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Global Food Safety Initiative scheme audit requirements regarding cleaning tool and utensil selection and maintenance – a review

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REVIEW ARTICLE

Abstract

Food industry cleaning tools and utensils have long been identified as a major source and vector of cross-contamination. UK Government funded study data, used to establish food industry guidance on microbiological sampling, showed that 47% of cleaning tools tested positive for *Listeria monocytogenes*. In 2017, Schäfer determined that 67% of equipment and utensils used in a poultry processing plant were contaminated with *L. monocytogenes*, even after cleaning. Despite this cleaning tools and utensils are rarely considered in relation to food safety. Fortunately, Global Food Safety Initiative (GFSI) approved food safety schemes, including those operated by the British Retail Consortium (BRC), the International Standards Organisation (ISO (FSSC 22000)) and Safe Quality Food (SQF), now each draw attention to them specifically. This review summarises information on the requirements of GFSI approved food safety schemes operated by BRC, FSSC 22000, SQF and International Featured Standards (IFS) , regarding cleaning tool and utensil selection and maintenance. It focuses particularly on requirements for hygienic design; materials of construction; and the development of cleaning and maintenance schedules, and offers expert guidance on how to comply with these. BRCv8: Section 4.11.6; ISO/TS 22000-1-2009: Section 11.2, 11.3, and 11.5; and SQF 8th ed.: Sections 10.2.9.2 and 10.2.9.8 all provide specific information relating to the selection and maintenance of cleaning tools and utensils. IFS v6.1 offers no specific guidance but Part 2, Sections 4.10.1 and 4.10.6 refer to cleaning and disinfection based on risk assessment, and cleaning utensils, respectively. The use of cleaning tools and utensils is ubiquitous in the food industry. Given their proven role as a major source and vector of contamination, and the GFSI Standard Scheme requirements, sharing knowledge of ways in which they can be controlled e.g. through hygienic design and maintenance, is essential in order to promote food safety and aid audit compliance.

Keywords: GFSI, standards, compliance, guidance

1. Introduction

Many external food safety and quality audits are now conducted by, or on behalf of, one of the four main Global Food Safety Initiative (GFSI) approved food safety schemes, these being:

- the British Retail Consortium (BRC) Global Standard for Food Safety;
- International Standards Organisations' Food Safety System Certification (ISO, FSSC 22000);
- Safe Quality Foods Program (SQF); and
- International Featured Standards (IFS) Food.

Between them these four GFSI approved schemes cover over 25,000 certified food suppliers in over 140 countries. Food manufacturers who hold GFSI scheme certification can demonstrate their compliance with food safety and quality standards more easily and thus protect and improve the reputation and income of their business globally.

Each GFSI scheme details comprehensive requirements regarding the maintenance of food safety and quality.

Food industry cleaning tools and utensils have long been identified as a major source and vector of cross-contamination. UK Government funded study data, used to establish food industry guidance on microbiological

sampling (Holah, 1998), showed that 47% of cleaning tools tested positive for *Listeria monocytogenes*. Another study determined that 67% of equipment and utensils used in a poultry processing plant were contaminated with *L. monocytogenes*, even after cleaning (Schäfer *et al.*, 2017). Despite this cleaning tools and utensils are rarely considered in relation to food safety.

Fortunately, GFSI approved food safety schemes, including those operated by BRC, ISO (FSSC 22000) and SQF, now each draw attention to them specifically.

2. Methods and results

Review of GFSI food safety and quality scheme requirements

Current (August 2018) versions of the four main GFSI approved food safety scheme were reviewed. The requirements of each, in relation to the selection and maintenance of cleaning tools and utensils is summarised below. The key requirements of each have been italicised.

British Retail Consortium v.8 (BRC, 2018)

Section 4.11.6
- Cleaning equipment shall be: *hygienically designed* and *fit for purpose, suitably identified for intended use* (e.g. *colour coded* or labelled), *cleaned and stored in a hygienic manner* to prevent contamination.
- Equipment used for cleaning high care and high risk areas shall be *visually distinctive* and *dedicated* for use in that area.

