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Biocides in Cleaning and Disinfection – Working Document

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1. Introduction

This is a working document developed by the UK food and biocides industries, providing an overview of biocides currently approved for use with food and feed to assist companies in their selection and appropriate use.

It will be updated as required.

Ensuring cleanliness of the food production environment is a fundamental requirement of food hygiene legislation and a Critical Control Point (CCP). Chapter V of the EC General Food Hygiene Regulation 852/2004 stipulates that:

"*All articles, fittings and equipment with which food comes into contact are to: (a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination*…"

Establishing, validating and monitoring the efficacy of cleaning and disinfection is a CCP so is covered by the requirements on Food Business Operators to use HACCP principles (Article 5, 852/2004).

Biocides are regulated through EU legislation, primarily the Biocidal Products Regulation 528/2012. Those that are approved for food and feed use, referred to as Product Type 4 (PT4) biocides, are listed in Appendix 1.

PT4 biocides can be used for direct contact with food:

- disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food or feed for humans and animals, and
- to impregnate materials which may enter into contact with food.

Since biocides are used to assure the safety of drinking (mains) water they can carry over into foods with which they come into contact.

Biocides that are of have ever been used as pesticides are also regulated by 396/2005 which sets Maximum Residue Levels (MRLs) of pesticides in or on food and feed. These are referred to as dual-use biocides.

It should be noted that MRLs are not safety levels, but relate to best agricultural practice in the use of pesticides in the field.

Food Business Operators (FBOs) must comply with the EC General Food Law (178/2002) and assure food safety and hygiene, including by ensuring that disinfection is consistently effective. Relevant MRLs for dual use biocides should be complied with.

The position of the European biocides and food industry regarding the regulation of biocidal active substances is in Appendix 2.

Aims of this Guidance

This guidance focuses on the responsible and effective use of biocides in cleaning and disinfection especially of food equipment and other food contact surfaces.

Cleaning and disinfection is carried out primarily to control pathogens.

The Pennington Reports (1997 and 2009) highlighted the importance of providing clear information on cleaning and disinfection to food businesses:

- At the Fatal Accident Enquiry of the Lanarkshire incident, Sheriff Cox drew attention to the fact that the butcher involved thought that a biodegradable detergent was in fact a bactericide and this ignorance led him to contaminate the whole of his premises and many cooked products with *E.coli* O157. (1997 report)

- The FSA should remove the confusion that exists among food business operators about what solution(s) should be used to prevent cross-contamination from surfaces and equipment. [Recommendation 6, 2009 report]

Two fatal outbreaks of *E coli* O157 were the foci of the Pennington Reports. However, *L. monocytogenes* causes the greatest number of deaths from foodborne disease in the UK, EU and USA.

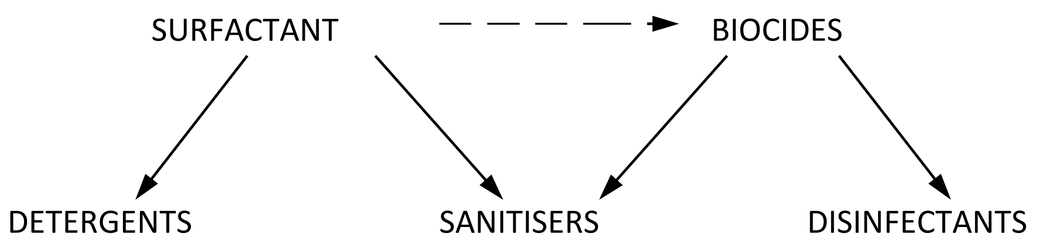
Cleaning and disinfection regimes for *L. monocytogenes* will also control other foodborne vegetative pathogens as it is particularly challenging because when it persists in food processing environments it is often in the form of a biofilm (Tomkin, 2002).

L. monocytogenes biofilms are difficult to eradicate as the biofilm protects the organism from environmental stresses. Although the majority of *L. monocytogenes* are attached to the biofilm, the cells in the upper layer can move around and were observed to transfer from the biofilms onto smoked or fresh salmon on contact (Truelstrup et al, 2011).

Routine cleaning and sanitation can be effective in preventing the establishment of biofilms (Aarnisalo, 2006). However, some studies suggest that effective cleaning and sanitation may not always be achieved for all surfaces (Salvat et al, 1995).

2. Definitions

A number of groups of formulated products are used to control hygiene in the food chain. Their relationship to other products and active chemicals is defined in the diagram below:



The active chemicals used in detergents and sanitisers are surfactants and biocides. Some surfactants also have biocidal activity and can perform a dual role in some formulations.

The definitions and understanding of these various products are essential to avoid confusion:

Biocide:	A chemical substance or microorganism intended to destroy, deter, render harmless, or exert a controlling effect on any harmful organism by chemical or biological means. See Table 3 for more detail on biocides, their advantages and disadvantages.
Cleaning:	The removal of food residues, dirt, grease and other undesirable matter. This requires physical energy, heat and/or chemicals (detergents). Cleaning only removes dirt from the surface but does not kill all bacteria.
Clean-as-you-go:	Maintenance of work areas in a clean and tidy manner at all times.
Detergent:	A chemical used to remove grease, dirt and food, such as washing-up liquid.
Disinfectant:	A chemical that reduces bacterial numbers to safe levels.
Disinfection:	The reduction of the number of microorganisms in the environment, to a level that does not compromise food safety or suitability.

High Risk Foods:	Foods supporting the growth of pathogens.
Hygiene schedule:	Documentation of procedures appropriate for dismantling or clean-in-place, cleaning and decontaminating (including methods, dosages and chemicals), the frequency of use or equipment and the monitoring procedures to assure compliance with hygiene requirements. The schedule includes in-plant environmental screening and also documentation for personnel hygiene systems.
Potable water:	Water meeting the minimum requirements laid down in Council Directive 98/83/EC, i.e. 'all water used in any food-production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption unless the competent national authorities are satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form.'
Sanitiser:	Chemicals that act as both detergent and disinfectant.
Surfactant:	The word is an abbreviation of the phrase 'surface active agent'. A surfactant is a chemical compound that reduces the interfacial tension between water and other liquids such as fats and oils. Surfactants types are cationic, anionic, non-ionic and amphoteric. An amphoteric surfactant can be either cationic or anionic depending upon the pH.

