21 CLEANING AND SANITATION

Principle

Cleaning and sanitisation programmes are a key prerequisite to ensure the adoption of good manufacturing practice (GMP). Cleaning will not be effective unless it is fully supported by management. The role of management is to define the hygiene standards required and to communicate these effectively to staff, usually by means of a comprehensive cleaning schedule and associated task procedures. Management must demonstrate commitment by providing the appropriate means, that is, the equipment, the chemicals and the training for staff.

General

21.1 **EU Regulation (EC) No. 852/2004** (as amended) on the hygiene of foodstuffs states that:

1. Food premises are to be kept clean and maintained in good repair and condition.
2. The layout, design, construction, siting and size of food premises are to:
   (a) permit adequate maintenance, cleaning and/or disinfection, avoid or minimise air-borne contamination, and provide adequate working space to allow for the hygienic performance of all operations;
   (b) be such as to protect against the accumulation of dirt, contact with toxic materials, the shedding of particles into food and the formation of condensation or undesirable mould on surfaces;
   (c) permit good food hygiene practices, including protection against contamination and, in particular, pest control.

21.2 Cleaning procedures must not only be consistent with food hygiene legislation but also with the requirements of environmental and health and safety legislation (see Chapters 41 and 42), and cleaning and disinfection must be undertaken using procedures designed to minimise the risk of product contamination.

Cleaning Schedules/ Procedures

21.3 Cleaning schedules coordinate cleaning activities and are a means of information transfer between management and staff. They should be established for external areas, the premises itself and equipment, plant and services. They should also be established for transport vehicles in the distribution supply chain. Individuals who have the appropriate level of competence and knowledge to develop an effective cleaning and disinfection regime should design cleaning schedules and associated procedures. The site hygiene plan and associated cleaning schedules and cleaning procedures should be based on a risk assessment approach (see 21.7). Documentation such as cleaning schedules and associated task procedures must be clear and unambiguous.

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Consideration must be given to the language skills, numeracy and literacy of staff. Cleaning schedules and associated task procedures must state as appropriate:

- what area or equipment is to be cleaned;
- who is to undertake the task (i.e. responsibility);
- when it is to be cleaned (i.e. how often);
- how it is to be cleaned (i.e. work instruction or task procedure, including how the equipment should be dismantled and reassembled);
- the time duration of the cleaning task, especially the required contact time for any chemicals used. Contact time is the time that the cleaning chemical has to be in contact with the surface in order to be effective;
- the materials to be used, that is, the cleaning chemicals and cleaning equipment (see 21.6);
- dilution rates and whether the chemicals are pre-diluted or need to be diluted by staff to the correct rate at the time of the cleaning operation;
- the requirements for rinsing between chemicals and if required the protocol for the pH testing of rinse water to ensure effective rinsing of equipment has taken place;
- the cleaning standard expected in terms of either visual standard or if microbiological or adenosine triphosphate (ATP) sampling is undertaken the standards to be reached to approve the cleaning task as having been effective;
- the operator personal safety aspects that need to be addressed to ensure that the personal protective equipment (PPE)/clothing that may need to be worn when handling concentrated chemicals and/or when completing cleaning tasks is defined;
- the health and safety of staff and the environmental concerns in the event of a spillage of chemicals and how such spillages should be contained and cleaned up to ensure adequate protection of the staff and the environment but also to minimise product contamination risk;
- who should be contacted in the event there is a problem during the cleaning task;
- which cleaning records need to be completed after the task has been completed and by whom;
- who is responsible for monitoring the task to ensure it has been effective and and completes the records to that effect;
- who is responsible for verifying after the cleaning and sanitation process that the standards of hygiene are as required and that the associated records are completed appropriately; and
- who is responsible for routinely auditing the whole process.