FSSC 22000 (ISO, 2017). ISO/TS 22002-1:2009 (2013) Prerequisite programmes on food safety – Part 1: food manufacturing

Claus 11.2
- Cleaning and sanitising agents and tools:
  - Tools and equipment shall be of *hygienic design* and *maintained* in a condition which does not present a potential source of extraneous matter

Clause 11.3
- Cleaning and sanitising programmes:
  - *Cleaning and sanitising programmes shall be established and validated* by the organisation to ensure that all parts of the establishment and equipment are *cleaned and/or sanitised to a defined schedule, including the cleaning of cleaning equipment*

Clause 11.5
- Monitoring sanitation effectiveness:
  - *Cleaning & sanitation programmes shall be monitored* at frequencies specified by the organisation to ensure their continuing suitability and effectiveness

Safe Quality Food Institute, 8th ed. (SQFI, 2017)

Section 10.2.9.2 & 10.2.9.8
- Equipment and utensils shall be *designed, constructed*, installed, operated, and *maintained to meet any applicable regulatory requirements and not pose a contamination threat to product*
- All equipment, utensils & protective clothing shall be *cleaned* after use or at a frequency to control contamination and *stored* in a clean and serviceable condition to prevent microbiological or cross-contact allergen contamination.

International Featured Standards v.6.1 (IFS, 2017)

No specific requirements

3. Guidance on how to optimise cleaning tool and utensil audit compliance

Based on the findings of the scheme reviews, guidance in relation to optimising cleaning tool and utensil audit compliance is given below. This guidance is based on best practice; regulatory requirements; well established risk assessment principles; and food safety and hygiene expertise.

Hygienically designed

The European Hygienic Engineering Design Group (EHEDG) are an independent, not-for-profit organisation populated by academic and industry volunteers who seek to *promote safe food by improving hygienic engineering and design in all aspects of food manufacture*. This is achieved through the development and provision of hygienic design related guidance, training and certification.

Making something that is *hygienically designed* means that it has been designed to be easy to clean. It also means that it will be fit for purpose regarding its durability and its materials of construction.

EHEDG Guideline No. 8 *Hygienic Equipment Design Criteria* (EHEDG, 2018) defines some fundamental principles regarding the hygienic design and construction of food industry equipment. They include:
- no sharp internal angles;
- all areas accessible for easy cleaning and disinfection – avoid deep recesses, nooks and crannies;
- of one-piece construction, or quickly and easily dismantled / re-assembled;
- smooth surface finish;
- made of food contact compliant materials, as appropriate.

As a rule of thumb – if you can see it you can clean it.

Fit for purpose / constructed to meet any applicable regulatory requirements and not pose a contamination threat to product

Cleaning tools and utensils that come into contact with food directly or indirectly, i.e. are used on food contact surfaces, should be made of materials that are compliant with the following Regulations (and subsequent amendments and updates):

- Regulation EU1935/2004 (EC, 2004) – Framework Regulation on materials and articles intended to come into contact with food.
- Equipment that is EU food contact compliant can display the 'Glass & Fork' mark shown at Figure 1.
- Regulation (EC) 2023/2006 (EC, 2006) – GMP for materials and articles intended to come in contact with food.
- EU Directive No. 10/2011 (EC, 2011) – Plastic materials and articles intended to come into contact with food. (plastic cleaning tools and utensils only).
- The US Food and Drugs Administration (FDA) Regulation CFR21 (FDA, 2018) – May change due to the introduction of the Food Safety Modernization Act (FSMA).
  - It is important to note that FDA compliance alone is NOT sufficient within the EU.

In Europe there is also a legal requirement for manufacturers of cleaning tools and utensils to the food industry to provide on request:

- migration test certificates; and
- Declarations of Compliance that contain information as defined in Article 16 of Regulation EC 1935/2004, containing the information set out in Annex IV of Regulation EC 10/2011.

Consequently, cleaning equipment and utensils must be appropriately food contact compliant and there should be evidence to support this, that is available to show to the auditor.

The EHEDG also provide guidance on materials of construction for equipment used in contact with food in their Guideline No. 32 (EHEDG, 2005).

Figure 1. The 'Glass and Fork' symbol used to denote EU food contact compliant material.

