CLEANING VALIDATION, PRACTICAL CONSIDERATIONS

Hein Timmerman[1*]

[1]Diversey Europe Operations B.V., part of Sealed Air, De Boelelaan 32, 1083 HJ Amsterdam, the Netherlands

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

Abstract

The EHEDG subgroup Cleaning Validation is working on a new guideline which will be ready in 2014. Cleaning and/or disinfection validation is defined as 'obtaining documented evidence that cleaning and/or disinfection processes are consistently effective at reaching a predefined level of hygiene, if properly implemented on equipment and production environment and used as intended'.

According to ISO 22000, verification is the 'confirmation through the provision of objective evidence that specified requirements have been fulfilled'.

The guideline has as goal to provide a complete validation approach suitable for Equipment manufacturers, cleaning products and cleaning equipment manufacturers, and all food producers. 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 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. 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.

Validation will require an understanding of all elements involved in the cleaning result such as the design and development for an effective program, the principles and calculations of residue limits for a 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 and reports, the tools used for monitoring, verification and revalidation. Key words: Cleaning validation, hygiene, cleaning result, monitoring, verification.

***Key words**: Cleaning validation, Hygiene, Cleaning result, Monitoring, Verification.*