BRCGS

Global Standard
FOOD SAFETY

EFFECTIVE ENVIRONMENTAL MONITORING

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Tel: +44 (0) 20 3931 8150
Email: publishing@brcgs.com
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Contents

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Introduction

This guidance identifies the processes and activities a company should carry out to check and maintain the quality of the environment within their production facility. The regular monitoring of areas such as drains, production lines and waste routes is vital to prevent microbiological and allergen contamination of food, packaging or other products. As people can easily spread contamination it is also important that staff are made aware of their impact on the production outcomes and given appropriate training.

The guidance describes how to draw up, implement and maintain an environmental monitoring programme (EMP). The programme should be a documented plan that includes identifying areas at risk, listing the organisms liable to be present, creating a schedule for testing, recording outcomes and ensuring staff receive the appropriate training.

The publication will be useful to those responsible for the design and implementation of environmental management programmes, auditors, food safety managers, factory managers, HACCP teams as well as food and distribution teams.

The guidance will be of particular use to sites either using or working towards certification for the Global Standard Food Safety (referred to as 'the Standard'). The latest version of the Standard can be downloaded from the BRCGS website and we have indicated the sections in the Standard this guidance refers to for reference.

Part I
What is Environmental Monitoring

Environmental monitoring is an important activity to assess the effectiveness of overall hygienic practices in a facility and provide necessary information to prevent possible microbial and allergen contamination of food products. Failing to monitor critical areas within the production environment, from air quality to waste flow, can result in the contamination of products. This could lead to non-conforming product, a customer complaint or other incidents. Ongoing monitoring enables identification of risks and prevention of contamination before it occurs.

Bodies identifying the need for environmental monitoring

The Food & Drug Administration (FDA) Food Safety Modernization Act (FSMA) states:
"We propose to require environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a significant hazard, by collecting and testing environmental samples."

The Codex Alimentarius international food standards state:
"Measures should be taken for sampling and testing the environment and food contact surfaces (e.g., protein and allergen test swabs, or microbiological testing for indicator organisms) to help verify that cleaning and disinfection programmes are effective and being applied properly.

The Global Food Safety Initiative (GFSI) Benchmark 2020 states:
GMP 8.11: "Procedure of housekeeping, cleaning and hygiene disinfection shall be established, implemented and maintained. Its effectiveness shall be verified, based on the risks associated with the product or activity. Cleaning activities shall not represent a food safety risk."

FSM 19.2: "A risk-based approach shall be in place to define the microbiological environmental monitoring programme which shall be established, implemented and maintained to reduce the risk of food contamination."

BRCGS Global Standard Food Safety states:
"Risk-based environmental monitoring programmes shall be in place for relevant pathogens or spoilage organisms. At a minimum, these shall include all production areas with open and/or ready-to-eat products."

Part 2
The Environmental Monitoring Programme

Audits for the Global Standard Food Safety record over 50% of the non-conformities for environmental monitoring involve incomplete environmental monitoring programmes, failure to fully implement the programme and missing or incomplete risk assessments. This section looks at what to consider when putting an environmental monitoring programme together.

Key components

According to the Standard an environmental monitoring programme (EMP) shall be risk-based and shall include at a minimum:

- sampling protocol
- identification of sample locations
- frequency of tests
- target organism(s) (e.g., pathogens, spoilage organisms and/or indicator organisms)
- test methods (e.g., settle plates, rapid testing and swabs)
- recording and evaluation of results.

The EMP and its associated procedures should be documented.

The programme should outline how testing will take place, who will be responsible for carrying out the testing, the locations that will be tested for the target organisms, and any actions necessary as a result. Over time this will show a pattern that may require further investigation or action to rectify – for example raising staff awareness, changing your cleaning regimes, testing more frequently.

Along with the above, the EMP should establish appropriate control limits and corrective actions to be taken in case of a failure to meet a control limit or if any results indicate an upward trend. The programme should be reviewed at least annually or following changes to the HACCP plan or if significant trends are identified in the results.

Developing the programme

When designing an environmental monitoring programme, it is important to identify all potential sources and carriers and the controls that need to be put in place. A risk assessment will help decide which locations to be sampled/tested.

The facility can be split into zones, with zone 1 being areas in direct contact with the product, zone 2 being any areas next to zone 1 and therefore at risk of transferring contamination. Zones 3 and 4 would be outside the production floor and would provide less risk of contamination. Each zone may incur a different environmental monitoring approach. Information on the risks, testing processes and outcomes within each zone need to be documented in the EMP.

Zones cover:
Direct food contact: surfaces that products touch during production. Examples include stainless steel (pipework), polypropylene (chopping boards), rubber (seals), teflon (conveyor belts), nylon (scrapers), polyester (conveyor belts).

Indirect food contact: those adjacent to or connected to food contact surfaces. Examples include conveyor rollers, frameworks, seals.

Before developing the programme, gather information from all relevant sources. This could include talking to a parent organisation or research organisation to see if a recall or issue has occurred with similar products. Assemble a multi-skilled and appropriately trained team, including those with an understanding of HACCP, engineering, production, hygiene and sanitation, technical, microbiology and purchasing.

Areas to include

Site plan

Start by creating a site plan. This is a map of your production facility that marks the locations of the areas being tested as part of the programme. This could include the following:

- the location of drains
- air handling units
- hand wash stations
- production lines
- waste routes

Drains and floors

A drain map should be available which should mention which direction they flow and what equipment is situated near them. The map should include the different types of drain. A risk assessment should determine the target organisms, the frequency of testing, the cleaning regime, and the member of staff responsible. You need to be aware of residues and water flow throughout the production cycle as you may not be looking for the same organism in every drain.