3. Management of Cleaning and Disinfection

Food Business Operators must use be a regularly reviewed, comprehensive, fully evaluated, confirmed and documented hygiene cleaning schedule for all equipment and food production environments, written by technical/production personnel and cleaning chemical representatives or other suitably qualified personnel.

Cleaning methods must be specified and documented and standards of cleaning, including laundering of protective clothing, must be compatible with the hygiene standards needed for the particular area of the facility.

A clean as you go system to prevent gross build-up of soiling, followed by comprehensive cleaning at the end of the production cycle. Methods used for 'clean as you go' should not generate aerosols which could contaminate adjacent lines or cross contaminate chemicals. It is important to keep the area as dry as possible.

Staff must be trained in the correct operation of hygiene schedules and the correct use of cleaning and decontamination equipment and ingredients, including chemicals.

There should be a pre-determined sequence of cleaning and disinfection. See section 6.

4. Biocides

Biocides used in the food industry are selected according to their intended use. See Table 1.

Table 1: Principal Categories of Biocides Used in the Food Industry

Environmental Biocides:	Quaternary Ammonium Compounds
	Iodophores
	Chlorine based agents
	Peracetic acid
Hand Biocides:	Quaternary Ammonium Compounds (Quats or QACs)
	Iodophores
	Chlorohexidine
	Polyhexamethylene biguanide
	Parachlorometaxylenol
	Triclosan
Carcass Biocides:	Hypochlorites
	Chlorate (source of chlorine dioxide)
	Organic Acids
Water Treatment Biocides:	Chlorine
	Chlorine dioxide
	Monochloramine

Table 2 summarises published literature regarding the effective removal of *L. monocytogenes* by commonly encountered sanitising agents.

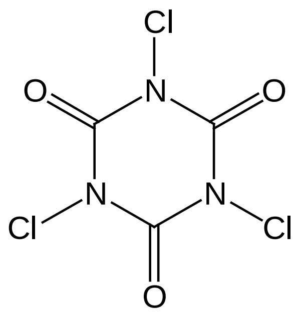
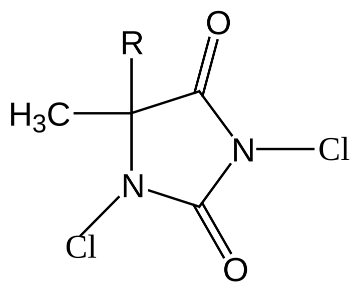
Table 2. The efficacy of sanitisers in removing *L. monocytogenes* contamination from poorly and properly cleaned surfaces or suspensions (Reproduced from Hoelzer et al)

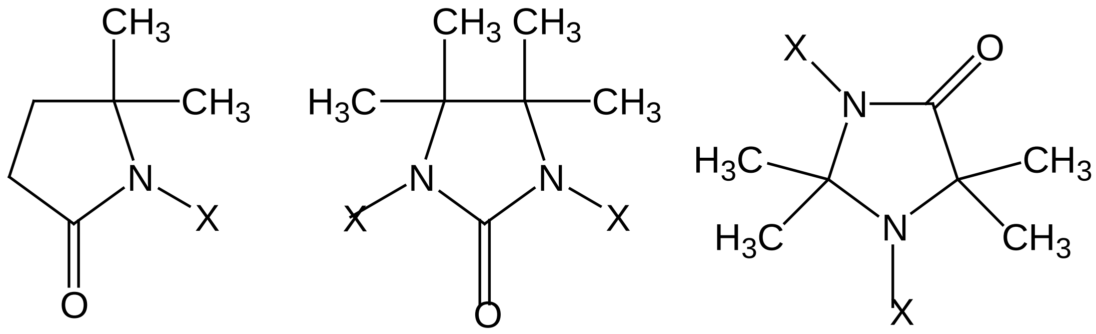
	In the absence of protein residues (effective cleaning)				In the presence of protein residues (poor cleaning)			
Sanitiser type	No. of studies reviewed	No. of observations	Total no. of replicates	Mean reduction (log cfu)	No. of studies reviewed	No. of observations	Total no. of replicates	Mean reduction (log cfu)
Acid-anionic	3	39	78	7.1	1	4	32	5.3
Halogen	3	27	124	3.8	2	9	60	2.4
Hypochlorite	11	321	891	5.5	4	38	117	2.8
Peracetic acid	6	177	484	4.6	2	24	52	3.8
Quaternary ammonium	5	59	262	6.1	2	8	56	5.3

Table 3: Main Classes of Biocides, their Advantages and Disadvantages

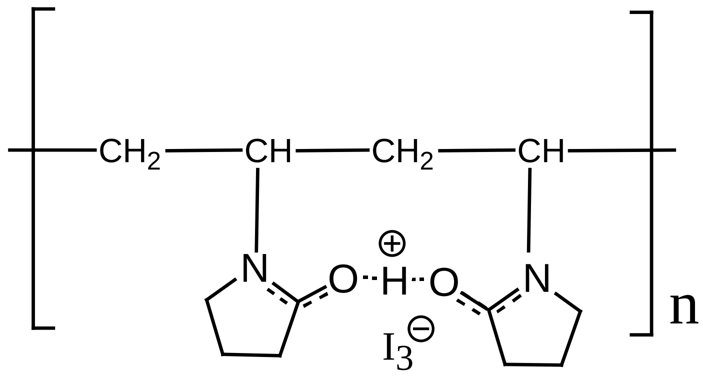
Acid-anionic	
Acid-anionic sanitisers are based on anionic surfactants (e.g. sodium salt of sulphonated oleic acid, dodecylbenzene sulphonic acid, sodium lauryl sulphate) in phosphoric acid. Use concentration: 100 - 200 ppm	
Advantages: 1. Non-staining, stable, long shelf life.	Disadvantages: 1. Effectiveness at acid pH only (pH2-3)