Cleaning and sanitising programmes shall be established, validated, conducted and monitored to a defined schedule

Establishing a cleaning and sanitising programme

To optimise GFSI scheme audit compliance cleaning tools and utensils should be managed in the following way:

1. develop validated tool/utensil cleaning and disinfection methods;
2. clean and disinfect tools/utensils to a defined frequency/schedule;
3. regularly monitor cleaning efficacy;
4. store tools/utensils appropriately;
5. regularly inspect and replace cleaning tools/utensils;
6. keep up to date records and documentation on cleaning tool/utensil management for audit inspection.

FSSC 22000, Clause 11.3 'Cleaning and sanitizing programmes' states that 'Cleaning and/or sanitizing programmes shall specify at a minimum:'

1. areas, items of equipment and utensils to be cleaned and/or sanitized;
2. responsibility for the tasks specified;
3. cleaning/sanitizing method and frequency;
4. monitoring and verification arrangements;
5. post-clean inspections;
6. pre-start-up inspections.

Wet cleaning of cleaning tools and utensils:
In general, food industry cleaning tools and utensils used in wet environments are decontaminated at the end of the production day, or more frequently if required, through immersion in warm water containing a detergent; by use of a hose (low, medium or high pressure); and/or use of manual cleaning; or by loading it into an onsite cleaning system, like a tray washer. These actions are usually followed by the application of a chemical disinfectant, before being rinsed and hung up or placed in an oven to dry. During the day, cleaning tools and utensils may also be placed in a 'sanitiser bath.' The sanitisers used in these baths tend to be a combined detergent-disinfectant chemical that is perceived to help remove soiling and disinfect the equipment simultaneously. However, the organic soiling on the cleaning tool can quickly reduce the efficacy of the disinfectant component of the sanitiser, and act as a protective barrier to the microorganisms present. Consequently, if the sanitiser solution is not changed at an appropriate frequency, it can become a 'soup' of food debris and microbes that can increase the risk of cross-contamination from the cleaning tool/utensil.

If manual cleaning of cleaning utensils is undertaken, the methods and chemicals used must not only be effective but also minimise the risk to the hygiene operative.

More recently, some manufacturers have started to use industrial dishwashers or washing machines to affect both cleaning and a thermal disinfection step into the decontamination process. A few food manufacturers also use an autoclave to subject the tools to a thermal sterilisation step following cleaning.

Dry cleaning of cleaning tools and utensils:
In some dry goods industries cleaning tools and utensils are not wet cleaned at all, for fear that the moisture introduced by the cleaning may not be completely removed by drying, subsequently leading to microbial growth and increasing the risk of cross-contamination. Instead equipment is used until it is deemed 'unfit for purpose' and then thrown away and replaced. In some high risk dry goods environments, like infant formula manufacture, brushes are sometimes just used once and thrown away rather than risk the possibility of cross-contamination. This is an expensive and wasteful practice, but it has been deemed the best way to ensure food safety for this critical consumer group.

The decision tree shown in Figure 2 provides a generalised overview of the cleaning processes that could be undertaken for cleaning tools and utensils used in dry and wet (high and low risk) environments.

However, the methods and frequencies of cleaning tool/utensil decontamination will depend on many things, including:

- what is being cleaned, e.g. environmental or food contact surface;
- type of contamination, e.g. microorganisms, allergens, foreign bodies, product residues (e.g. meat or fish species, organic or non-organic);
- the risk level of the food being produced, e.g. low risk, high care, high risk, ambient stable;
- type of food product/environment, e.g. wet, dry;
- type of clean, e.g. interim, daily, weekly, periodic deep clean;
- type of consumer, e.g. infants, elderly, allergic, health compromised.

Developing a decontamination program based on risk assessment:
The key to determining an effective decontamination program for cleaning tools and utensils is to base it on risk assessment. This requires the determination of risk based on consideration of the 'hazards' present, the 'likelihood' that they will occur, and the 'severity' if they do, followed the subsequent implementation of appropriate 'controls' to reduce the risk to an acceptable level. It is essential that those involved in conducting the risk assessment have the appropriate level of knowledge, experience and access to existing information to enable them to competently identify the hazards, assess the risk and implement the correct controls. Professional cleaning tool, utensil and cleaning chemical manufacturers/suppliers should be able to offer additional, bespoke information and advice on the most appropriate and effective way to clean/use their products in any given food production environment.