21.4 Cleaning schedules may be designed to address daily, weekly, monthly, quarterly, six-monthly and annual tasks separately or all on one format. Cleaning may be monitored by the quality control function as part of a routine site hygiene audit, or cleaning may be monitored instead as part of production procedures by a hygiene team leader or equivalent. Verification of cleaning

will occur at a prescribed frequency and by defined competent individuals such as the quality control manager or designate, and will encompass a variety of activities, including auditing of records, visual audits of premises, review of swabbing results, microbiological testing of food products, customer complaint data etc. (see 21.12).

21.5 The cleaning schedule needs to ensure effective, economic cleaning. Equipment should be installed so as to facilitate effective cleaning. The practices used will vary with the size and type of manufacturing premises and number of staff involved. Cleaning schedules should be in place to ensure that external areas are kept clean and free from rubbish. Particular attention should be paid to waste storage areas. The cleaning requirements for chill and cold stores, road vehicles and shipping and air freight containers need to be considered. Cleaning schedules need to be developed with appropriate protocols to minimise the risk of product contamination and determine the effectiveness of cleaning.

The quality control manager or designate must determine a site hygiene plan, otherwise termed cleaning and disinfection protocol, that is appropriate to the business and the products manufactured, especially in terms of high- and low-care requirements. Consideration should be given to the generation of aerosols that could contaminate nearby surfaces, packaging, ingredients or products. The control of allergenic materials and the disposal of cleaning equipment that may have come into contact with allergenic materials must also be considered.

The implementation of the cleaning schedule will only be effective if there are sufficient resources available in terms of time, trained personnel, suitable chemicals and cleaning equipment. Consideration should be given to the level of cleaning, for example routine cleaning at one level and then further deep cleaning programmes at designated intervals. Deep cleaning may need to be undertaken during periods of production shutdown and non-production, and engineering and maintenance resources may also need to be programmed where equipment dismantling is required. If equipment is dismantled, appropriate controls should be in place to ensure that machine parts are not placed directly onto the floor. Controls include, but are not limited to, tables, designated racking and so forth. A hygiene clearance/sign back into production procedure should be in place for all cleaning tasks, but additional clearance procedures may be adopted following deep cleaning activities to ensure the risk of product contamination is minimised. The cleaning schedule and associated task procedures must be validated before implementation and monitored by staff to ensure they are sufficient to deliver the food safety objectives of the manufacturing organisation. Verification activities must take place over and above monitoring to demonstrate that the hygiene management system as a whole is functioning effectively (see 21.12).

Site Hygiene Plan

21.6 The quality control manager should develop and validate a site hygiene plan and associated procedures for the site. The site hygiene plan should be reviewed at regular intervals to determine its appropriateness and effectiveness in ensuring a hygienic manufacturing site and minimising the risk of potential product contamination. The Food Standards Agency (FSA) publication *E. coli O157 – Control of cross-contamination: Guidance for food business operators and enforcement authorities* (2014) stresses the importance of not only validating the hazard analysis critical control point (HACCP) plan, but also ensuring that disinfectants are purchased and used in compliance with validated dilution levels and contact times. The guidance states that the use of disinfectants or sanitisers that meet BS EN 1276:2009, BS EN 1650:2009 + A1:2013, BS EN 13704:2002 and BS EN 13697:2015 should be considered. In order to promote efficacy they must be applied to visibly clean surfaces and be used 'strictly in accordance with the manufacturer's instructions relating to proper dilution of the chemical, the effective temperature range and the necessary contact time. Since effective chemical disinfection can only be achieved on visibly clean surfaces, a cleaning stage is required first'. Validation of cleaning and disinfection processes is especially critical if dual use of equipment and machinery for slicing, mincing or vacuum packing of raw and ready-to-eat foods forms part of the manufacturing process. Where possible, there should be designated machinery to prevent this risk from occurring. Where this is not possible, effective disinfection is a key prerequisite to ensuring food safety. Validation of cleaning methods should also assess the potential for cross-contamination by cleaning equipment. The guidance further requires that food business operators (FBOs) should 'ensure that they are using the appropriate disinfectant products by confirming with their suppliers that the products they are using meet, as a minimum, the specifications of these standards. This information may also be obtained from the label of the product, or by contacting the manufacturer directly.'[1] Records should be maintained of all validation and revalidation activities.