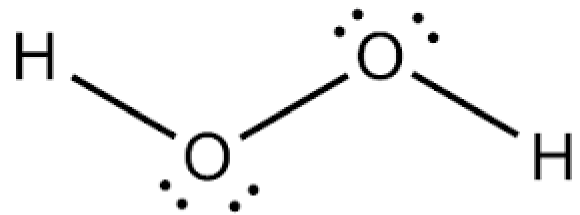
2. No objectionable odour. 3. Removes and prevents milkstone and waterstone formation. 4. Effective against a wide spectrum of organisms (certain viruses, some bacteriophage. 5. Stable in concentrated form or use dilutions, action enhanced by high temperatures. 6. Non-corrosive to stainless steel. 7. Provides short duration residual bacteriostatic effect on stainless steel equipment.	2. Generation of foam. 3. Low activity against spore forming organisms. 4. Corrosive to metals other than stainless steel.
Amphoterics	
Amphoterics have the general formula R-NH-CF2-COOH. They have substantial detergent activity and are suitable for manual application, spraying and soaking. Activity depends on the molecule used.	
Advantages: 1. Freely soluble in water 2. Effective against most vegetative bacteria and, at higher concentrations, yeasts and moulds. 3. Non-tainting 4. Low toxicity 5. Non-corrosive 6. Free rinsing 7. Detectable chemically 8. Biodegradable 9. Stable in concentrate and solution	Disadvantages: 1. Loses some activity at low temperatures and concentrations 2. Extended contact time required 3. Very sensitive to changes of pH 4. Can be incompatible with common anionic detergent components. 5. Sensitive to water quality

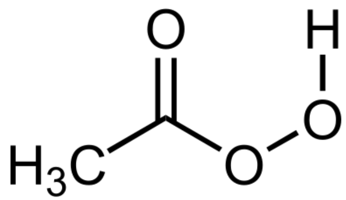
Biguanides	
Suitable for manual application, spraying, soaking or recirculation to combat Gram negative and Gram positive vegetative bacteria. At higher concentrations they are also effective against yeasts and moulds.	
Advantages: 1. Water soluble 2. Non-foaming 3. Non-tainting 4. Low toxicity 5. Biodegradable	Disadvantages: 1. Lose some activity at low temperatures 2. Effectiveness reduced in acid solution and inactivated above pH9 3. Of the two common biguanides, chlorhexidine is no longer permitted to be used in food area disinfection and PHMB has recently been reclassified to suspected of causing cancer.
Halogens	
<u>Chlorine-Based (see also Hypochlorite)</u> Active chlorine has been in use for many years as a disinfectant in the food industry because of its efficacy and cost. The active chlorine carrier may be a liquid based on inorganic chlorine compounds, such as sodium hypochlorite, or powder forms based on organic chlorine compounds such as dichloroisocyanurate. Most often the bactericidal effect of active chlorine is best in a neutral or weakly acidic condition (pH5-pH7), but chlorinated alkaline cleaners also have an excellent bactericidal effect against all groups of microbes. Chlorine achieves a very fast kill of viruses, bacteria, yeasts, and moulds. Activity against sporeforming bacteria is slightly slower.	*Chlorocyanurate*  *Chlorohydantoins*  R = methyl, ethyl

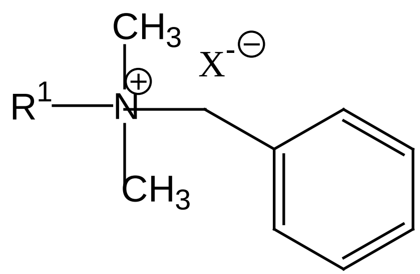
	Water soluble N-Halamines  X = Cl, Br
Advantages: 1. Broad bacterial spectrum activity 2. Unaffected by hard water scales 3. Non-filming 4. Can be used at cool water temperatures without affecting activity 5. Freely soluble and free rinsing 6. Biodegradable 7. Decomposes to non-toxic products	Disadvantages: 1. Stability of concentrate is limited and of dilutions very limited. 2. Efficacy affected by organic soil 3. Precipitation when used in iron-laden water 4. Short residual effect after disinfecting. Rule of thumb: if chlorine is used as a sanitiser prior to production, the equipment should be used within one hour after disinfection. 5. Corrosivity of hypochlorite solutions on metals such as stainless steel and aluminium must be assessed.

Hypochlorite	
Sodium hypochlorite (NaOCl) is widely used for surface decontamination, bleaching and odour removal both in the home and industrially. It is also widely used to disinfect water, e.g. drinking water and swimming pools. NaOCl is unstable. Chlorine evaporates at a rate of 0.75 gram active chlorine per day from the solution. NaOCl decomposes it comes in contact with acids, sunlight, certain metals and when heated. NaOCl is a strong oxidiser and reacts with flammable compounds and reducing agents. In solution it is a weak base that is inflammable. When NaOCl dissolves in water hypochlorous acid (HOCl) and the less active hypochlorite ion (OCl^-) are formed. The pH of the water determines how much HOCl is formed. Hydrochloric acid (HCl), sulphuric acid (H_2SO_4) or acetic acid can be used to lower the pH to increase its formation. HOCl decomposes into HCl and oxygen, which is a very strong oxidiser.	<u>Best practice NaOCl storage guidelines to minimise chlorate build-up</u>: 1. Buy NaOCl with low as possible levels of chlorate (<1.5 mg/l) 2. Store correctly: • In the dark • In the cool (at 5°C degradation to chlorate in the absence of heavy metal contamination is very limited. Every 10°C increase increases degradation rate 3-4 fold) • Note degradation is increased when the initial solution is more concentrated (at 20°C 12.5% solution degrades to 10% in 100 days). • Store in UPVC reinforced with glass fibre reinforced polymer (GRP) resin or a full post cured vinylester GRP laminate. 3. Do not add new NaOCl to old - this promotes chlorate formation. 4. Reduce the level of suspended solids to nearly undetectable levels to significantly reduce degradation.
Advantages 1. Powerful germicides controlling a wide range of microorganisms. 2. Deodoriser. 3. Non-poisonous at use concentrations. 4. Free from toxic residuals. 5. Colourless and non-staining.	Disadvantages: 1. Short shelf life. 2. Adverse effect on skin. 3. Corrosive on some metals 4. Gives off chlorine gas when mixed with acids. 5. Precipitation when used in iron-laden water.