Flow rates in the drains should be adequate for the utilities. Water pooling in the drains should be avoided as this causes the debris to gather around the drain. Constant drain overflows should be addressed to avoid the spread of bacteria and allergens.

Water on a site should be tested and analysed at least once a year, but the type of test and the frequency should be based on risk, the source of the water and usage. Tests should include the microbiological and chemical quality of the water.

Gully drains

Gully drains remove surface water and have removable gratings to enable cleaning. Liquids flow into channelled gullies covered in a grating of a maximum length of 500mm. They should have a lateral slope towards the outlet of the channel, forming a profile such as a V or U shape in the base of the channel. Channels should have the same constant slope in the longitudinal direction toward the outlet of the channel of minimum 1% but preferably more.

Pot drains

Pot drains have slope that runs towards the water trap and are able to completely drain. The pot must have a removable water trap that allows full accessibility to the pipe system for cleaning. They should be cleaned with water jets and rodding (i.e. with scrappers and brushes attached to flexible structures pushed or propelled down the pipes).
The size in production areas should have a frame a minimum of 200x200mm or outside diameter of 200mm to enable solid waste collection.

Refer to: The Standard, Section 8 – Building fabric in high-risk and high care zones. An example drain plan can be found in Appendix 1.

Air quality

Dust and aerosols can contain both bacteria and allergen particles that can be blown to areas where cross contamination (cross contact) can occur. Controlling the air quality in the production environments using air handling units can minimise the risk, but the units themselves need to be checked and cleaned on either a quarterly or half-yearly basis. Units should be checked for bacteria, spores, and moulds.

It is important to understand how efficient the filter systems within the air handling units are performing. Tests should be monitoring the density of microbiological and particulate matter in the air. You could use a range of air quality tests including settle plates or air samplers but the method used will be specific for the areas and degree of air circulation. Settle plates are better for areas where there is a lot of air movement. Air samplers are better for areas where there is little air movement.

Refer to: The Standard, Section 8 – High-risk, high-care and ambient high-care production risk zones

Hygiene equipment

These items are often missed from a programme and not fully captured in a cleaning schedule but it is important to include them in the list as they can and do act as vectors for the movement of bacteria around production areas.

People

People are a primary source for the spread of bacteria within a manufacturing environment because of what they touch, use and wear. All staff on site should be made aware of this and must be informed during their induction of their responsibilities relating to food safety. The environmental monitoring programme should consider the movement of staff, visitors, raw materials and finished products around the facility. All these should be evaluated against the risk of contamination, specifically with the monitoring of *Listeria*.

Since 40% of people carry *Staphylococcus aureus* as part of their normal bodily microbial population regular handwashing is important, particularly if they are operating in high-care or high-risk areas and/or with open product. Hand swabs in these areas need to be taken in the region of once a month in these higher risk areas but not immediately after handwashing. Typically 20% of the workforce in the high-care/high-risk area should be swabbed on a rotational basis.

The use of protective clothing and footwear along with the ability to wash hands will minimise risk. Identify wash stations/sinks on the site plan.

Refer to: The Standard, Section 7 - Personal hygiene. An example plan of sinks can be found in Appendix 1.

Product storage and equipment

Include equipment used for the moving and storing of ingredients into the programme. Product trays, product trolleys, pump trucks, Eurobins and racks can pass over drains in all areas and have the potential to transfer bacteria in aerosols around the factory. They can be a carrier because small surface areas, wheels, the underside and corners can be difficult to clean. It is good practice to differentiate equipment used in high-risk/high-care areas from low risk.

All new equipment should be suitable for food contact, where applicable, and should be incorporated into the programme. The EMP should describe the cleaning recommendations and identify sample points. These details are based on the equipment design.

Waste and waste disposal

Waste needs to be moved from a high-risk or high-care area to a low-risk area. If this is through a hatch, then the floor or hatch door area needs to be swabbed. Bins containing wet product need to be in the programme once washed but this is not necessary for bins that only contain bagged product.

Tray wash areas

Tray wash areas provide areas for all bacteria likely to be present in manufacturing environments to spread. These need to be included in the programme to verify that the controls (people, barrier, time, location) in place are effective.

Part 3
The Programme in Practice

Sampling strategies
When writing the programme, a risk assessment should decide what areas will be sampled or tested and how this will be conducted. A sample plan will define the number of samples to be selected, the acceptance or rejection criteria and the statistical confidence of the result.

Time separation
Time separation could be used to separate products with different risks, such as the segregation of high-care products from lower risk ones. If used, it should be considered when developing the programme.

Testing
There are several methods that can be used to either monitor or verify the effectiveness of the environmental controls. These include swabbing (using sterile stick swabs or sterile sponge swabs), contact plates, settle plates, air samplers, and visual inspections, etc.

1) Adenosine Triphosphate (ATP) - is a biological chemical found in all organic material. If an ATP Rapid Test shows the presence of organic materials it means that the location is not clean and could potentially contaminate products during the manufacturing process. ATP hygiene tests provide an instant result and can therefore be used for positive releasing equipment. Protein detection kits are also available that can give a presence/absence result.

There are numerous devices available which all measure the amount of bioluminescence by a reaction between the substrate Luciferin and the enzyme Luciferase in the presence of ATP. Results are referred to as relative light units (RLU's).

Whichever ATP detection method is chosen, the system and associated protocols, results etc. needs validating for each site and surface being tested. This takes both time and technical resources. There needs to be benchmarking against traditional swab methods, which may form part of this validation. As a result, many companies rely on the information provided to them by the manufacturer or pick an arbitrary figure as the designated 'pass' mark. Some manufacturers give a 'Pass', 'Warning' and 'Fail' figure. Others may give a 'Pass' and 'Fail' or a numerical value. When used as a method for positive release this is used after the cleaning but before the disinfecting of surfaces.