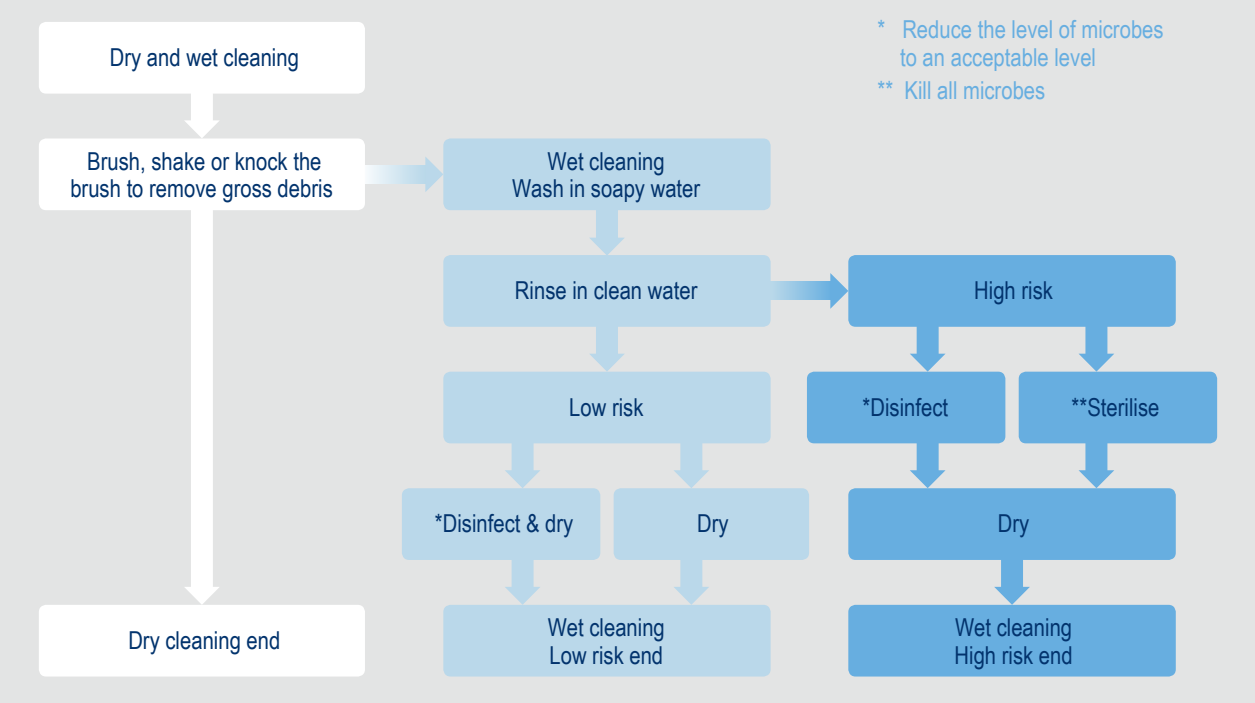

Figure 2. A generalised cleaning process decision tree (courtesy of Vikan).

Hazard analysis and critical control point (HACCP): HACCP principles are commonly used in the food industry to identify, evaluate, and control hazards which are significant for food safety. The concept was first used by the Pillsbury Company in the late 1960's for the safety of food intended for the US Space Programme. From here it has developed into a comprehensive seven-point system which can be used to identify, evaluate, and control hazards which are significant for food safety (FAO/WHO, 2009), and has been adopted into European and US legislation. The seven-point system is comprised of:

1. conduct a hazard analysis;
2. determine the critical control points (CCPs);
3. establish critical limits;
4. monitor the control of CCPs;
5. establish corrective actions;
6. establish verification procedures;
7. fully record procedures and results.

HACCP principles can also be used to develop risk-based cleaning and disinfection programs.