6. Unaffected by hard water scales. 7. Non-filming, 8. Can be used at cool water temperatures without affecting activity. 9. Easy to handle, store and transport. 10. Most economical to use.	6. Short residual effect after disinfecting. Rule of thumb: if chlorine is used as a sanitiser prior to production, the equipment should be used within one hour after the disinfecting procedure. 7. To minimise chlorate build-up
Iodophor Sanitisers	
Iodophors are disinfectants formed by combinations of iodine with various carrier compounds. They release iodine in an acid medium and have biocidal properties against bacteria, viruses and some spores. The amount of active ingredients to achieve the same killing power is lower in iodophors than in active chlorine-based products. Iodophors are used for general disinfection and cleaning. However, hard water and the presence of large amounts of organic material reduce the activity of iodophors. They can function effectively in the presence of traces of organic material. Usually by increasing the temperature of the disinfecting solution, the killing time is reduced, and this is true for the iodine type products as well. Iodine will gas off at temperatures of 39°C-49°C and the loss of the iodine is high. It is standard practice to use iodophors at room temperature.	

Advantages:	Disadvantages:
1. Stable, long shelf-life. 2. They are active against all microorganisms except bactericidal spores and phages. 3. They are unaffected by hard water salts, with the exception of water which contains large amounts of chlorides, leading to corrosion of stainless steel and aluminium.	1. Not as effective against spores and phages as chlorine. 2. Expensive. 3. Stain porous metal surfaces and plastics. 4. Severely affected by alkaline conditions above pH 7.
Hydrogen Peroxide	
Hydrogen peroxide produces non-contaminating residues of water and oxygen. It used in the pharmaceutical and food industries for food contact and non-food contact surfaces including aseptic packaging areas. Hydrogen peroxide may be stabilised, e.g. silver compounds, the residues of which need to be considered. Most hydrogen peroxide applications consist of hydrogen peroxide injection into flowing water to control biological growth, to add oxygen, to remove chlorine residues and to oxidize sulphides, sulphites, metals and other easily oxidized materials. The suitability of hydrogen peroxide for these applications is influenced by pH, temperature and reaction time. Hydrogen peroxide can be combined with other agents, e.g. peracetic acid and peroxone (from reaction of hydrogen peroxide with ozone). It can also be used as a vapour for fogging.	

Advantages: 1. Powerful germicides controlling a wide range of microorganisms – bacteria, spores, fungi, yeasts, viruses. 2. Deodoriser. 3. Non-poisonous at use concentrations. (Safety depends on the applied concentration). 4. Free from poisonous residuals. 5. Colourless and non-staining. 6. Easy to handle. 7. Most economical to use.	Disadvantages: 1. Short shelf life. 2. In concentrated solutions increasing the temperature of the solution accelerates hydrogen peroxide destruction, the rate increasing by a factor of 2.2 for every 10°C rise in temperature. 3. Adverse effect on skin. 4. Corrosive on some metals. 5. Forms explosive mixtures upon contact with organic compounds. 6. Must be transported in polyethylene, stainless steel or aluminium containers. 7. Occupational exposure limit: 1ppm over an 8 hour period.
Peracetic Acid (Peroxyacetic Acid, PAA)	
Peracetic acid (also known as peroxyacetic acid) is a colourless liquid with a characteristic acrid odour reminiscent of acetic acid. Peracetic acid is an active oxygen-based sanitiser composed of hydrogen peroxide, peracetic acid, and acetic acid in combination. Peracetic acid destroys microorganisms by an oxidative action. It can be highly corrosive. Use: typically 50-200ppm active PAA	Peracetic acid 
Advantages: 1. Remains effective at temperatures as low as 0˚C 2. Very effective against most bacteria (gram positive and gram negative) at low concentrations and generally	Disadvantages: 1. Concentrate has a strong odour. 2. Concentrate is to be handled carefully. 3. Once diluted it has a limited shelf life

effective against yeasts, moulds and spores at higher concentrations. 3. Non-tainting 4. Non-toxic in use dilutions, decomposition products toxicologically safe - residuals turn into water and acetic acid 5. Incidental food contact does not affect taste of milk or beverages. 6. Freely soluble 7. Free rinsing 8. Can be detected chemically 9. Biodegradable 10. Good stability in concentrate 11. Not significantly affected by hard water 12. Low corrosivity at use concentration 13. No staining 14. No foaming 15. Compatible with acid rinse.	4. Only suitable for use on glass or stainless steel surfaces 5. Efficacy affected by organic soil 6. Expensive
Quaternary Ammonium Compounds (QACs, Quats)	
QACs are natural biochemicals involved in the transmission of neuromuscular impulses in mammals. Synthesized QACs are surface-active cations which have sanitising/disinfecting and mild detergent actions. They act as one-step cleaner/sanitizers in aqueous solution or when combined with detergents. QACs are generally more effective in slightly alkaline media and their efficacy can be significantly improved by formulation with sequesterants such as EDTA and with non-ionic surfactants. Since they are particularly effective against Gram positive bacteria such as *L. monocytogenes* they are widely used in food	 $R^1 = C_{12} - C_{18}$ $X^{-} = Cl, Br.$

production and food-handling establishments, and in agricultural settings. They are effective against skin flora particularly staphylococci and find use in hand based sanitisers. In appropriate dilutions, QACs are effective, non-toxic, biodegradable disinfectants. Even in the presence of hard water and/or moderate amounts of organic material, they have a broad spectrum of antibacterial, antifungal and antiviral activities. When used in recommended concentrations, they are tasteless, odourless and virtually non-toxic. Use concentrations: 200 ppm solution and a one minute exposure.	
Advantages: 1. Stable, long shelf life. 2. Active against many microorganisms. 3. Forms a bacteriostatic film. 4. Non-corrosive and non-irritating to skin. 5. Stable in the presence of organic matter. 6. Stable to temperature changes. 7. Good penetration qualities. 8. Combined with non-ionic wetting agents, it makes a good detergent sanitiser.	Disadvantages: 1. Effectiveness reduced at low temperatures 2. Possible taint problems 3. Incompatible with common anionic detergent components. 4. Slow to dissipate (residue problems). 5. Germicidal efficiency varied and selective. 6. Foam problem in mechanical application. 7. Detectable chemically 8. Generally biodegradable

6. Cleaning and Disinfection in Practice

A dirty surface cannot be disinfected effectively as the biocidal active cannot come into contact with bacteria trapped in and under soil. Extraneous organic material also dilutes and neutralises biocides before they are applied so surfaces must be cleaned. Neither large quantities of disinfectants nor high-pressure application can replace effective and thorough pre-disinfection cleaning.