Rapid hygiene testing is also a good training tool - enabling personnel to see a clear and immediate link between hygiene practices and hygiene test results.

The presence of ATP does not indicate the presence of micro-organisms, especially the target organisms, but only indicates clean/unclean areas.

Therefore, ATP may be useful as part of an environmental monitoring programme but using ATP tests without additional pathogen or spoilage tests is unlikely to meet the full need or intention. The Standard requires a risk-based environmental monitoring programme which monitors relevant pathogens or spoilage organisms (statement of intent 4.11.8) and ATP in isolation would be insufficient to achieve this.

2) The use of agar plates – used to identify the presence of Coliforms or Enterobacteriaceae, TVC's, *Pseudomonas*, *Staphylococcus aureus*, *Listeria* spp, *Salmonella* spp and yeast and moulds. Samples need to be collected using an appropriate method such as swabbing.

Swabbing

Swabbing involves wiping a surface with a sterile swab and testing for the presence of bacteria on a surface that appears clean. The most common swabs are sterile dry stick swabs, sterile moistened stick swabs and moistened sponge swabs.

The sterile stick swabs should be used for swabbing locations that are difficult to access and an area of 10cm x 10cm should be swabbed. The sterile sponge swabs should be used for swabbing an area of 30cm x 30cm.

Swabbing can be carried out at the beginning of production, post clean or during production to ascertain the hygiene status of the area during production.

The number of swabs carried out is based on an assessment of the size and site risk category, historical data and scientific information. Therefore, in high-risk/high-care areas a figure of between 100 and 200 swabs may be performed per week in line with this assessment. In a lower risk environment e.g., a bakery, with no kill or chill step you could expect to reduce this to between 10 and 45 swabs per week. The size and complexity of an operation will be factors in establishing how many swabs to carry out and the site will need to justify their decision if questioned in an audit.

Refer to: The Standard, Section 4 – Environmental Monitoring

Contact plates and settle plates

Settle and contact plates are used to detect yeasts and moulds present in the atmosphere. Settle plates, containing the appropriate agar are placed on horizontal surfaces and left exposed for a minimum of an hour, then covered. Contact plates are used such that the agar in the plate touches the surface being tested at a given time, then covered. These are then incubated in a laboratory for the required time.

Air particle samplers separate particles from a known volume of air and subject them to weight determination and/or chemical analysis. This is achieved primarily by filtration and impaction. These are not used specifically for the collection of spores but particulates in the air. It is good to run a test weekly or monthly but a risk assessment is advisable to determine the correct frequency for each site.

If a company undertakes or subcontracts their tests for analyses the laboratory used shall have laboratory accreditation or operate in accordance with the requirements and principles of ISO/IEC17025. This includes proficiency testing where applicable. Documented justification shall be available where accredited methods are not undertaken.

Refer to: The Standard, Section 5 Product Control

Target organisms

These may be specific pathogens that present a risk to the product or environment (e.g. *Listeria* spp in wet environments or Enterobacteriaceae in dry environments), specific spoilage organisms (e.g. yeast or mould) or hygiene indicator organisms (e.g. total plate count, total coliforms).

Table 1 shows the potential target organisms for the different categories of products.

Table 1 Environmental monitoring programmes and product categories

Category Number	Category Description	Example Products	Storage	EMP potential organisms to monitor
1	Raw red meat	Beef/veal, pork, lamb, venison, offal, other meat	Chilled, frozen	Coliforms/Enterobacteriacea *Salmonella*
2	Raw poultry	Chicken, turkey, duck, goose, quail, farmed and wild game and shell egg	Chilled, frozen	Coliforms/Enterobacteriaceae *Salmonella*, TVC
3	Raw prepared products (meat and vegetarian)	Bacon (including smoked bacon), comminuted meat and fish products (e.g. sausages and fish fingers), ready-to-cook meals, ready prepared meat products, pizzas, plant-based prepared meals, steamer meals	Chilled, frozen	Coliforms/Enterobacteriaceae, *Salmonella*, TVC
4	Raw fish products	Wet fish, molluscs, crustaceans	Chilled, frozen	Coliforms/Enterobacteriaceae *Salmonella*, TVC
5	Fruit, vegetables and nuts	Fruit, vegetables, salads, herbs, nuts (unroasted)	Fresh	Coliforms/Enterobacteriaceae, *Salmonella*, *Pseudomonas*, yeast and moulds
6	Prepared fruit, vegetables and nuts	Prepared/semi processed fruit, vegetables and salads including prepared ready-to-eat salads, coleslaws, frozen vegetables	Chilled, frozen	Coliforms/Enterobacteriaceae, *Salmonella, Pseudomonas*, yeast and moulds, *Listeria* spp
7	Dairy, liquid egg	Liquid egg, liquid milk/ drinks, cream, liquid tea and coffee creamers, yogurts, fermented milk-based products, fromage frais/ crème fraiche, butter Ice cream Cheeses – hard, soft, mould ripened, unpasteurised, processed, cheese food Long-life milks, non-dairy products (e.g. soya milk), ambient yogurts, custards etc. Fruit juices (includes freshly squeezed and pasteurised, smoothies) Dried whey powder, dried egg, dried milk/milk formulation	Chilled, frozen, ambient	*Listeria*, Coliforms/ Enterobacteriaceae

