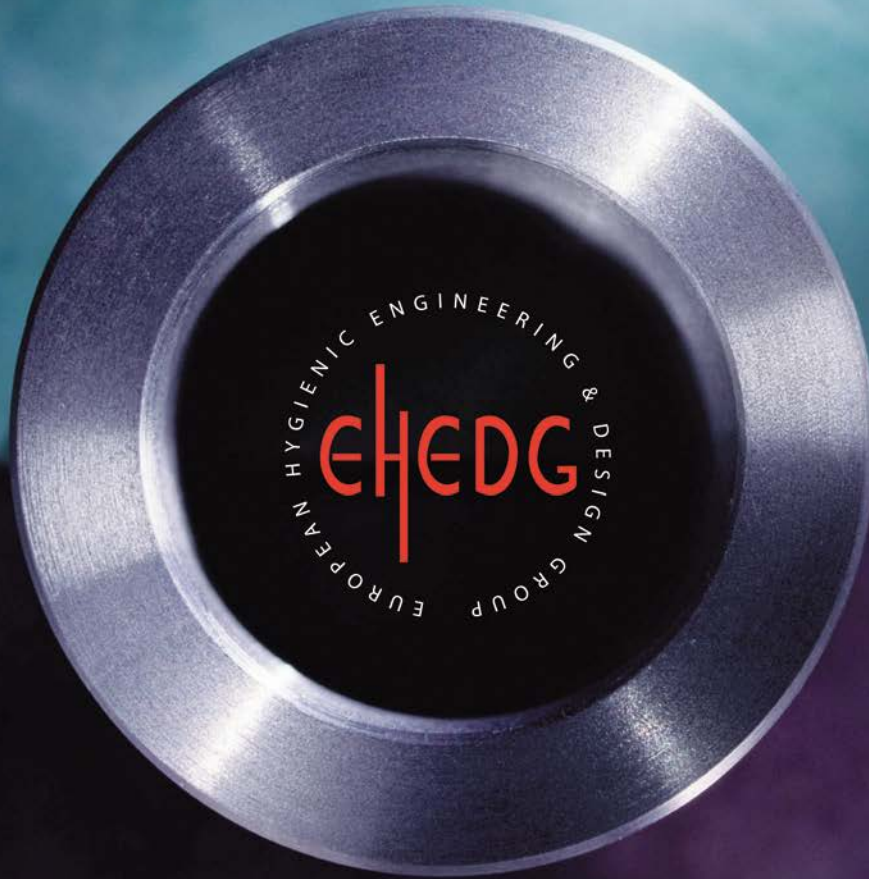


EHEDG Guidelines



DOC 45 – Part 1

CLEANING VALIDATION IN THE FOOD INDUSTRY – GENERAL PRINCIPLES

April 2016





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CLEANING VALIDATION IN THE FOOD INDUSTRY – GENERAL PRINCIPLES*

April 2016

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Foreword

Dear Reader,

This EHEDG guideline entitled 'Cleaning Validation in the Food Industry – Part 1 General Principles' is the first one of a series of EHEDG guidance documents addressing specific topics in this field, developed under the umbrella of the EHEDG Working Group 'Cleaning Validation'. New topics are decided on a case-to-case basis by taking into consideration the priorities set by this Working Group and by putting together a dedicated expert's team for the specific work item. Proposals for new work items may be handed in to EHEDG Sub-Committee Product Portfolio following the EHEDG document development procedure as outlined in SCP 1-1 which is available for download from the EHEDG website, see http://ehedg.org/uploads/SCP_Masterfile.pdf. EHEDG Sub-Committee Product Portfolio invites all members of the EHEDG community to play an active part in this process of guideline development. Improve knowledge by sharing experience!

Yours

Dr. Peter Golz, Chairman EHEDG Sub-Committee Product Portfolio

Introduction

The food industry has to make products which can safely be consumed. Physical, chemical and biological cleanliness is a prerequisite for food safety. A variety of hazards can contaminate food such as microorganisms and their toxins, previous products and ingredients active as allergens, residues of cleaning and disinfection agents and lubricants. Therefore, process and ancillary equipment need regular and effective cleaning, with or without disinfection, to ensure the control of such hazards and to prevent the cross-contamination of food products. In the following, "cleaning with or without disinfection" will be shortened to "**cleaning**".