Effective cleaning must therefore be carried out before applying a sanitiser to reduce the number of microorganisms.

See Appendix 4 for example hygiene recording templates.

Summary Approach - Cleaning:

- Remove gross debris from surfaces
- Apply detergent to loosen soil and bacteria and hold them in solution or suspension
- Rinsing with water, to remove loosened soil and residues of detergent
- Dry cleaning or other appropriate methods for removing and collecting residues and debris; and where necessary, disinfection.

The choice of detergent depends on the type of soiling, on water hardness, the temperature of the method, the types of surfaces and safety. In general, alkaline detergents are used for the removal of organic soils, while acidic detergents are used on inorganic soils. Detergent suppliers normally have a range of options for varying and specific circumstances.

Once cleaning has been completed, disinfection must be carried out using biocide appropriate to the type of surface material to be disinfected. For example, caustic products are corrosive to soft metals (e.g. aluminium). Check the manufacturer's recommendations regarding suitability of chemicals.

Summary Approach – Disinfection:

- Always make up a fresh solution of disinfectant. If disinfectant is stored after it has been diluted it may not be fully effective. This can allow bacteria to survive and become resistant to the biocide.
- Always follow the manufacturer's instructions. Read the entire biocidal product label and follow dilution instructions explicitly to ensure that the safest, most effective concentration is applied.
- Apply the biocide in accordance with instructions, to every surface and recess, starting at the highest point and working downwards.
- Leave the biocide on surfaces for as long as indicated in the instructions.

Verification of Cleaning and Sanitation:

- Efficiency of cleaning and sanitation should be checked, recorded and verified at routine intervals and documented formally (see Appendix 4 for example hygiene recording templates)

- The frequency of verification should be based on risk assessment

- Monitoring methods include:

    - Visual inspection
    - Microbiological swabs
    - In process/finished product testing
    - Microbiological checks of rinse water
    - Hygiene/housekeeping audits

- Corrective action must be carried out as required to improve cleaning and disinfection results

- Possible causes of disinfection failure include:

    - over-dilution of disinfectant during pre-mixing or application
    - incomplete or inadequate cleaning
    - poor disinfectant penetration or coverage
    - insufficient contact time on surfaces
    - Inadequate temperature and humidity while the material is being applied.
    - Inactivation or neutralization of the disinfectant, due to the presence of residual cleaning liquids which were not adequately flushed away before the disinfectant was applied.

Disinfectant Data Checklist:

Items to be considered in ensuring responsible disinfectant use food production or handling applications include:

- Product name
- Product manufacturer
- Product licensed or approved in country and region
- Active ingredients
- Entire label read by applicators and supervisors
- Label safety precautions
- Label residue precautions
- Other products used or combined/mixed
- Dilution rate
- Final concentration
- Temperature of diluent
- Product toxicity; oral, skin and eye contact
- Product carcinogenic
- Corrosive to materials

7. Risk Assessment of Biocides Remaining on Contact Surfaces

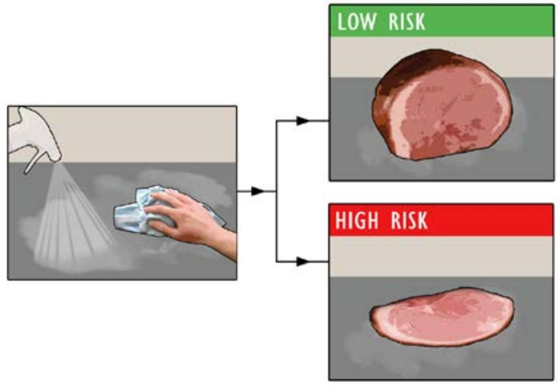
BRC Global Food Standard Issue 7 clause 4.11.3 states:

"*As a minimum for food contact surfaces and processing equipment and environmental cleaning in high care/high risk areas limits of acceptable and unacceptable cleaning performance shall be defined. This shall be based on the potential hazards (e.g. microbiological, allergen, foreign body contamination or product to product contamination). Acceptable levels of cleaning may be defined by visual appearance, ATP bioluminescence techniques, microbiological testing or chemical testing as appropriate. Where cleaning procedures are part of a defined pre-requisite plan to control the risk of a specific hazard the cleaning and disinfection procedures and frequency shall be validated and records maintained. This shall include the risk from cleaning chemical residues on food contact surfaces.*"

Risk Assessment

Disinfectants are applied to an area of food contact surface. The residue limit relates to the weight of the food. Therefore, the areas likely to give rise to the highest residues are those with a high ratio of surface area to weight, i.e. thin or finely sliced foods in direct contact with disinfected equipment.

Meat slicers or mincers are examples of areas with potential to lead to high residues of disinfectant.



Control Measures

Having identified the areas likely to give rise to the highest residues, the options are then as follows:

1. Take samples of the food and send them for analysis to confirm levels of residue and identify whether further actions are necessary. Analysis results will only give indicative values for complex or processed foods as there are no validated methods for them. Results can be used to determine whether there are high levels of contamination and therefore whether further actions are necessary.
2. Disinfect smaller items thermally in a dishwasher if practical to do so.
3. Disinfect with a biocide which does not give rise to lasting residues. Alcohol and Peracetic acid are alternatives.
4. If disinfectants are used to protect plant equipment overnight, it may be possible to use more dilute solutions based on long contact time efficacy data.
5. For larger sites with limited product ranges, consider discarding the first few items off the production line. These are likely to take away most of the residues with them.
6. Rinsing or wiping disinfectants away after use will substantially reduce the levels on the surface.
7. Separate out cleaning steps from disinfection steps. Use a dedicated cleaning product for some of the processes to reduce overall disinfection consumption.
8. Switch to an alternative disinfectant. This is at best a short term solution since all other biocides are expected to encounter similar issues to QACs. This is also invariably an expensive option.