Hazards

Start by identifying any hazards (biological, chemical or physical agents) associated with the cleaning activity that have the potential to cause harm. Typical hazards associated with cleaning tools and utensils include:

- food debris (including allergens);
- plastic (cleaning tool/utensil fragments and bristles);
- cleaning chemical residues;
- food poisoning and spoilage organisms.

Likelihood and severity (risk assessment)

The risk associated with each hazard is determined by comparing the likelihood of the hazard occurring with the severity if it does. A grid, like that shown at Figure 3, is often used to help assess the risk.

If the likelihood and severity are both low, then the risk will be low, and the hazard may not require control. However, if the likelihood and severity are both high then the risk will be high, and controls should be considered. Assessment of likelihood and severity will be based on knowledge, experience and any existing information available.

Priority should be given to the control of the high-risk scenarios identified.

Controls

Controls are any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

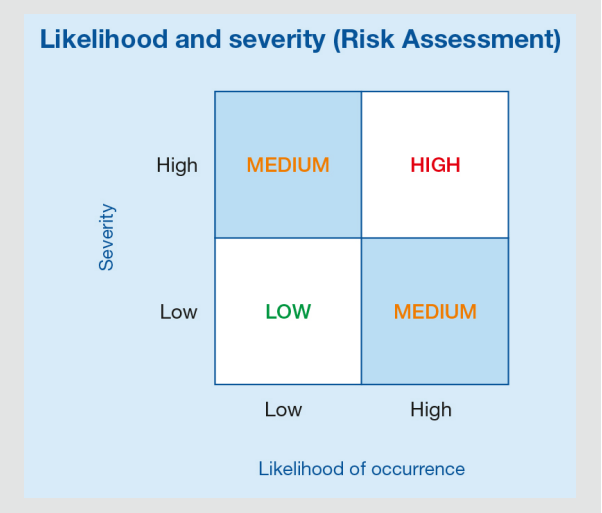

Figure 3. An example of the type of grid used to assess the risk from a hazard by comparing its likelihood and severity.

Validation – will it work?

There is a requirement within FSSC 22000 to 'establish and validate' cleaning tool 'cleaning and sanitizing programmes'.

Clause 11.3

- Cleaning and sanitizing programmes:
  - Cleaning and sanitizing programmes shall be established and validated by the organization to ensure that all parts of the establishment and equipment are cleaned and/or sanitized to a defined schedule, including the cleaning of cleaning equipment.

Different cleaning and sanitising programmes may need to be developed and validated for different types of cleaning tool, or for the same type of cleaning tool used for different tasks. This may require a degree of trial and error to ultimately determine an effective (validated) programme that consistently achieves the level of decontamination required.

Ultimately, each validated cleaning and sanitising programme should detail the:

- items of cleaning equipment (types and usage) that the method is suitable for;
- cleaning and disinfection chemicals to be used (water; detergent and disinfectant, including supplier, name, and product code). The temperature, concentration and contact time of the chemicals used should also be provided;
- decontamination equipment to be used, e.g. brush, tray washer;
- decontamination method/actions, e.g. scrubbing, rinsing;
- decontamination frequency, e.g. daily, weekly;
- level of decontamination required and how this should be measured and recorded.

And each cleaning and sanitising programme should be validated under 'worst case scenario' conditions, i.e.:

removal of contamination from the most difficult part of the cleaning tool/utensil to clean;
- removal of worst case degree of expected soiling;
- use of the maximum time expected between use and cleaning;
- use of the minimal cleaning requirements stated – e.g. if a cleaning method says to use 2-4% detergent at 30-40 °C, validate at 2% and 30 °C.

Further advice on cleaning validation is available from EHEDG (2016)

Monitoring – has it worked?

Clause 11.5
- Monitoring sanitation effectiveness:
  - Cleaning and sanitation programmes shall be monitored at frequencies specified by the organization to ensure their continuing suitability and effectiveness.

Monitoring, in the context of this review, is the use of methods that determine whether the validated cleaning methods have been conducted effectively, in a time frame that allows for rapid detection and correction of any shortfall in the decontamination achieved. Should shortfalls be identified, the decontamination procedure can be repeated immediately until the desired level is achieved.