National and international legislation requires the food industry to put on the market safe food and equipment manufacturers to provide cleanable equipment (1, 2). The validation of cleaning and/or disinfection operations is necessary to ensure compliance and to provide documented evidence that an approved cleaning procedure will provide clean equipment, suitable for its intended use. Following a validated cleaning baseline, optimization of the cleaning operation can be undertaken with a subsequent reduction of chemicals, energy, water, labour, downtime and effluents.

Surfaces that are in the scope of cleaning validation are those which are exposed intentionally or unintentionally to the product and surfaces from which splashed product, condensate, liquids or material may drain, drop, diffuse or be drawn into the product or onto product contact surfaces or surfaces that come into contact with packaging materials. They are designated as "Product contact surfaces" in the EHEDG Glossary. Cleaning validation is not necessarily required for potentially non-critical cleaning of floors, walls and the outside of equipment, unless required by hazard evaluation.

There is sometimes a misinterpretation of the words validation, monitoring and verification. The following definitions are appropriate. **Validation** is any action proving and documenting that a process, procedure or method actually and consistently leads to the expected results and thus meets the cleaning objective of hazard control. It should not be confused with verification. Once 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"(3).

Whilst not a food safety issue, the principles of this document can also be used for the validation of cleaning programmes intended to control quality or brand protection issues. For example the removal of meat substances before the production of vegetarian dishes, or the removal of pork residues in meat factories processing a number of animal species. In these cases the detection of DNA residues remaining on surfaces may be undertaken.



1 Scope

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, to prevent possible cross-contamination of hazards between products. This document focuses on the overall concept of cleaning validation and is intended as a general guideline for use by food manufacturers and inspectors. It is not the intention to be prescriptive in specific validation requirements. This document serves as general guidance only, and the principles may be considered useful in their application in the production of safe food, and in the development of guidelines for the validation of specialized cleaning or inactivation processes.

Normally cleaning validation would be applicable for critical cleaning such as cleaning of product contact surfaces between production of one product and another, in particular if the food is intended to be consumed by certain high-risk consumers that include pregnant women, neonates, immuno-compromised adults and the elderly or consumers suffering from allergies. Further, cleaning validation is recommended if there is a significant risk of contamination and cross-contamination with hazards such as pathogens, toxins or allergens. It can be used for any type of cleaning operation by food equipment manufacturers, engineering companies, food manufacturers and providers of services and chemical products.

2 Glossary

The definitions of the [EHEDG Glossary](#) apply to this document. Definitions specific to this document are given below.

Cleaning validation

Obtaining the documented evidence that cleaning with or without disinfection processes, if properly implemented, is consistently effective at achieving a predefined level of hygiene on product contact surfaces identified during the hazard evaluation.

Monitoring

Conducting a planned sequence of observations or measurements to assess whether control measures are operating as intended.

Process Air

Conditioned or treated air used within process equipment or as part of the product process (e.g. headspace air or compressed air from a filter).

Product contact surfaces

Surfaces exposed intentionally or unintentionally to the product and surfaces from which splashed product, condensate, liquids or material may drain, drop, diffuse or be drawn into the product or onto product contact surfaces or surfaces that come into contact with product contact surfaces of packaging materials.

Qualification

A formal process of obtaining the documented evidence that the equipment and utilities are fit for their intended use. Qualification is often a part of (the initial stage) of validation, but the individual qualification steps alone do not constitute process validation.

Retrospective validation

Involves the evaluation of past cleaning processes on the condition that composition, procedures and equipment remain unchanged (4, modified).

Revalidation

Repeated validation of an approved process (or a part thereof) to ensure continued compliance with established requirements (4).

Standard operating procedure (SOP)

An authorized written document giving instructions for performing operations (e.g., equipment operation, maintenance and cleaning, sampling, analyses).



Validation protocol (or plan)

An approved document describing the activities to be performed in a validation, including the acceptance criteria for the approval of a cleaning process and the validation personnel's responsibilities.