8. Further Reading and References

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Appendix 1: PT4 Biocides

Name	EC_No	C
2,2-dibromo-2-cyanoacetamide (DBNPA)	233-539-7	1
2-Phenoxyethanol	204-589-7	1
5-chloro-2-(4-chlorphenoxy)phenol (DCPP)	429-290-0	3
6-(phthalimido)peroxyhexanoic acid (PAP)	410-850-8	1
Active Chlorine: manufactured by the reaction of hypochlorous acid and sodium hypochlorite produced in situ		
Alkyl (C12-16) dimethylbenzyl ammonium chloride (ADBAC/BKC (C12-16))	270-325-2	6
Alkyl (C12-18) dimethylbenzyl ammonium chloride (ADBAC (C12-18))	269-919-4	6
Alkyl (C12-C14) dimethylbenzylammonium chloride (ADBAC (C12-C14))	287-089-1	8
Alkyl (C12-C14) ethylbenzylammonium chloride (ADEBAC (C12-C14))	287-090-7	8
Amines, C10-16-alkyldimethyl, N-oxides	274-687-2	7
Amines, N-C12-C14 (even-numbered)-alkyl trimethylenedi-, reaction products with chloroacetic acid (Ampholyt 20)		1
Biphenyl-2-ol	201-993-5	9
Calcium hypochlorite	231-908-7	7
Chloramin B	204-847-9	1
Chlorine dioxide	233-162-8	1
Didecyldimethylammonium chloride (DDAC (C8-10))	270-331-5	6
Didecyldimethylammonium chloride(DDAC)	230-525-2	7
Disodium peroxodisulphate/Sodium persulphate	231-892-1	7
Ethanol	200-578-6	6
Formic acid	200-579-1	6
Glutaral (Glutaraldehyde)	203-856-5	1
Glycolic acid	201-180-5	7
Glyoxal	203-474-9	1
Hydrogen peroxide	231-765-0	7
L-(+)-lactic acid	201-196-2	7
Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (Mixture of CMIT/MIT)		5
Monohydro chloride of polymer of N,N‴-1,6-hexanediylbis[N′-cyanoguani dine] (EINECS 240-032-4) and hexamethylenediamine (EINECS 204-679-6)/ Polyhexamethylene biguanide (monomer:1,5-bis(trimethylen)-guanylguanidinium monohydrochloride) (PHMB)		2
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine (Diamine)	219-145-8	2

Pentapotassium bis(peroxymonosulphate) bis(sulphate)	274-778-7	7
Peracetic acid	201-186-8	7
Peroxyoctanoic acid		3
Poly(oxy-1,2-ethanediyl), .alpha.-[2-(dide cylmethylammonio)ethyl]- .omega.- hydroxy-, propanoate (salt) (Bardap 26)		9
Propan-1-ol	200-746-9	7
Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, salts with 1,2-benzisothiazol-3(2H)-one 1,1-dioxide	273-545-7	6
Reaction products of: glutamic acid and N-(C12-C14-alkyl)propylenediamine (Glucoprotamin)	403-950-8	1
Salicylic acid	200-712-3	6
Silver	231-131-3	7
Silver copper zeolite		1
Silver nitrate	231-853-9	7
Silver sodium hydrogen zirconium phosphate	422-570-3	2
Silver zeolite		
Silver zinc zeolite		1
Sodium 2-biphenylate	205-055-6	1
Sodium dichloroisocyanurate dihydrate	220-767-7	5
Sodium hypochlorite	231-668-3	7
Sulphur dioxide	231-195-2	2
Symclosene	201-782-8	8
Tetrachlorodecaoxide complex (TCDO)	420-970-2	9
Tosylchloramide sodium (Tosylchloramide sodium - Chloramin T)	204-854-7	1
Troclosene sodium	220-767-7	2

Appendix 2: Joint position paper on setting Maximum Levels for biocides in food

Brussels, 2 March 2016

Cefic-EBPF, A.I.S.E., FOODDRINKEUROPE & ECFF

Introduction/Background

In May, September and November 2015, the European Commission (DG SANTE) presented a note for discussion on Maximum Residue Levels (MRL) to the competent authorities for biocidal products. The purpose is to develop a policy approach for the establishment of Maximum Levels (ML) of biocidal active substances in food and feed and specific migration limits in food contact materials.

OVERALL INDUSTRY POSITION

The undisputed goal of the policy has to be food safety and maintaining high levels of food hygiene. Overall, we do not consider default limit values appropriate for biocides in food. Only in those cases of food related applications where a health concern exists, should Maximum Levels be set according to the need. This should be achieved by a step-wise approach. The first step is to identify critical use areas by a tiered health based risk assessment. Should the tiered health based risk assessment raise any health concerns, Maximum Levels for this biocide in food would be established in a second step. Trace levels of biocides in food should be regulated under one single piece of legislation. Based on past experience, we consider Reg. 396/2005 an inappropriate legislative tool for biocides in food.

OUR KEY MESSAGES

Food safety and food hygiene have to remain the key objectives

Industry considers food safety as the number one priority. This therefore has to be the main objective of the overall policy regarding biocides and their use in the entire food chain. Maintaining high levels of food hygiene is of utmost importance and significantly helps to prevent illness from food poisoning and food borne illness. This must be achieved via the right balance between an effective control of harmful organisms and safeguarding consumers from exposure to unintended traces of biocidal products.

A default approach is not appropriate for biocides

We concur with the Commission that the majority of biocidal uses are not concerned with food exposure. Moreover, it has to be acknowledged that there is no direct application of biocides to food or feed. The assumption of any residual presence by default is hence unfounded. Therefore, we consider the application of default limit values not appropriate for biocides. Only in those cases of food related applications where a health concern exists, should Maximum Levels be set according to the need.

Step-wise approach is the appropriate tool

We strongly support a pragmatic and health-risk based approach, as suggested by the Commission, for the identification of areas where the setting of Maximum Levels is considered to be appropriate. This should be achieved by a step-wise approach. The first step is to identify the use areas of concern by a tiered health based risk assessment. Only in cases where such assessment raises a specific health concern should Maximum Levels for this biocide in food be established in a second step.

