FoodEfficiency

A food safety guidance document.

Cleaning and hygiene validation of process and production equipment.

Supporting a high level of food safety in process equipment and production facility.

Introduction and Scope

The purpose this guidance is to describes different methods and views on how to monitor and validate the efficiency of cleaning and general hygiene level of the production and process equipment used within food manufacturing sites, with specific attention to cheese manufacturing sites.

The scope of the guidance covers the validation and monitoring of production and process equipment, which is in direct contact with food products.

Non-product contact surfaces and general production environment is not included in the guidance document, personal hygiene of employees is also not included in the scope.

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Background

From time to time processing sites may face problems with e.g. biofilm on equipment, bacteriophage problems, coliform bacteria in products or by-products, high total bacteria counts in whey, or high microbiological counts in finished products.

Such issues may result in production problems, products with reduced shelf life or products, which cannot be sold to specific markets due to restrictions on microbiological limits, and worst case product recall.

Most of the problems can be avoided by an efficient monitoring and control program of daily cleaning and hygiene level, as described in this guidance, and a thorough follow up on identified trends and non-conformances.

Definitions

Product contact surface - All equipment surfaces with which the product may, intentionally or unintentionally (e.g. due to splashing), come into contact and be drawn back into the main product or product container, or from which condensate may drain or drop into the product, including surfaces (e.g. unsterilised packaging) that may indirectly cross-contaminate product contact surfaces or containers. A risk analysis can help to define areas of cross-contamination.

Management responsibility

The site management team must at all time ensure that an efficient cleaning and monitoring program is in place covering production and process hygiene, and that this program is validated and evaluated on regular basis as a part of the site quality management program.

The production team must ensure that the cleaning and monitoring program is implemented and followed, that changes to production activities are reported and evaluated against the program, and non-conformances are reacted upon.

The maintenance team is responsible for keeping an adequate maintenance program ensuring the efficiency and safety of equipment.

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General approach to cleaning and hygiene validation

A cleaning program must as a minimum take following into consideration;

- design and material of equipment
- product on the equipment
- production hours
- cleaning chemicals, time and temperature

When changes are made to production, product or equipment the effect of the changes must be considered and where necessary changed to ensure efficient cleaning. Examples of such chances can be changes in fat or protein content or increased operation/running hours. External suppliers may be consulted for further support, and specific validation should be carried out to ensure the changes do not have a negative effect on the cleaning performances.

Cleaning validation must be carried out on regular basis and can be done as visual inspection, surface testing or product testing and is described in the sections below. It is recommended that method and frequency for cleaning validation is described within the quality management system.

Methods

A large number of methods exist to validate cleaning efficiency in food manufacturing sites. In this section the most common analyse and inspections methods will be presented.

CIP validation – general monitoring

For each site CIP validation must take place on regular basis – preferably as part of the agreement with the CIP chemical supplier. The program must as a minimum include regular monitoring on:

- temperature and time of the cleaning program
- concentration of cleaning chemicals
- flow of the cleaning liquid

Visual inspection

Operator inspection

Visual inspection can be as simple as looking for product residuals on or in the equipment, e.g. by opening the manhole of a tank or silo after cleaning, looking for cheese fines on a conveyer belt or swiping a surface with the hand or a clothe to see if is feels/looks clean. This gives a good impression of whether sufficient cleaning has taken place or not.

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UV testing

UV testing will identify areas with insufficient cleaning (e.g. biofilm) and can be used for regular inspection. UV testing is also recommended for checking weaknesses in design or material, wrongly placed or poorly maintained CIP balls and wear and tear of material, as such issues will allow for product residuals to develop into biofilm with potential microbiological growth.

Riboflavin testing / Dye testing

Riboflavin testing is a fluorescence test, which can be used for weak point testing and cleanability testing. The examination of the basic accessibility to, as well as the complete wetting of all areas in which a verification of cleanability through the cleaning medium, is required to carry out this testing.

Cracks in surfaces or poor welding, e.g. in silos, can be identified by using dye testing. It is recommended that dye testing is introduced as part of regular inspection and maintenance plan in critical areas, e.g. product tanks.

Furthermore dye testing is also recommended during manufacturing or commissioning of new equipment or when there is a suspicion of defects.

Surface testing

The purpose for conducting surface testing is to ensure that the surface is free from biofilm, allergens, lime scale and chemicals. Different methods are available for different types of testing.

In order to validate the efficiency of cleaning testing on biofilm and allergens should be carried out before disinfection takes place.