Validation report

An approved document in which the records, results and evaluation of a completed validation programme are assembled and summarized. It may also contain proposals for the improvement of processing and/or equipment. (4, modified)

Verification

Confirmation, through the provision of objective evidence, that specified requirements have been fulfilled.

Worst-case

A condition or set of conditions encompassing the upper or lower processing limits for operating parameters and circumstances, within SOPs, which pose the greatest chance of product or process failure when compared to ideal conditions (4, modified).

3 General Considerations

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"(2). 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.

There are two basic approaches to cleaning validation – one based on evidence obtained through testing, and one based on the analysis of historical data (retrospective validation). Whenever possible, validation through testing is preferred. Retrospective validation is no longer encouraged and is no longer applicable, if the production of safe food has failed. Validation may include challenge or worst-case tests, which determine the robustness of the cleaning process. If possible, it is recommended that the whole processing line is validated.

There should be SOPs detailing the cleaning process, the sampling and the analytical methods. All procedures described in the SOPs should be validated.

At least three consecutive applications of the cleaning procedure should be performed and shown to be successful to prove that the method is validated.

There should be an appropriate system including organizational structure and documentation infrastructure, sufficient personnel and financial resources to perform the validation tasks in a timely manner. Management and staff responsible for quality assurance should be involved. Personnel with appropriate qualifications and experience should be responsible for performing cleaning validations. If cleaning operations are outsourced, the personnel of the contractor should be involved in the validation process.

The present guidelines will follow the steps illustrated in Figure 1.