Category Number	Category Description	Example Products	Storage	EMP potential organisms to monitor
8	Cooked meat/ fish products	Cooked meats (e.g. , ham, meat pâté, hot eating pies, cold eating pies), molluscs (ready to eat), crustaceans (ready to eat), fish pâté Hot smoked fish, poached salmon	Chilled, frozen	Coliforms/Enterobacteriaceae, *Salmonella, Listeria* spp
9	Raw cured and/ or fermented meat and fish	Parma ham, ready-to-eat cold smoked fish, cured fish (e.g. gravlax), air-dried meats/salami, fermented meats, dried fish	Chilled	Coliforms/Enterobacteriaceae *Salmonella*, yeast and moulds, *Listeria* spp
10	Ready meals and sandwiches, ready-to-eat desserts	Ready meals, sandwiches, soups, sauces, pasta, quiche, flans, meal accompaniments, cream cakes, trifles, assembled high-risk sweet desserts	Chilled, frozen	Coliforms/Enterobacteriaceae, yeast and moulds, *Listeria* spp
11	Low/high acid in cans/glass/ plastic containers	Canned products (e.g. , beans, soups, meals, fruit, tuna) Products packed in glass (e.g. sauces, jams, pickled vegetables) Products packed in plastic pouches (e.g. baby food) Pet food	Ambient	
12	Beverages	Soft drinks including flavoured water, isotonics, concentrates, squashes, cordials, minerals, table waters, ice, herbal drinks, food drinks	Ambient	*Pseudomonas*
13	Alcoholic drinks and fermented/ brewed products	Beer, wine, spirits Vinegars Alcopops	Ambient	Yeasts and moulds
14	Bakery	Bread, pastry, biscuits, cakes, tarts, breadcrumbs	Ambient frozen	Yeasts and moulds

Category Number	Category Description	Example Products	Storage	EMP potential organisms to monitor
15	Dried foods and ingredients	Soups, sauces, gravies, spices, stocks, herbs, seasonings, stuffing, pulses, legumes, rice, noodles, nut preparations, fruit preparations, dried pet food, vitamins, salt, additives, gelatine, glacé fruit, home baking, syrups, sugar, tea, instant coffee and non-dairy coffee creamers	Ambient	Yeasts and moulds
16	Confectionery	Sugar confectionery, chocolate, gums and jellies, other sweets	Ambient	Yeasts and moulds
17	Cereals and snacks	Oats, muesli, breakfast cereals, roasted nuts, crisps, poppadoms	Ambient	Yeasts and moulds
18	Oils and Fats	Cooking oils, margarine, shortening, spreads, suet, ghee, salad dressings, mayonnaise, vinaigrettes	Ambient	
n/a	Packaging	Cardboard film/plastic	Ambient	Yeasts and moulds

Examples of organisms and bacteria that can be identified through testing

1. Hygiene indictor organisms

Total Viable Count (TVC)
Also known as total plate count or total aerobic count.

TVC is a quantitative test for all aerobic living microorganisms in a sample. This includes bacteria, yeasts and moulds. This test is used as an indicator of post process contamination of heat processed foods that receive minimal handling and/or an indicator of the effectiveness of cleaning of high-care/high-risk food contact environment.

Enterobacteriaceae
These are a group of bacteria that originate in the gut of warm-blooded animals and are widespread in the environment and even though the group largely comprises of harmless bacteria, it also includes pathogens like *Salmonella* and Shiga toxin-producing *E.coli* (STEC).

Testing for Enterobacteriaceae can be used to validate, verify and monitor critical control point processes, hygiene and cleaning.

These bacteria are killed by cooking, hence, testing for Enterobacteriaceae is a useful indicator of post-process contamination of heat-processed foods which are subject to further handling or processing.

Coliforms
Coliforms are a part of the Enterobacteriaceae group of bacteria and therefore, the testing can be used in a similar way as Enterobacteriaceae but will give lower results for the food and swab samples. Therefore, they are used more frequently for water testing rather than food. These bacteria are also killed by cooking.

E. coli
E. coli is part of the coliform group of bacteria. This test is commonly used as an indicator of faecal contamination, but it can also be isolated from the environment and therefore, occasionally detected in raw produce. Although most *E.coli* may not cause illness, Shiga toxin-producing *E.coli* (STEC) is a rare *E.coli* which is extremely pathogenic.

2 Pathogens

Listeria
Listeria monocytogenes is a common bacterium that causes an illness called listeriosis. It is particularly prevalent in chilled ready-to-eat foods that do not require further cooking or reheating. The other species of listeria are non-pathogenic and can be used to monitor cleaning practices and places where *listeria monocytogenes* will linger.

Salmonella
Salmonella bacteria can be found in both animal and human intestines and causes an infection called salmonellosis. Infection is usually through contaminated water or food. The bacteria is usually spread by inadequate cooking and cross-contamination.

Normally, cooking will destroy *Salmonella*. Testing will identify any post-process contamination.

Staphylococcus aureus
Staphylococcus aureus is bacterium found on human skin and respiratory tract. It is generally safe but can also cause issues if the bacteria enters the body, for example through broken skin or a medical procedure.

3. Spoilage organisms

Yeast
Yeasts cause spoilage by production of carbon dioxide gas when sugars are fermented. Yeasts are generally found in high sugar foods and also in acidic products.

Mould
Moulds are aerobic and cause spoilage by producing mycelium and spores on the surface of food making them visually unacceptable. Some moulds are resistant to acid and high sugars and can spoil a wide range of products. Most moulds do not cause illness however, moulds that produce mycotoxins can cause adverse health effects in humans.

Pseudomonas
Pseudomonas is commonly found in soil and water and is mainly associated with spoilage of chilled food and beverages. Pseudomonas is associated with raw produce and process waters used for product cooling or as an ingredient.

Table 2 shows incubation times for several organisms. Confirmatory tests for *Listeria* and *Salmonella* should be carried out following all presumptive positive tests. These time factors need to be taken into consideration in the environmental monitoring programme so that decisions can be made in appropriate time scales.