Examples of monitoring methods include the use of:
- visual inspection;
- adenosine tri-phosphate (ATP) rapid detection sampling swabs;
- protein rapid detection sampling swabs;
- allergen rapid detection Lateral flow sampling devices.

The analytical monitoring methods used should themselves be validated. This validation should be conducted by the method manufacturer (will it work under defined controlled conditions of use) AND by the end user (will it work under my conditions of use?). Just because the manufacturer has validated the method, doesn't necessarily mean it will work at point of use.

Verification – Is it working consistently?

Verification, in the context of this review, is the use of methods, in addition to validation and monitoring, which determine whether the validated cleaning methods have been conducted effectively and/or are still effective.

These tend to involve sample analysis where the results can take longer (days) to obtain, and the review of monitoring data (trend analysis).

Examples of verification methods include the use of:
- microbial sampling and analysis;
- periodic review of visual inspection check/sign off sheets;
- periodic review of ATP, protein, allergen, microbial swab test results.

Should individual monitoring and verification results, and/or a review of past results indicate an acute or chronic hygiene issues it should prompt the implementation of corrective actions. These could include a review of the validated decontamination method, and the monitoring and verification sampling methods.

Records of method validation, monitoring, and verification, and of the results, reviews and corrective actions taken should be kept for auditing/due diligence purposes.

Maintained and stored in a hygienic manner

Cleaning tools and utensils should be:
- regularly inspected for damage and wear and tear;
- replaced as appropriate, based on risk assessment.

It is recommended that descriptions/images of what is acceptable and what is not, and records of tool inspection and replacement be kept for auditing/due diligence purposes. Figure 4 shows a brush that has reached an unacceptable level of contamination.

Do not make poor quality repairs to damaged equipment, such as that shown in Figure 5, as this can increase the safety risk to the food product.

Stored

Storage of cleaning tools and utensils can help minimise damage to the equipment and cross-contamination. It also improves efficiency by providing a place for the tools to be

Figure 4. A badly contaminated broom in need of cleaning or replacement (courtesy of Vikan).

Figure 5. A scraper repaired using white plastic tape. Repairs like this increase the risk of product contamination and audit failure (courtesy of Vikan).

stored and quickly found when needed. The use of shadow boards, like that shown at Figure 6, also provides a quick visual check as to whether something is missing from the storage station.

To minimise the risk of cross-contamination brushes, squeegees, scrapers, etc. on racks and shadow boards should be stored:

- head down;
- with heads distant from other equipment handles;
- in a single row so that equipment above does not drip onto equipment below;
- on racks and shadow boards that are regularly cleaned and disinfected, as appropriate.

Racks and shadow boards should be either freestanding; mounted at a distance from the wall that allows the wall and the back of the rack/board to be cleaned; or secured to the wall by an easy attach/detach mechanism that makes them easy to remove and clean behind.

Figure 6. An image of a shadow board.

Shadow boards should be made of waterproof/non-absorbent material. Ideally, both the board and the printing inks used for the shadows should be food-contact compliant and appropriately temperature and cleaning chemical-resistant.

The use of coloured stickers should be avoided as they can peel and flake (creating a foreign body issue) or bubble and crack (creating a crevice for contamination to accumulate in).

Suitably identified for intended use / visually distinctive

The use of colour coded cleaning tools and utensils, storage systems, and colour zoning site plans, like those shown at Figure 7 and 8, respectively, can provide a visual check that only tools and utensils colour coded for use in that area are used.

Colour coding can be used to segregate between cleaning tools and utensils used for:

- food contact and non-food contact surfaces;
- drains;
- meat species;
- un-processed and processed product areas;
- glass;
- allergens.

It also aids compliance with HACCP prerequisite programs and provides auditors with evidence of equipment control.

Figure 7. Colour coded storage rack for cleaning tools and utensils (Vikan).