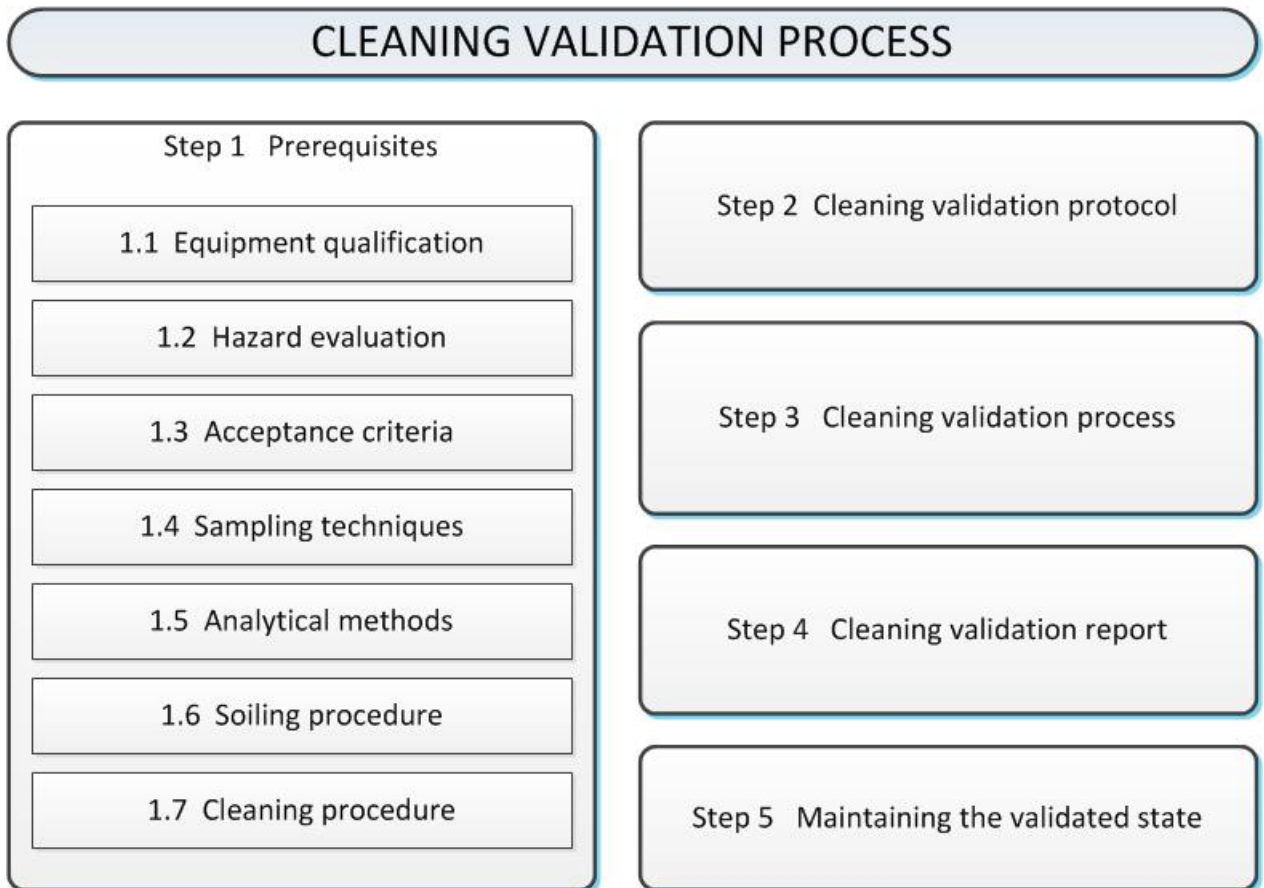


Figure 1 – Steps of the cleaning validation process

4 Prerequisites (Step 1)

4.1 Equipment qualification (Step 1.1)

Qualification is the formal process of obtaining the documented evidence that the equipment (including cleaning equipment and systems) and utilities are fit for their intended use. The process of qualification should be a logical, systematic process and should be adapted to the function and operation of the equipment (EHEDG Doc. No. 34).

This prerequisite consists of documenting that the specifications established by the food producer have been achieved by the equipment manufacturer, with respect to legal requirements and EHEDG Documents No. 8, 10, 13, 14, 16, 17, 20, 21, 25, 30, 32, 37, 42, 43 and 44.

In addition, it should be checked that cleaning agents do not by themselves or by their reactivity with food components harm the personnel, the final consumer or equipment when used as intended.

The chemical characteristics of the water supply should be known, especially as regards hardness or other relevant parameters. The microbiological load of water should be appropriate to the degree of cleanliness required.

Where process air is actively used in the cleaning process, a hazard evaluation should be conducted to determine its required quality.

4.2 Hazard evaluation (Step 1.2)

This prerequisite consists of documenting the *a priori* evaluation of factors that could have an impact on the cleaning results. This should be done through the careful examination of the documented description of the

equipment or premises including any connection to other equipment. In addition, this should be done with consideration of the food process and cleaning procedure, while accounting for:

- the criticality of the food process, i.e. the degree of cleanliness that is requested with consideration to the food safety level expected in the end product, with regard to e.g. allergens, DNA or microbiological criteria;
- identification of the most difficult parts to clean, and those which will need disassembly;
- the physicochemical and microbiological properties of the product (e.g., viscosity, water activity, pH, allergens, nutritional components, adhesion, reactivity) and of the soiling material deposited during the processing;
- the period and conditions for storage of uncleaned equipment before cleaning, and the time between cleaning and equipment reuse;
- the type of cleaning, whether intermediate during production (between batches or product lines) or post-production;
- the influence of the process conditions on the nature and degree of soiling;
- cleaning method(s) used; and
- the type of cleaning agents

It can be expected that the cleaning of unhygienically designed equipment or installations will be more complicated and time consuming than compliant ones.

4.3 Acceptance criteria (Step 1.3)

This prerequisite consists of documenting the cleanliness criteria that have to be achieved for the process in relation to the end product specifications and criteria based on the HACCP plan.

The acceptance criteria established for contaminant levels in the sample should be based on the food safety policy of the manufacturer and the hazard evaluation. The approach for setting the limits can be product-specific or products can be grouped into families and the worst-case product chosen. Regarding the 'surfaces', the criteria may be expressed as maximum limits for the amount of residual on the surface of the equipment after cleaning, e.g.:

- in $\mu\text{g}/\text{cm}^2$ for organic matter;
- in CFU/ cm^2 for microorganisms (CFU = colony forming unit); and
- in nd/surface area for microorganisms, DNA or chemicals (nd = not detectable);

Based on the hazard evaluation, certain allergenic material or toxins should be below the detection limit of the best available analytical methods;

The criteria may also be expressed as the amount of residual in the '*rinsing fluid*' after cleaning, e.g.:

- in $\mu\text{g}/\text{mL}$ for organic matter or allergens;
- in $\mu\text{g}/\text{mL}$ for inorganic compounds (e.g. calcium);
- in $\mu\text{g}/\text{mL}$ for detergent and/or disinfectant; and
- in CFU/ mL for microorganisms;

The amount of residual organic matter may also be expressed in terms of relative light units (RLU) when the ATP-method is used.