Table 2 Times, media numbers and temperatures for selected microorganisms

Organism (s)	Incubation Temp (s) (°C)	Number of Media	Overall Incubation Time (hrs)
Enterobacteriaceae/Coliforms	37 ± 1°C	1	24 ± 2
TVC	30 ± 1°C	1	72 ±3
Staphylococcus	37 ± 1°C	1	24 ±2
Salmonella	41.5 ±1/37± 1°C	3	72 ±6
Listeria	30 ± 1/37 ± 1°C	3	72 ±6
Pseudomonas	25 ± 1°C	1	44 ±4

Taken from: Microbiology – Departmental Methods (Campden BRI)

Prompting a review

According to the Standard an environmental monitoring programme should be reviewed at least once a year. This may be accomplished as a part of the HACCP review or a separate one.

Other situations that may instigate a review include:

- Negative results: Pass trends showing an extensive lack of positive results should call into question whether the locations are being tested in the right way or for the correct organisms. The aim of the programme is, after all, to identify areas of concern.
- Finished product data: when a positive test on a product implicates the effectiveness of the environmental monitoring programme.
- Complaint data: If complaint trends identify potential environmental contamination.
- Operational changes: these can be as simple as changes from manufacturing one type of product to another or making a temporary change in the process.
- Publication of new scientific information, such as the identification of a micro-organism not previously associated with a specific product type, or information relating to the survival of a pathogen in specific environmental condition
- Positive results from the monitoring of incoming raw materials.

Refer to: The Standard, Section 1 – Senior management commitment, Section 2 – Describe the product, Section 3 – Complaint handling, Management of incidents, product withdrawal and product recall

Recording and evaluating

Control limits

Appropriate control limits shall be defined for the environmental monitoring programme.

The site will need to establish appropriate control limits and the actions to be taken if these are exceeded or when there is a trend towards increasingly positive results. The control limits and actions may be based on:

- the organism measured, its level and the location of the positive result
- when the testing was completed (e.g., was the sample taken pre- or post-cleaning?)
- any legal or customer limits

Refer to: The Standard, Section 4 – Housekeeping and Hygiene

Root cause analysis

An important part of an effective corrective action process is the identification of the root or underlying cause of the non-conformity and the implementation of suitable action to prevent recurrence. Root cause analysis is a process of investigating an identified issue which allows you to understand the cause and put it right.

Examples of root cause analysis tools include:
- fishbone
- brainstorming/thought shower
- mind mapping
- 5 whys

The root cause analysis process should include:
- the reasons for carrying out the analysis
- the trained or authorised person who will be completing the analysis
- the method being used
- results of the analysis and any subsequent preventive actions
- the methods for the verification of the completed actions.

A documented procedure that includes this information, as well as evidence of any root cause analysis and preventive action that the site has carried out should be kept. It is up to the site to establish a procedure for the completion of RCA.

Refer to: The Standard, Section 3 – Preventive and corrective action

Correction and corrective action

In case of positive results, corrective actions may include:
- immediately giving the area a thorough clean
- isolating the product. It may need to be recalled or withdrawn from the supply chain
- increasing handwashing
- retraining staff on the importance of procedures
- reviewing procedures and amending if required
- re-swabbing to check actions have been successful.

Using data trends

Graphical representations of any number of determinants and numbers of positive detections or out of specifications are a useful way to show trends within the factory environment. The graph below illustrates that over a period of 29 days the percentage of swabs deemed to be passes has dropped from 99% to 90% indicating a decrease in the overall standard of cleaning. This should have been noted around day 7. The irregular drops in passes could suggest a particular team needed re-training or a process was not being completed on these days.

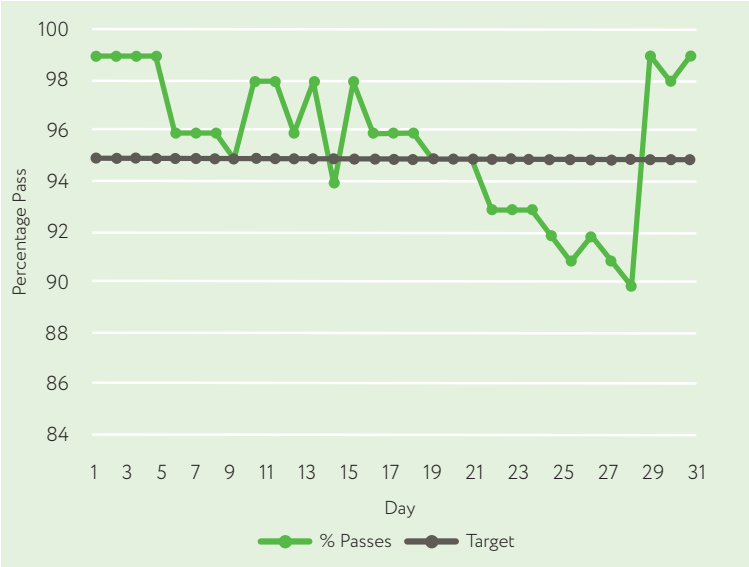


Figure 1 A graphical representation of swab results against target level

The table below illustrates the responses required in relation to specific organisms detected in either the EU/UK or the USA.