ATP testing

ATP testing is an easy way to check for biofilm and other build up and should be done after cleaning or before production start-up to ensure the equipment is clean. ATP testing must always be done prior to disinfection, as the disinfection detergent may have an impact on the testing result.

The RLU acceptance level must be determined during the implementation of the ATP monitoring equipment, but on surfaces with direct food contact many sites have demonstrated ATP levels below 100 RLU.

Recommended test: 3M Clean-Trace Surface ATP

Over time the ATP result may increase due to build up of lime scale on surfaces and additional cleaning or de-scaling is required.

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Swab testing microbiological

Microbiological swab testing can be used to test for either general hygiene (coliform bacteria, as recommended by the Danish Dairy Sector Guidance), pathogen bacteria (e.g. listeria monocytogenes or listeria ssp) or specific bacteria or yeast which may cause problems in the final products either because of general spoilage or because of customer requirements.

If high levels of microbiological counts are found in process steps and equipment prior to the contaminated area these areas must also be inspected e.g. by UV testing, in order to identify the source of contamination.

Swab testing protein

Some ATP tests have been specifically developed to test for certain types of proteins and can therefore be used also for testing of allergens.

Rinse water testing

Testing on rinse water is recommended in closed equipment or in areas, which are difficult to reach, but where water may be poured over the item and collected at rinse water. ATP testing (3M Clean Trace Water – Free ATP and 3M Clean Trace Water Plus – Total ATP) or microbiological testing can be applied for rinse water testing. Ensure that the sampling valve is also included in the CIP program.

Products and by-products

Validation of cleaning and hygiene can also be conducted by microbiological testing of products and by-products. The same considerations should be given as described under microbiological surface testing.

It is important to notice that product testing on pathogen bacteria alone is not recommended as validation, this must at all times be done together with surface testing and environmental testing.

When using product testing for validation remember that the testing is done because of validation and not as final product testing, therefore the presence of e.g. coliform bacteria is an indicator of a hygiene or cleaning problem even though the level may be below specification limits or be reduced in a later process, e.g. such as during maturation of a product.

Examples of by-product testing can be microbiological testing of cheese whey or buttermilk. Cooling water or cheese brine testing may also be seen as an indicator of hygiene levels due to a carry-over effect from product or previous process steps.

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Monitoring of trends

A large number of samples are taking to validate our processes and ensure high quality products and the result must be carefully monitored to see if there is any development of a negative trend.

From time to time we see a trend building up indicating that something may be wrong – quick reaction is required in order to avoid a major problem building up and a potential product recall.

Surface testing

An increase in e.g. ATP results can be related to build up of biofilm from insufficient cleaning, left over of chemicals or wear & tear of the surface. Additional cleaning and/or testing is required. Where possible validate with UV testing of equipment.

An increase in microbiological levels must also be followed up, first of all by ensuring that cleaning programs are followed (time/temperature/concentration), secondly the surface condition must be investigated for wear & tear, build up of lime scale or improper cleaning by using ATP or UV testing.

Product or by-product testing

Increased level of bacteria or yeast in the product can be related to one or more issues, e.g. problems with production or process equipment (e.g. build up of biofilm), change in the manufacturing process, changes in storage temperature or time, usage of new ingredients of different quality.

Together with additional surface testing further investigation for each of these area is required, preferably using the LEAN tools such as Fish Bone for root cause investigation.

Contracts with equipment manufactures

When purchasing new production and process equipment hygienic design and cleaning ability must always be mentioned in the contract. References should as a minimum be made to relevant standards on hygienic design and relevant welding standards, a few examples are given under “More information and references”.

It is also recommended that dye testing of critical units is a requirement in the contract and that the equipment in general is inspected once it has been in production for a number of months to ensure there is no build up of biofilm.

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More Information and References

Food safety standards and requirements for cleaning and hygiene validation:

- BRC Food Safety Issue 7 section 4.11
- IFS version 6, Section 4.10
- ISO22000:22002-1, section 8

More information on hygienic design, process equipment and food safety can be found on following webpages:

- EN 1672-2 + A1:2009 Food processing machinery – Basic concepts – Part 2: Hygiene requirements
- ISO 18593:2004 Microbiology of food and animal feeding stuffs – Horizontal method for sampling techniques from surfaces using contact plates and swabs
- European Hygienic Engineering and Design Group – Guidelines
- European Commission – General Food Law
- European Food Safety Legislation
- European Commission - Regulation on Microbiological Criteria for Food Stuff

General information on process equipment for dairy manufacturing can be found in the TetraPak Dairy Processing Handbook