Residual contamination deviating from the acceptance criteria (soil, microorganisms, and cleaning agents) should lead to question the cleaning as well as the disinfection. The absence of contaminants is not always a reliable indication of a good cleaning and can be the result of an inadequate sampling or analytical method.

The places that should be sampled and where these acceptance criteria apply are the difficult-to-clean ones determined in the previous step.



Regarding the 'end product', the maximum concentration of contaminants should be given if available e.g. for allergens. In general the regulatory criteria are sufficient, but it is recommended in some cases for the food manufacturer to establish its own criteria linked to specific performance criteria.

4.4 Sampling techniques (Step 1.4)

Methods of visual and sensory evaluation

The primary criteria of the success of the cleaning programme is visual cleanliness and the absence of odours and films. It is pointless to further examine equipment that doesn't meet these criteria. UV light helps in detecting traces of residual material. Similarly, dyes can be used to help evidence residuals. A boroscope (endoscope) can be used to visually check if the difficult to access hard-to-clean spots in CIP systems are effectively cleaned. Disassembly may also be required.

Methods of sampling

Two methods of sampling are considered to be acceptable: **direct and indirect sampling**. A combination of the two methods is generally the most desirable.

Direct sampling of surfaces is the most commonly used and can be done with the help of swabs, wipes, sponges or scraping devices. ISO 18593 (5) describes the sampling techniques with swabs and contact plates. The sampled area (expressed in cm²) should be known. As this type of sampling is poorly reproducible, the operators should be carefully trained. It should be realized that sampling, no matter which technique/device is used, collects only a fraction of the microbiological population of the sampled surface: repeated samples taken at the same location still collect bacteria. The ratio:

$$\frac{\text{number of CFU collected by sampling}}{\text{total number of CFU present}}$$

represents the recovery rate and depends on many factors, such as the surface material, the microbiological population, the composition of the soil, the sampling device, the force of application, the operator, etc. As stated above, while a high CFU number is an indication of inefficient cleaning, the absence of CFU is not an indication of good cleaning. The detection of residual CFU should lead to questioning the quality of the cleaning as well as the disinfection phase of the cleaning process.

Indirect samples of known volume of rinse water can be collected and their contents as chemical or microbiological residual assessed. This method allows sampling of large surfaces, of areas that are inaccessible or that cannot be routinely disassembled and provides an overall picture. It may be useful for checking for residues of cleaning agents.

4.5 Analytical methods (Step 1.5)

The analytical methods used to detect residuals or contaminants should be specific for the substance or the class of substances to be analyzed (e.g. product residue, detergent residue). Whichever method is used, it should be validated and its limit of detection and quantification should be known and should be sufficiently sensitive to detect the established acceptable level of the residue or contaminant in relation with the material, the soil and the sampling technique. The specificity, sensitivity and reproducibility of the analytical methods should be known. Note: if levels of contamination or residual are not detected, it does not mean that there is no residual contaminant present after cleaning. It only means that the contaminants are not present in that specific sample at levels higher than the detection limit of the analytical method.

A neutralization step is needed before a microbiological analysis is done to validate a disinfection process, in order to quench any inhibition caused by residuals of the disinfection agent. The neutralization compounds can be added to the swab/wipe diluent solution or to the culture medium and have to be checked for their appropriateness.

4.6 Soiling procedure (Step 1.6)

This prerequisite consists of documenting the worst-case situation as regards soiling, or the grouping of the soiling scenarios that should be examined.

The soiling procedure should be identical to the chosen worst-case scenario. Yet, where long production runs are foreseen (e.g. one month), the simulation of such long runs may not be practicable. It is recommended to begin the experimentation with short runs of increasing duration.