Table 3 Examples of actions to take in response to positive detections on products

Organism	Environmental Testing	Action		Product Testing (cfu/g)	Action	
		EU/UK	USA		EU/UK	USA
Listeria monocytogenes	Present	Clean/re swab/ isolation of product	Inform competent authority (FDA/ USD)	Present	Inform competent authority (FDA/ USDA)	Retest/recall
Salmonella spp	Present	Clean/re swab/ isolation of product	Inform competent authority (FDA/ USD)	Present	Inform competent authority (FDA/ USDA)	Retest/recall
TVC	Present		Report to customer?	>10 <10^6	Report to customer	Retest
Enterobacteriaceae	Present	Clean/re swab/ isolation of product	Clean/re swab/ isolation of product	>20	Report to customer	Retest
Coliforms	Present	Clean/re swab/ isolation of product	Clean/re swab/ isolation of product	>20	Report to customer	Retest
Pseudomonas spp	Present	Clean/re swab/ isolation of product	Clean/re swab/ isolation of product	>10 <10^6	Report to customer	Retest

There are a number of corrections and corrective actions that can be undertaken in light of specific swab failures as part of programme protocols. Root cause analysis should be used to determine the most appropriate and effective preventive actions.

Reasons for not implementing a full environmental monitoring programme

There may be areas, within a processing environment, that are thought to not need a full environmental review, due to risk assessment or the nature of the product not deemed as a concern:

- low risk to low-risk transfer
- low risk with a microbiological loading reduction step

There is always a need to monitor the environment, even if it is only the air that is being tested on an ongoing basis.

Part 4
Additional Reading

Global Standard Food Safety, BRCGS. The latest issue can be downloaded from brcgsbookshop.com

Airborne Microorganism Levels in Food Processing Environments, J.T. Holah, et al, Campden and Chorleywood Food Research Association, 1995

Cleaning and disinfection of food factories: a practical guide (Guideline 55, Second edition), Campden BRI, 2020

Effective Allergen Management, BRCGS, 2022

Effective microbiological sampling of food processing environments (Guideline 20), Campden BRI, 1998

Food Microbiology - an introduction (Key Topic 12) Campden BRI, 2006

Guidelines for Assessing the Microbiological Safety of Ready-to-Eat Foods Placed on the Market, GOV.uk, 2009

Hand hygiene: guidelines for best practice (Guideline no. 62) Campden BRI, 2009

Materials of Construction for Equipment in Contact with Food, EHEDG, 2005

Microbiological Hazards Datasheet e-book, Safefood 360, 2021

Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, Department of Agriculture Food Safety and Inspection Service (USA), 1996

The types of food *listeria* can be found in, www.food.gov.uk/safety-hygiene/listeria

Understanding Air Quality Requirements and Air Filter Specifications in Food Production, BRCGS, 2018

Water quality for the food industry - management and microbiological issues (Guideline G27), Campden BRI, 2000

Understanding Root Cause Analysis, BRCGS, 2018

Yeasts and moulds - occurrence and control in the food industry, Campden BRI, 2007

Appendix 1 - Case Study: Blitz's Bakery

For the purposes of this guidance document a case study, Blitz's Bakery, has been created to demonstrate some of the practical considerations when creating, updating, and maintaining an EMP. The example used details of a site where the scope of certification is "The mixing and baking of bakery components; the mixing of sweet sauces; the filling and icing of bakery components to produce chilled and ambient flour confectionary products and desserts, packed into films, cartons, and paper cases". Products from this bakery fall into either category 7 or 14 as shown in table 1.

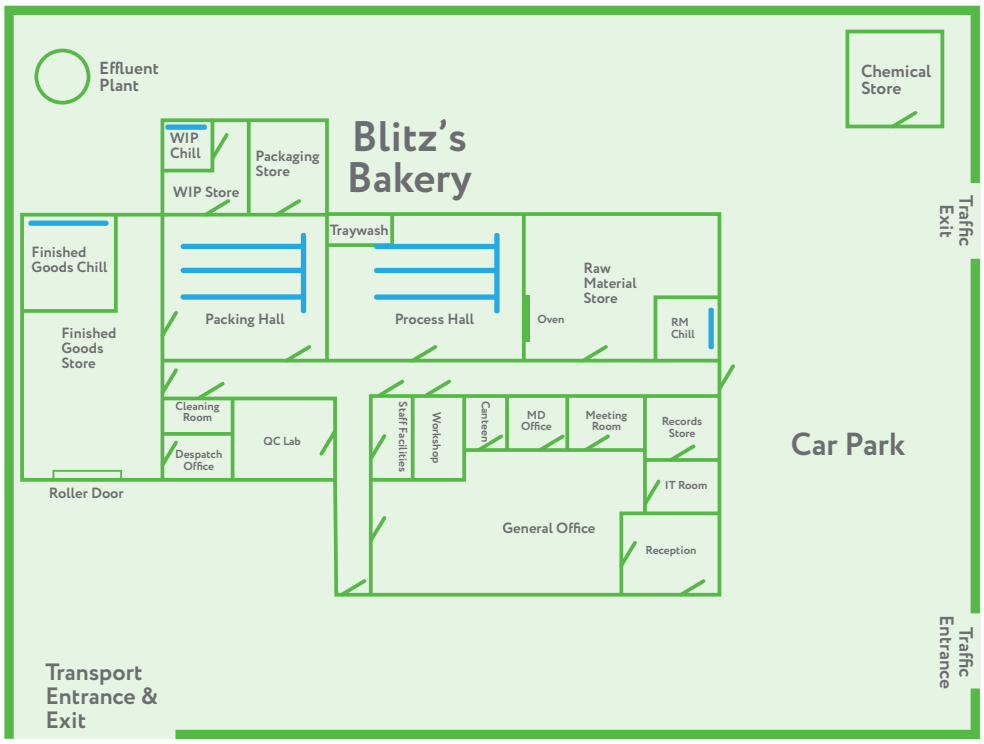
Air quality

Based on the use of 'air socks' in both the Process Hall and Packing Hall at Blitz's Bakery, these 'socks' would be cleaned on a quarterly and six-monthly basis respectively. The environment should be monitored for yeast and moulds because of the potential for yeast and mould spores to survive in the air handling units (AHUs).