21.7 Risk assessment must be undertaken that is specific to the manufacturing unit to determine the level of cleaning and disinfection required. The site hygiene plan should be developed to address the following points as appropriate to the site and the type of product manufactured:

(a) The food products being manufactured will influence the requirements for those products in terms of cleaning and disinfection. Low-risk products may not require a full disinfection process to take place, especially where the product is not in direct contact with the equipment, whereas a high-risk product will require both cleaning and disinfection to be undertaken at the food premises.

[1] https://www.food.gov.uk/sites/default/files/ecoli-cross-contamination-guidance.pdf.

(b) It needs to be determined whether a clean-down process is required between different products during a production run or the cleaning process will be undertaken at the start and end of the production period (i.e. daily, per shift or between production runs).
(c) It needs to be determined who will undertake the cleaning, i.e. will there be a designated hygiene team or will the production staff undertake the cleaning at the end of production or intervals as determined?
(d) If a hygiene team is used, will they be internal staff or will cleaning be outsourced to a cleaning contractor? Cleaning contractors should be approved as per the supplier approval procedure (see Chapter 23).
(e) The budget for cleaning needs to be determined. The cost of water, equipment, labour, chemicals, energy, production down time and waste treatment should be considered.
(f) The chemical supplier should be approved as per the supplier approval procedure (see Chapter 23). The chemical supplier should be able to demonstrate compliance with the BS EN standards highlighted in 21.6 and also as applicable:
    - the suitability of the chemicals for the tasks being undertaken;
    - the efficiency of the chemicals especially with regard to key pathogens/microorganisms. The potential for spore formers surviving the disinfection process should also be considered;
    - a knowledge of current personal health and safety at work, and environmental legislation and how it pertains to their products and the associated controls that are required to ensure compliance;
    - an ability to provide material safety data sheets for the chemicals supplied;
    - an ability to undertake the required level of operator training; and
    - demonstrate how the chemicals should be used in practice to deliver the required level of hygiene standards.
(g) The plan should take into account the areas to be cleaned, the structure and layout of the premises and the type and condition of the surfaces for floors, walls, ceilings and doors. It should also differentiate between food and hand contact services that require a disinfection process to take place and non-hand and non-food surfaces where cleaning alone may be sufficient.
(h) The plan should also take into account the equipment type, design, purpose and the type of cleaning that is required. Some equipment can be fully cleaned without dismantling while other equipment may require full dismantling. Cleaning may involve both partial cleaning and deep cleaning. Other equipment may involve a lot of pipework and a cleaning-in-place (CIP) system may be used (see 21.11).
(i) The plan should take into account that water hardness will affect the types of chemicals that can be used.
(j) The plan needs to take into account the type of soiling on a given surface or piece of equipment and whether the cleaning

task is the removal of general debris, grease and/or involves the removal of material with a high microbial loading.

(k) The plan needs to reflect the situational factors in the manufacturing unit, such as the presence of services, including water, steam, electricity and drainage.

(l) The plan needs to reflect the supervision and training needs of the staff, as well as the mechanism for assessing the effectiveness of training and the influence of the plan on the requirements for refresher training for staff.

(m) The plan needs to identify the records that need to be completed following cleaning; and

(n) An inventory and stock rotation system should be set up to ensure that the actual volume of chemical used complies with expected volumes. Any discrepancy between actual and expected usage must be fully investigated by the appropriate personnel.

21.8 It is important that the quality control manager has sufficient understanding and is competent in the development of cleaning protocols. It is critical that she/he can distinguish between the different terminology and be aware of the potential issues if an incorrect type of chemical is used. All chemicals used in food environments should be food grade, non-toxic, non-corrosive and non-perfumed, and should not cause tainting.

