigated. As last step the documented report should include a cleaning validation master plan and/or policy components, the appropriate documentation for cleaning validation protocols and reports, the tools used for monitoring, verification, revalidation, and validation maintenance for validated cleaning processes.

Validation will require a deep understanding of all elements involved in obtaining a consistent cleaning result.

***Key words**: Cleaning validation, ATP, Alternative materials.*

1. Introduction

Earlier this year European Hygienic Engineering and Design Group - EHEDG has published a guideline 45 Cleaning Validation in the Food Industry - General Principles, Part 1 (2016). [1] National and international legislation requests the food industry to put on the market safe food and equipment manufacturers to provide cleanable equipment. The validation of cleaning operations is necessary to ensure compliance. Further advantages are the: optimization of cleaning operations, reduction of costs and chemicals usage.

2. Cleaning validation

The objective of cleaning validation is to prove that the equipment is consistently cleaned of: product, microbial residues, chemicals and soiling, including allergens to an acceptable level, and to prevent possible cross-contamination of hazards between products. There is sometimes a misinterpretation of the words validation, monitoring and verification. The following should be understood. Validation should not be confused with verification. Once that a cleaning process has been validated, it is routinely applied, and the process is monitored and verified. In ISO 22000, monitoring is defined as: "conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended" and verification is defined as "confirmation, through the provision of objective evidence, that specified requirements have been fulfilled". Verification is the application of checks or tests, at regular intervals, to ensure the cleaning procedure is still working and continues to deliver the required level of cleaning. Verification of cleaning may include internal audits, record reviews, swabs or tests of the cleaned equipment and the assessment of staff to ensure they have a clear understanding of the cleaning procedure.

In the US the new Food Safety Modernization Act (FSMA) Key Requirements are stating that [2]: "Covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls".

The rule sets requirements for a written food safety plan that includes:

- Hazard analysis: The first step is hazard identification, which must consider known or reasonably foreseeable biological, chemical, and physical hazards. These hazards

could be present because they occur naturally, are unintentionally introduced, or are intentionally introduced for economic gain (if they affect the safety of the food).

- Preventive controls: These measures are required to ensure that hazards requiring a preventive control will be minimized or prevented. They include process, food allergen, and sanitation controls, as well as supply-chain controls and a recall plan.

- Oversight and management of preventive controls: The final rule provides flexibility in the steps needed to ensure that preventive controls are effective and to correct problems that may arise.

- Monitoring: These procedures are designed to provide assurance that preventive controls are consistently performed. Monitoring is conducted as appropriate to the preventive control. For example, monitoring of a heat process to kill pathogens would include actual temperature values and be more frequent than monitoring preventive maintenance activities used to minimize metal hazards, which could be a simple record of the date on which the activity took place.

- Corrective actions and corrections: Corrections are steps taken to timely identify and correct a minor, isolated problem that occurs during food production. Corrective actions include actions to identify a problem with preventive control implementation, to reduce the likelihood the problem will recur, evaluate affected food for safety, and prevent it from entering commerce. Corrective actions must be documented with records.

- Verification: These activities are required to ensure that preventive controls are consistently implemented and effective. They include validating with scientific evidence that a preventive control is capable of effectively controlling an identified hazard; calibration (or accuracy checks) of process monitoring and verification instruments such as thermometers, and reviewing records to verify that monitoring and corrective actions (if necessary) are being conducted.

Product testing and environmental monitoring are possible verification activities but are only required as appropriate to the food, facility, nature of the preventive control, and the role of that control in the facility's food safety system. Environmental monitoring generally would be required if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control.