AHUs without 'air socks' in the Raw Material Chill, Work in Progress Chill and Finished Goods Chill should be cleaned quarterly and the areas monitored for yeast and moulds along with TVC. Swabbing post-clean should also be carried out to determine if the hygiene and maintenance schedule is adequate due to the potential of moisture niches to arise.

Ducting in roof voids, if present should be checked at least annually for yeast and moulds and swabbed for TVC's to ascertain the microbial quality of incoming air.

Fig 2 Air handling unit plan

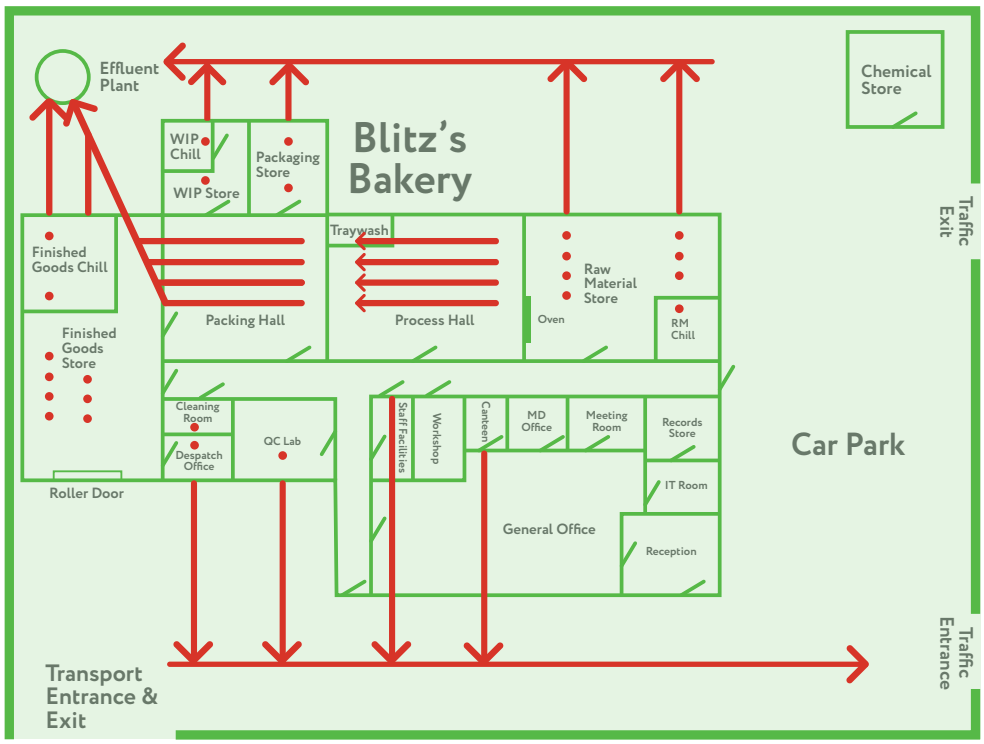


= air handling unit

Drains and floors

Using a 20-metre gulley drain run as an example, it would be sensible to divide this drain into four virtual sections and swab each virtual section on a weekly basis. Therefore, the whole drain would be swabbed over a four-week rolling period in a high-risk environment giving a total of 16 test points for four drains. For the Raw Material Store it is best practice to divide the number of spot drains proportionally so that each drain is swabbed at least monthly and in lower risk environments, best practice would suggest an annual frequency.

Fig 3 Drain plan



● = pot drain → = gulley drain (arrow indicates direction of flow)

Table showing a recommended sampling plan for *Listeria* based on Blitz's Bakery scope and risk zones.

Area	Item	Frequency	Number of samples annually
Raw Material Store	pot drains	Weekly	52
Raw Material Chiller	pot drains	Weekly	52
Process Hall	gulley drain	1 ¼ Weekly (each)	48
Tray Wash	gulley drain	1 ½ Weekly (each)	48
Packing Hall	gulley drain	1 ¼ Weekly (each)	48
Packaging Store	pot drains	3 Monthly	4
Work in Progress Chill	pot drains	Monthly	12
Finished Goods Chill	pot drains	Monthly	12
Finished Goods Store	pot drains	Monthly	12
Despatch office	pot drains	3 Monthly	4
Cleaning Room	pot drains	3 Monthly	4
QC Office	pot drains	3 Monthly	4

Time separation

In this case study time separation is used with cream and fruit filled higher risk product being manufactured chronologically prior to the low-risk ambient bakery products.

Swabbing

Dependent on the risk zone, the following table shows the timeframes for drain swabbing.

Table showing areas and frequencies for proposed *Listeria* testing

Location	Frequency	Organism
Raw Material Chiller	All points monthly	*Listeria monocytogenes*
Work In Progress Chiller	All points monthly	*Listeria monocytogenes*
Process Hall	All points monthly	*Listeria monocytogenes*