Point of control of the correct use of an authorised biocidal product

In case of disinfectants for product type 4 (food and feed area), industry considers the determination of traces of biocides on surfaces as the right point of control of the correct use of an authorised biocide as part of the HACCP (Hazard Analysis and Critical Control Points) concept. In case of water treatment (PT 5) (for food processing, irrigation etc.), industry considers the right point of control to be the water rather than the food.

Single framework approach – but not Regulation 396/2005

Industry favours that the setting of Maximum Levels is regulated under one single framework. This will ensure legal certainty and clarity, and reduces complexity for all the stakeholders involved. Based on recent experience, we consider that Reg. 396/2005 is an inappropriate framework since it has been developed for products directly applied on food/food commodities according to good agricultural practices, and involves a completely different approach and objective for the setting of Maximum Levels.

Industry considers the terminology 'residues' not appropriate for biocides, as no biocidal product is purposely applied to the food. By using the term 'residues', many regulators automatically consider the plant protection products legislation. 'Traces' is a more appropriate wording for unintended levels of a substance in food. Unintended levels lead to the definition 'contaminant' according to the contamination legislation (Article 1, Reg (EEC) 315/93[1]). When avoiding the terminology 'residue', also MRL becomes ML.

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[1] 'Contaminant' means any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination.

Appendix 3: CFA Produce Washing Protocol

The Chilled Food Association established leafy produce and non-leafy produce wash protocols in 2005 and 2006, respectively, with the aim of reducing excessive doses of hypochlorite in particular. The protocols were consolidated in 2010 to introduce further consistency into produce washing, e.g. hypochlorite dosing and pH control.

Washing (primary and secondary) is the removal of soil, other gross debris, and plant tissue exudates that occur during cutting. Sanitising is treating water with an agent that is designed to prevent cross-contamination during washing. Washing and sanitising has the potential, if properly controlled, to reduce the overall microflora of leafy vegetables and herbs. However it will not eliminate microbiological contamination; therefore, minimising the potential for contamination in the field from the seed onward is key to assuring microbiological quality.[1]

Primary wash:

*<10ppm free chlorine (if used)
<100 ppm total chlorine (if used)
pH 6-7 if chlorinated, otherwise no constraint
Maximum 2 minute residency if chlorinated, otherwise no constraint
Ratio minimum 4:1 litres water:kg product, dependent on the fragility of the produce

Secondary Wash:

*<25ppm free chlorine (if used)
<100 ppm total chlorine (if used)
pH 6-7 if chlorinated, otherwise no constraint
Maximum 2 minute residency if chlorinated, otherwise no constraint
Ratio minimum 4:1 litres water:kg product, dependent on the fragility of the produce

* The minimum required amount of chlorine should be determined by validation
Alternative sanitisers may be used if properly validated - See CFA's Produce Decontamination Assessment Protocol: Part 2 - Washwater Validation (CFA/55/10).

[1] FAO/WHO. 2008. *Microbiological hazards in fresh leafy vegetables and herbs: Meeting Report*. Microbiological Risk Assessment Series No. 14. Rome.

CFA/043/16

Appendix 4: Hygiene Planning and Assessment Recording Templates

Advisory Note: these templates are offered as examples of good practice, but it is essential that they are re-worked so they are specific to the particular work-place where they are used. It is particularly important that any instructions, forms or schedules accurately reflect work-place methods, equipment and practices.

Template	Topic
1	Cleaning and disinfection after operation
2	Cleaning during operation
3	Deep cleaning
4	Cleaning and disinfection of special items/areas
5	Cleaning frequencies and cleanliness thoroughness
6	Cleaning and disinfection directory
7	Visual cleanliness inspection planning
8	Visual monitoring verification
9	Microbiological monitoring planning
10	Microbiological monitoring verification

Examples of cleaning schedules for small food businesses can be found in:

- FSA Safer Food Better Business Pack: https://www.food.gov.uk/sites/default/files/multimedia/pdfs/publication/cleanschd-sfbb-0513.pdf
- http://www.food.gov.uk/sites/default/files/multimedia/pdfs/pdf-ni/safe-catering.pdf (Northern Ireland)
- FSS Cook Safe: http://www.foodstandards.gov.scot/sites/default/files/cshrcleaning.pdf (Scotland)

Also look to trade association websites for help and any associated Primary Authority Assured Advice.

TEMPLATE 1: CLEANING AND DISINFECTION AFTER PRODUCTION

Approved, date. ___.___.-___, ______(plant representative)

date. ___.___.-___, ______(control official)

Room area	**Hygiene area**
Operative	
Precleaning	
Disassembly of machinery	
Pre-rinse	
Washing	
Settling time	
Disinfection	
Rinsing	
Removal of protective covers and disinfection of protected items	
Drying	

Completion instructions:

The form is used to describe in as much detail as possible, what is to be cleaned and disinfected, how and by using what tools, as well as indicating who does the cleaning and disinfection.

TEMPLATE 2: CLEANING AND DISINFECTION DURING PRODUCTION

Approved, date. ___.___.-___, ______(plant representative.)

date. ___.___.-___, ______(control official.)

Room area	**Hygiene area**
During Production	
During a break	
In special circumstances	

Completion instructions:

The form is used to describe in as much detail as possible, what is to be cleaned and disinfected, how and by using what tools, as well as indicating who does the cleaning and disinfection.

TEMPLATE 3: DEEP CLEANING

Approved, date. ___.___.-___, ______(plant representative.)

date. ___.___.-___, ______(control official)

Room area	**Hygiene area**
Operative	
Prewash	
Disassembly of machinery, and the cleaning and protection of objects that cannot withstand washing	
Pre-rinsing	
Washing	
Rinsing	
Settling time	
Disinfection **Hot handling**	
Rinsing	
Removal of protective covers and disinfection of objects that cannot withstand washing. **Description**	

Completion instructions:

The form is used to describe in as much detail as possible, what is to be cleaned and disinfected, how and by using what tools, as well as indicating who does the cleaning and disinfection.