Equipment manufacturers in the European Union have to deliver "Instructions" that "must indicate recommended products and methods for cleaning, disinfecting and rinsing, not only for easily accessible areas but also for areas to which access is impossible or inadvisable". Initially, the equipment manufacturer may only be able to give general guidance to the food producer, as he does not know the specific use of each installation. Therefore, it is the responsibility of the food producer himself to validate his own procedure for the cleaning process, as it will be commonly applied. He will have to take into account, for example: the type of raw materials, the previous and following step in the food processing chain, the food processing itself, the expected shelf life and intended use of the processed food, the chemicals used for cleaning, and the duration of the operations. It is recommended that this cleaning validation be done in collaboration with the equipment supplier, chemicals supplier, any cleaning contractors, specific customers, etc., as appropriate. The following factors are key to the successful validation of cleaning:

- Planned allocation of time: The validation of cleaning is not a quick one-day study. Factory complexity obviously has an influence on time and number of people required.
- Clearly defined responsibilities.
- A validation team with an expert as leader.
- The use of adequate monitoring tools.
- The use of the operators input during the entire validation process.
- Coaching of people involved in cleaning and disinfection.

When a change occurs in equipment, food manufacturing process, ingredient, cleaning agent, etc. and at predefined time intervals, revalidation is needed.

At present there is no law that requires explicitly a "Cleaning Validation", but there are several legal requirements on hygiene, hygienic design, cleanability, cleaning, sanitation, hazard analysis and the control of hazards and the overall requirement on delivering safe and non-hazardous food. Cleaning Validation is one important element to fulfil these requirements.

Some important laws on national, European and international level are the following:

- USA:

- cGMP for human food/dietary supplem. 21 CFR Part 110/111.

- FDA-2011-N-0920-1979 - Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based - Preventive Controls for Human Food.

- Germany:

- Law on Food and Feed (LFGB) and subordinated regulations.

- Europe:

- Food Hygiene Package: Regulations (EC) 852/2004 etc.

- Machinery Directive 2006/42/EG.

- International / several Nations: Codex Alimentarius (food hygiene, HACCP) CAC/RCP 1-1969.

In addition, there are standards that concretize the requirements of the law, e.g.:

- DIN EN 1672-2 "Food processing machinery - Basic concepts - Part 2: Hygiene requirements" and

- DIN EN ISO 14159 "Safety of machinery - Hygiene requirements for the design of machinery" to substantiate the European machinery directive.

The Global Food Safety Initiative series of approved schemes such as the BRC, SQF, FSSC 22000 and IFS set out clear requirements for cleaning and disinfection of a food plant. These standards address cleaning as a PRP. Under GFSI it is required to have appropriate standards of housekeeping, cleaning and hygiene and these shall be maintained and validated at all times and throughout all stages.

Cleaning validation is a documented process that shows evidences to demonstrate that the cleaning methods which have been found applicable and acceptable for a process/product, achieve consistently the required levels of cleanliness. The typical steps illustrated in Figure 1.

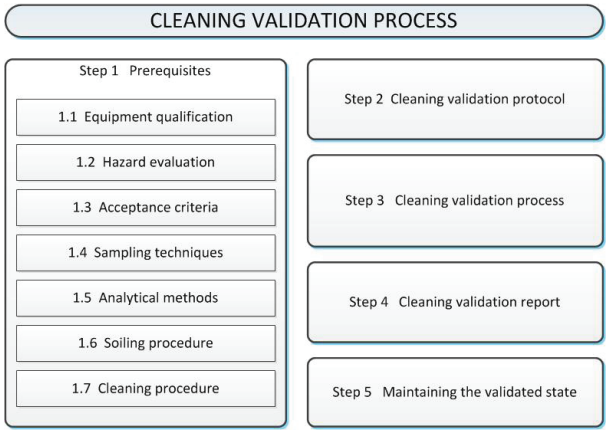

Figure 1. Cleaning validation process

The objective of the cleaning validation is to demonstrate the effectiveness of the cleaning procedures in the removal of product residues, degraded products, preservatives, allergens, and/or cleaning/disinfecting/cross contamination/enzymatic agents that can post a risk to the consumer of manufactured food products.

The validation of cleaning, assuring a standard and consistent results has become a topic of high priority in the food processing industry. This validation is used to show proof that the cleaning system consistently will perform as expected and provides scientific data that consistently will meet pre-determined specifications for the residuals. However, when starting a new Greenfield plant, the integration of a validation approach from the design phase is a good base to achieve the required result. When an existing plant or line requires an effective and validated cleaning program, a huge amount of effort will be needed. It is a fact that over 80 % of existing cleanings executed on a daily base in the food industry are not validated and poorly documented, and can be one of the root causes of food safety incidents, related to underperforming cleaning routines.