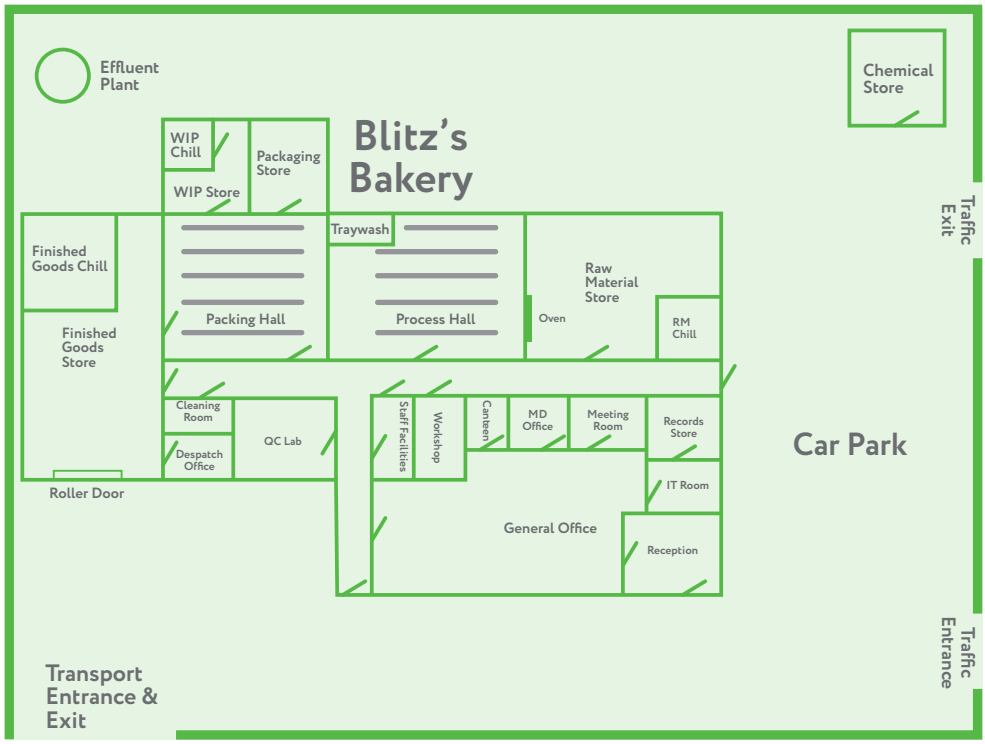
More hand swabbing would typically be performed in the Process and Packing Halls due to elevated risk of contamination in these areas. Hand swabs would be performed and assessed in these areas to measure the effectiveness of handwashing. See table below for a suggested hand swabbing frequency for the bakery.

Table showing suggested frequency for monitoring of staff hand swabbing at Blitz's Bakery

Location	Frequency	Organism(s)
Process Hall	Quarterly	*S aureus*, Enterobacteriaceae or Coliforms
Packing Hall	Quarterly	*S aureus*, Enterobacteriaceae or Coliforms
Raw Material Store	Twice yearly	*S aureus*, Enterobacteriaceae or Coliforms
Finished Goods Store	Twice yearly	*S aureus*, Enterobacteriaceae or Coliforms
Washroom	Quarterly	*S aureus*, Enterobacteriaceae s or Coliforms
Offices	Annually	*S aureus*, Enterobacteriaceae or Coliforms

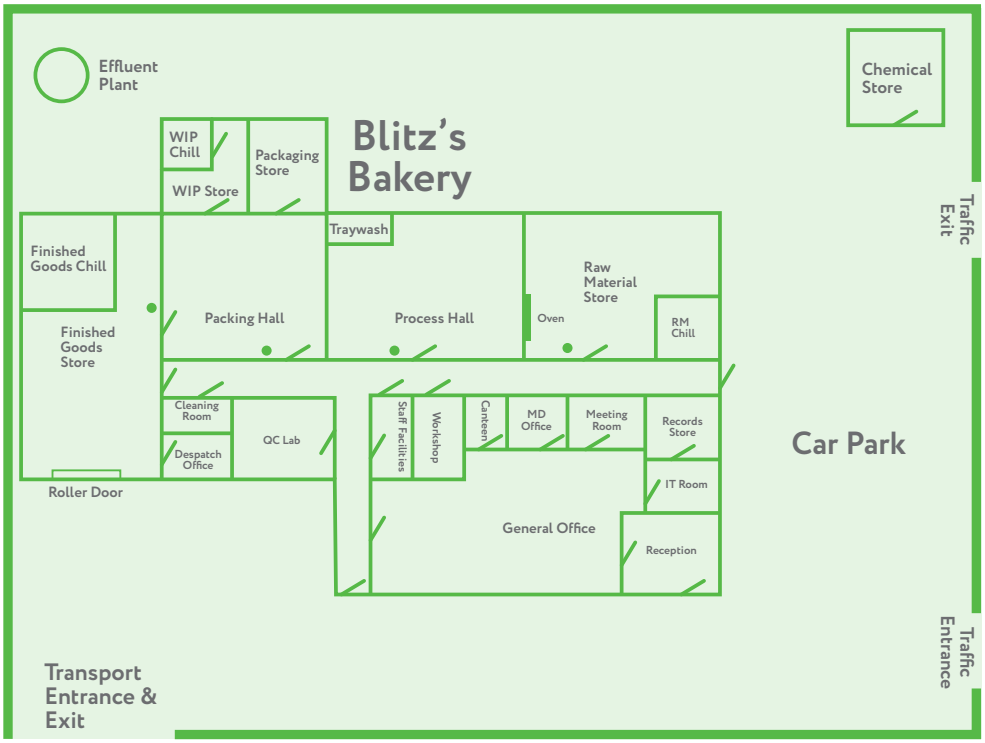
Process Lines post clean would be expected to be swabbed for ATP as a positive release system in the Process Hall and possibly swabbed for TVC, Coliform or Enterobacteriaceae. All engineering and or maintenance work carried out is followed by cleaning and sign off, which should include as a minimum ATP monitoring.

Fig 3 Production Lines plan



= production lines

Fig 4 Sink plan



● = placement of sink

BRCGS
Floor 2
7 Harp Lane
London EC3R 6DP

T: +44 (0)20 3931 8150
E: enquiries@brcgs.com
W: brcgs.com
W: brcgsbookshop.com
W: brcgsparticipate.com