TEMPLATE 4: CLEANING AND DISINFECTION OF SPECIAL ITEMS/AREAS

Approved, Date. ___.___.-___, ______(plant representative)

Date. ___.___.-___, ______(control authority)

Factory area:
Cleaning and disinfection of special items/areas: **-**
-
-

Completion Instructions:

The form is used to describe in as much detail as possible, what is to be cleaned and disinfected, how and by using what tools, as well as indicating who does the cleaning and disinfection.

Special items/areas are, for example waste containers, cold areas, cold pant/equipment, ventilation system openings, pipes, electrical equipment, the surroundings of electrical switches, vehicle.

APPENDIX 5: CLEANING FREQUENCIES AND CLEANING EFFICACY

Approved, date. ___.___.-___, ______(plant representative)

date. ___.___.-__,________(control authority)

Room	(Hygiene area)	Cleaning efficiency and frequency Ordinary	Deep cleaning
Walls: Lower portions			
Upper portions			
Doors			
Ceilings			
Upper constructions (list)			
-Roof beams/struts			
-Electric leads			
-Supporting pillars			
Windows			
Floors			
Stands			
Staircases			
Cupboards			
Surfaces (list)			
-			
-			
Equipment/Plant (list)			
-			
-			
-			
Tools (list)			
-			
-			
-			
-			

Special items/areas (list)		
-		
-		
-		
-		
Others		
-		
-		
-		

Completion Instructions:

The description of cleaning and disinfection must be made for each room. In this description 'room' means a single room or room group, which can be cleaned in the same way.

Work surfaces, equipment and tools in the room are to be listed.

Cleaning frequencies (once a day, as required, weekly, twice yearly) are specified for production area construction, equipment, tools and special items/areas according to their particular requirements.

Cleaning frequencies for ordinary cleaning and deep cleaning are specified (for example after production, during breaks in production, May and December).

Special items/areas are, for example, waste containers, cold/chilled areas, ventilation system openings, pipes, electrical equipment, the area surrounding fuse boxes, electrical switches, transport vehicles.

TEMPLATE 6: DIRECTORY OF DETERGENTS AND DISINFECTANTS

Approved, Date___.___.-___, ______(plant representative)

Date ___.___.-___, ______(official authority)

Detergent or disinfectant	**Usage**

TEMPLATE 7: PLANNING OF THE INSPECTION OF VISUAL CLEANLINESS

Approved, Date ___.___.-___, ______(plant representative.)

Date ___.___.-___, ______(official authority)

Room area	**(Hygiene area)**	**Inspection prior to commencement of production**	**Inspection,** **Time**	**Inspection,** **Time**
Walls: Lower portion				
Upper portion				
Doors				
Ceilings				
Upper contructions (listing)				
- Roof beams/struts				
- Electric leads				
- Supporting pillars				
Windows				
Floors				
Staircases				
Cupboards				
Surfaces (list)				
-				
-				
-				
-				
-				
Equipment/Plant (list)				
-				
-				
-				
-				
-				

Tools (list)			
-			
-			
-			
-			
-			
Special items/areas (list)			
-			
-			
-			
-			
Others			
-			
-			
-			

Surfaces washed daily are to be inspected on a daily basis before commencement of production.

Less frequently cleaned surfaces, equipment and tools are to be inspected in accordance with a planned programme. Please ensure that any items listed here are a true reflection of what is used and in place.

TEMPLATE 8: VERIFICATION OF VISUAL CLEANLINESS

Approved, Date. ___.___.-___, ______(plant representative)

Date ___.___.-___, ______(official authority)

Date. ___.__ time___ Operative _____

Room area	**(Hygiene area)**	**Cleanliness rating**	**Corrective action**	**Corrective action completed (operative and time)**	**Approved (operative and time)**
Walls: Upper					
Lower					
Doors					
Ceilings					
Upper constructions (list)					
- Roof beams/struts					
- Electric leads					
- Supporting pillars					
Windows					
Floors					
Stairs					
Cupboards					
Surfaces (list)					
-					
-					
-					
Equipment/plant (list)					
-					
-					
-					
Tools (list)					
-					
-					
-					

-					
Special items/areas (list)					
-					
-					
-					
Others					

Checking visual cleanliness applies to a room area (one room or room group) buildings, equipment, tools and special equipment/plant.

Corrective actions:

1. Clean again immediately
2. Clean at a specified (noted) time
3. Clean in combination with deep cleaning
4. Remove (work or broken, can no longer be cleaned)
5. Modify cleaning programme

The operative checking visual cleanliness, the operative carrying out corrective actions and the person approving corrective actions are to initial and date the form.

You also may use other systems of verification, for example ATP testing on some critical areas to check that disinfection has been carried out, as this cannot be determined by visual checking.

TEMPLATE 9: PLANNING MICROBIOLOGICAL MONITORING

Approved, Date. ___.___.-___, ______(plant representative)

Date. ___.___.-___, ______(official authority)

Room area	(Hygiene area)	Microorganism/ result	When	Microorganism/ result	When
Surfaces (list)					
-					
-					
-					
Equipment (list)					
-					
-					
-					
Tools (list)					
-					
-					
-					
-					
Special items/areas (list)					
-					
-					

The standard is defined according to results and specifications

Limits values are defined according to results and specifications

TEMPLATE 10: VERIFICATION OF MICROBIOLOGICAL MONITORING

Approved, Date. ___.___.-___, ______(plant representative)

Date. ___.___.-___, ______(official authority)

Date. ___.__ time ___ Operative _____

Microorganism/ result__________

Result evaluator ____________

Room area	Hygiene area	Result	Action/ Corrective action	Corrective action operative and time	Approved
Surfaces (list)					
-					
-					
-					
Equipment (list)					
-					
-					
-					
Tools (list)					
-					
-					
-					
Special items/areas (list)					
-					
-					

The sampler/checker, result evaluator, corrective action operative and person approving corrective actions initial and date the form.

Action: Repeat sample

Corrective actions:

1. Clean again immediately
2. Clean at a specified (noted) time
3. Clean in combination with deep cleaning
4. Sanitation [deep] cleaning
5. Modify cleaning programme

The operative checking visual cleanliness, the operative carrying out corrective actions and the person approving corrective actions are to initial and date the form.