The validation of process lines is more than the line-up of single equipments. Implementation of a new validation plan will require a holistic approach, and can absorb a huge amount of time of a dedicated team and will have an economic impact. Finding the balance between a theoretical and academic proven method and the practical realisation of the validation plan will require good insights in current available technologies and their practicality on the plant floor. Keeping in mind that simple engineered line modification, like changing of a pump type, addition of a valve, the addition of a new instrument can require a new validation of the process line.

Validation will require a deep understanding of all elements involved in the cleaning result such as the importance of design and development for an effective program, the principles and calculations of residue limits for a wide variety of residue types, routes of administration, and dosage types the selection of available analytical methods, along with appropriate levels of analytical method validation, the selection of sampling methods and sampling sites, along with proper selection of blanks and controls the appropriate strategies and documentation for sampling recovery studies, the presence of a cleaning validation master plan and/or policy components, the appropriate documentation for cleaning validation protocols and reports, the tools used for monitoring, verification, revalidation and validation maintenance for validated cleaning processes. The process of cleaning validation consists of 2 major phases:

- Preparation work.
- Actual testing.

During both phases documentation is generated [3]. For validation of CIP, innovative technology can be applied. TTS-Ciptec technology enables to determine the efficiency of CIP washes and verify cleanliness and better hygiene of production lines. And effective washes save costs. The system is based on a unique and patented spectrophotometric measurement and statistical data analysis.

The system can identify:

a) How long each CIP wash removes product and therefore determine the optimal length for the wash.

b) Recoverable product amount left in the processing object at the end of a production run.

The system reduces loss of raw materials and COD on effluent as well prevents unnecessary load of the cleaning liquids. The cleaning performance increases and optimized cleaning times can be set leading to water, energy and chemical savings as well more production time becomes available.

So the use of correct tools can not only provide excellent validation data, but also lead to significant operational savings. Validation decisions must be taken based on facts and collected data. Statistical analysis can reveal the length of the safety margins of your washes. A Six Sigma approach can be applied to calculate safety margins (Figure 2). If an object is washed once per day, increasing the safety margin from 4 sigma to 6 sigma will reduce the number of times the object is still unclean from twice a year to less than once in 800 years.

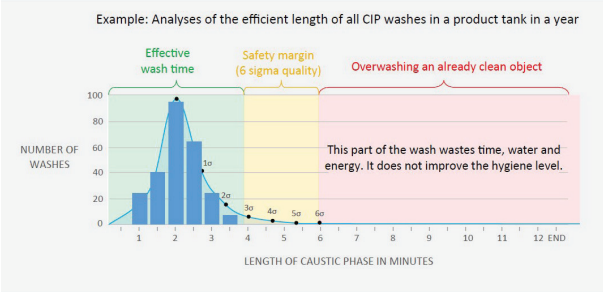

Figure 2. Six sigma application on cleaning analysis

3. Conclusions

- The food manufacturer has the overall responsibility for validation within his company - this includes the responsibility for the cleaning validation. He has assured the correct cleaning of production equipment and surrounding premises in front of the authorities and he is responsible for supplying the market with safe products of good quality. To be able to perform a successful cleaning validation he should be supported by the manufacturers of production and cleaning equipment as well as by the suppliers of the used cleaning agents.
- Ideally these parties work together in a cooperative manner with the common goal to secure clean production equipment. The partnership between the food operator and his supplier of cleaning chemicals and optimization services is essential to assure a focused and professional validation approach.
- However, it will be a crucial task to define a balanced strategy in grouping the tasks and simplify the validation work, in order to keep the validation implementation a task which will not disrupt the company's efficiency.

4. References

[1] EHEDG (2016). *Document No 45: Cleaning Validation in the Food Industry - General Principles, Part 1*

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[3] Timmerman H. (2013). *Cleaning validation, practical considerations*. Journal of Hygienic Engineering and Design, Vol. 2, pp. 3-5.