21.9 Care should be taken to avoid mixing of cleaning agents since their chemical nature may cause them to interact and could result in a health and safety hazard to staff working in the area.

21.10 Detergents are formulated to remove soil and dirt. Disinfection can be achieved by using:

(a) heat and/or steam as moist heat is most effective. Steam cleaners can also be used to disinfect machinery or surfaces. However, the use of heat to disinfect is costly and often impractical. As a result, chemical disinfectants are now widely used (see (b)). When using heat to disinfect equipment the efficiency is based on a relationship between temperature and time, for example equipment may be disinfected in sterilising units where equipment is immersed in water at 82 °C for 30 seconds;

(b) chemicals – the chemical disinfectant used will depend on a number of requirements, including:

- the amount of grease and soiling;
- the effectiveness of the chemical against the type of micro-organisms under consideration;
- the temperature and chemical contact time;
- the equipment and type of surfaces;
- water hardness;
- the potential for taint;
- the method of application; and
- the detergent that has been used prior to disinfection.

Disinfectants or sanitisers should meet the requirements of the relevant BS EN Standards (see 21.6) 1276:2009 or BS EN 13697:2015 (see 21.6). Liquid hand wash that has disinfectant properties should conform to the requirements of the BS EN 1499:2013 standard. This information on disinfectants and sanitisers should be available on the label of the product, or may be obtained from the supplier or manufacturer. A sanitiser is a chemical that both cleans and disinfects. A sanitiser reduces the number of cleaning steps because it has both detergent and disinfectant properties and does not require an intermediary rinse. However, sanitisers are not effective on heavy soiling and can be expensive.

Cleaning in Place

21.11 Food production systems, especially in dairies or drink manufacture, often have a number of bulk tanks, interconnecting pipework and pasteuriser systems. It would be impracticable to dismantle this system for cleaning and personnel entry into bulk tanks would not be safe, so the equipment is cleaned 'in place'. Cleaning in place (CIP) allows equipment and pipework to be cleaned between processing runs. When designing a CIP system, the following factors are important:

- the cleaning requirement for each piece of equipment, run of pipework or tank/vessel;
- flow rate, temperatures and chemical concentrations;
- the mains services required for CIP cleaning, for example water temperature, automatic dosing systems and waste systems;
- the time available for cleaning;
- the programme of chemicals to be used and the temperature of the cleaning chemicals; and
- the possibilities for recycling of detergents.

A schematic plan should be available to demonstrate that the CIP system has been hygienically designed and validated (see 21.6), and a log of changes and subsequent revalidation is maintained. It is very important in the development of CIP cleaning systems that:

- the automatic chemical dilution equipment is routinely monitored to ensure it is operating correctly and the chemicals are of the required dilution;
- there is adequate separation between lines being cleaned and lines filled with products, for example double seat valves or blanks in pipework;
- there are no dead legs in the pipework that are not cleaned;
- that in-line filters do not impede the flow rate required and that they are cleaned as part of the process and inspected at a frequency defined by risk assessment;
- transfer pipes are not put into the system as a temporary measure and then are not cleaned because they are not part of the CIP system;

- the cleaning chemicals are non-foaming;
- the in-line pumps are of sufficient capacity to give the flow rate required;
- the temperatures are appropriate to ensure effective cleaning;
- the cleaning times are validated to ensure that there is sufficient contact time for the chemicals with surfaces;
- the levels of chemical in stock can be determined to identify if the correct amount of chemical has been used;
- the rinse water is checked to ensure that all chemical has been removed before the system is put back into production, for example pH monitoring;
- the location and mesh size of filters is determined as well as the monitoring activities associated with the filters;
- spray-ball or rotary cleaning head systems in tanks are checked to ensure that all areas of the tank receive a coverage of chemical and there is an adequate spray pattern; and
- all flexible hoses are cleaned as part of the CIP routine. Flexible hoses should also be capped and stored in a designated area when not in use.