In some cases, it might be useful to add microorganisms in the treated food to be able to measure the cleaning effect in terms of microbiological load reduction. Microorganisms can also be used to contaminate surfaces or coupons in order to be able to estimate the efficacy of the disinfection process alone. As it is not advised to introduce pathogenic microorganisms in industrial settings, microbiological surrogates can be used, providing that the behaviour of the surrogates mimic effectively the pathogens they replace. The addition of surrogates has to be strictly controlled to avoid unduly contamination of the environment.

4.7 Cleaning procedure (Step 1.7)

Criteria for the initiation of cleaning (e.g., contamination limit, run-time, product change-over) should be established.

Appropriate cleaning procedures should be established as Standard Operation Procedure (SOP) and should be approved for the intended cleaning purpose. As a minimum, the SOP should detail

- cleaning frequency and non-production times;
- water quality;
- cleaning and disinfecting agents;
- cleaning process parameters (equipment used, concentration of chemicals, time, temperature, pressure, flow rate) and their recording;
- responsibilities and qualifications of the persons involved; and
- monitoring of the cleaning process including calibration of the sensors.

Adequate training has to be performed for the personnel in responsible for cleaning, monitoring and sampling. This also has to be applied to contractor's staff.

5 Establishing the cleaning validation protocol (Step 2)

The cleaning validation should be described in the cleaning validation protocol which should formally be approved. The validation protocol is an indispensable document and covers in detail the complete process of validation, summarizes all reflections made and allows verification that all prerequisites are in place. Validation protocols consist of the following elements:

- objective of the validation process;
- the need to validate individual or groups of products;
- personnel responsible for performing and approving the validation study;
- identification and status of qualification of the equipment and installation;
- results of the hazard evaluation and the acceptance criteria;
- interval between the end of production and the begin of cleaning procedures, worst-case scenarios, if appropriate;
- description of worst-case scenarios applied (e.g., run time, soiling / type of product, chemical concentration, temperature, time, flow, pressure);
- cleaning procedure in details (SOP) including routine monitoring requirements;
- number of cleaning cycles to be performed consecutively (minimum three);
- detailed soiling procedure if appropriate;
- sampling procedures and description of sampling points;
- test methods;
- corrective actions if acceptance criteria are not met;



- forms to document the test results;
- references; and
- supporting appendices for reference which may include;
 - detailed process flow;
 - Piping and Instrumentation Diagram (PID);
 - process set points;
 - validation and verification data;
 - photographic evidence of visual inspection and sampling points; and
 - supporting documentation (cleaning procedures / records).

6 Undertaking the cleaning validation process (Step 3)

A minimum of three consecutive trials that meet the validation objectives are required for a successful validation. If any trial does not meet the validation objectives the validation process should be stopped and the cleaning procedure and validation protocol reviewed. The validation process then should start from the beginning after appropriate corrections.

7 Establishing the cleaning validation report (Step 4)

The results of the cleaning validation should be presented in a cleaning validation report stating the outcome and conclusions. The relevant cleaning records (signed by the operator and reviewed by quality assurance) and source data should be retained. This final document of the cleaning validation procedure may include:

- a short summary about the objective and the course of the validation process;
- summary and evaluation of the results with comments and conclusions;
- description of deviations from the protocol, if applicable, and justification;
- general conclusion and outline of the field of application;
- attachments and annexes, e.g. monitoring protocols, analytical results, photos of sampling;
- approval of the validation; and
- determination of critical points for monitoring and verification.

8 Maintaining the validated state (Step 5)

Within a validation and revalidation policy (including frequency of revalidation), food producers should plan cleaning validation in a manner that will ensure both regulatory compliance and that food safety and quality are not compromised. There should be periodic revalidation, as well as revalidation after equipment, food process and cleaning programme changes. The frequency and extent of revalidation should be determined using a risk-based approach together with a review of historical data, regarding monitoring and verification.

Periodic revalidation should be performed to assess process and equipment changes (e.g., aging, breakdown) that may occur over a period of time.

Changes requiring revalidation may include changes in the equipment, changes in the raw material (e.g. with different viscosity), changes in the manufacturing process, process line overhaul (shutdown and re-commissioning), cleaning procedures, cleaning chemicals and parameters, production area or support system changes, appearance of negative safety or quality trends, and appearance of new findings based on current knowledge and legislation.

Changes should be controlled and documented by a qualified person including the process to decide about the need for a revalidation.

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