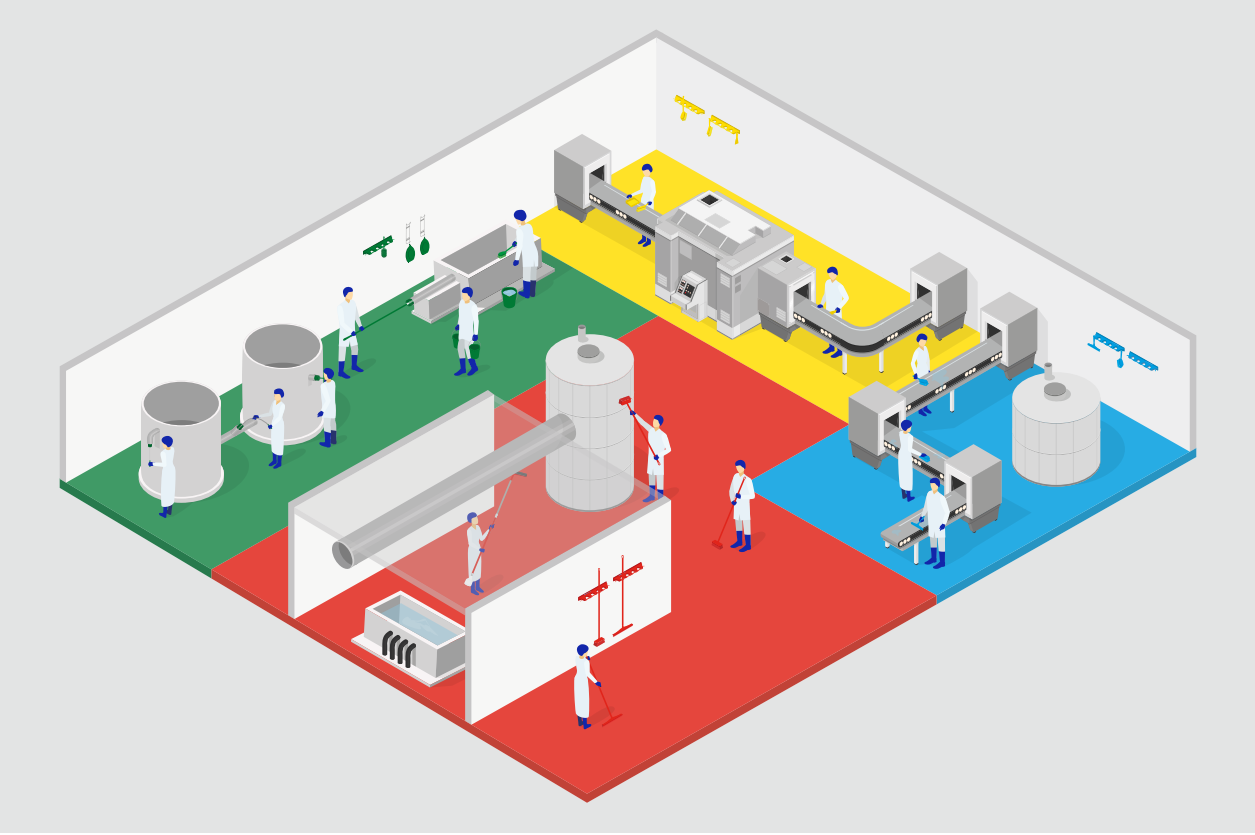

Figure 8. An example of a colour zoning site plan (courtesy of Vikan).

4. Top five tips to aid audit compliance

1. Remember that cleaning equipment and utensils can be a major source and vector of contamination.
2. The appropriate selection and maintenance of cleaning equipment and utensils is a requirement of GFSI food safety schemes operated by BRC, FSSC 22000 and SQF.
3. Cleaning equipment and utensils likely to come into contact with food or food contact surfaces must be appropriately food contact compliant. FDA compliance alone is NOT sufficient in Europe.
4. Choose equipment that is fit for purpose (based on risk assessment) and audit compliant – food contact compliant, hygienically designed, colour coded, distinctive.
5. To minimise the risk of cross-contamination and maximise audit compliance cleaning equipment and utensils should regularly be cleaned, inspected and replaced, and stored appropriately.

5. Significance

The use of cleaning tools and utensils is ubiquitous in the food industry. Given their proven role as a major source and vector of contamination, and the GFSI Standard Scheme requirements, sharing knowledge of ways in which they can be controlled e.g. through application of hygienic design and scheduled maintenance, is essential to promote food safety and aid audit compliance.

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