CIP systems must not only be validated, but also monitored and verified to ensure continued effectiveness. Activities that should be undertaken include analysis of rinse water and/or first product through the lines (which is sent to waste until approved as suitable for packing), usage data for cleaning chemicals and ATP bioluminescence testing.

Efficiency of Cleaning

21.12 The efficiency of cleaning and sanitisation should be checked and recorded at routine intervals by the quality control manager or designate. The frequency of checks should be based on risk assessment. The hygiene standards required should be defined. Mechanisms of monitoring and verification of the effectiveness of cleaning include:

- visual inspection;
- contact microbiological swabs;
- ATP bioluminescence techniques;
- food material and product testing, where risk assessment has identified the potential for chemical residues to be present in food if cleaning procedures are not suitably followed;
- microbiological testing of part-processed and finished products; and
- microbiological and chemical checks of rinse water.

The monitoring and verification of cleaning activities should be formally documented, records maintained, any trends analysed and, where required, corrective action implemented to improve cleaning and sanitisation practices. Follow-up inspections should be undertaken to ensure that the corrective action has been implemented and is effective. These records should be maintained as part of the due diligence system.

Biofilms

21.13 The formation of biofilms is a major concern in food manufacturing environments. Biofilms are caused by micro-organisms that adhere to each other and also to a surface. If biofilms form then this will reduce the efficacy of disinfection systems, especially as they can provide harbourage for pathogenic and spoilage organisms such as *Salmonella* spp. and *Listeria monocytogenes*. The type of biofilms formed will depend on the environment within the manufacturing unit in terms of the products manufactured and processed, and thus the nutrients and pH within the environment, and temperature. The risk of biofilm formation is greater in areas of the factory which are cleaned and/or dismantled at a lower frequency, e.g. in-line filters or pipework joints and seals, and there is potential for sloughing from the biofilm into liquid if there is a change in flow rates and pressure. It is critical in the manufacturing environment to be aware of the potential for biofilm formation and to develop cleaning programmes and associated monitoring and verification that minimise the likelihood of biofilms occurring.

Equipment and Storage

21.14 There must be controls in place to ensure safe and secure storage of cleaning and sanitisation chemicals when they are not in use. The quality control or hygiene manager, as appropriate, should develop procedures to ensure that:

- chemicals are kept in secure, closed, labelled containers and used according to manufacturers' instructions;
- chemical stores are secure, locked and bunded, and away from food areas;
- stock is rotated correctly and chemicals are used within their duration marking;
- food containers are not used for storage of cleaning chemicals;
- health and safety data are available and reliable for all chemicals;
- cleaning chemicals for food-processing areas and for toilet areas where these are non-food grade are stored separately;
- correct protective clothing is used; and
- spillage procedures are developed and implemented.

21.15 Appropriate cleaning equipment must be used. It should be fit for purpose and not be a source of contamination in itself. Consideration should therefore be given to using non-wooden equipment and/or equipment that is so coloured that a foreign object can be easily identified in the finished product, for example brush bristles. Cleaning equipment that is used in designated areas should be colour coded to prevent its use in another area, for example external equipment, internal machines, floor cleaning, internal factory, toilets and welfare areas. This is especially important in manufacturing units where there are designated high- and low-care areas. A colour-coded site plan may prove effective in communicating where equipment can be used. The use of mops, especially string mops, should be risk assessed to determine that they can be effectively cleaning and disinfected after use.

Cloths should be adequately controlled and be single issue where deemed appropriate within the hygiene risk assessment. Surfaces should be allowed to air-dry, but if the task procedure requires that they must be wiped after cleaning, this must be with a single-use cloth, a sanitising wipe or blue paper towel that is appropriately disposed of to prevent contamination. If an item is found to be incomplete, for example dustpan and plastic handle broom, then the brittle material control procedure should be implemented (see 19.36–19.42). If disposable single-issue gloves are used by personnel during cleaning, they should be adequately controlled. The equipment should be cleaned and stored so as to minimise the potential for product contamination. Equipment should be allowed to air dry in designated racks.