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Hygiene in food processing

Edited by
H. L. M. Lelieveld, M. A. Mostert,
J. Holah and B. White



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1

Introduction

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The Codex Alimentarius Commission (CAC) defines food hygiene as ‘all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain’ (Anon., 1997). Similarly, the EU’s General Food Hygiene Directive has defined food hygiene as ‘all measures necessary to ensure the safety and wholesomeness of foodstuffs’ (Anon., 1993). The Directive includes all stages of the supply chain in this definition, from harvesting, milking or slaughter through to the point of consumption. Hygiene is defined in very broad terms, potentially incorporating any measure designed to prevent contamination of food, whether from a physical, microbiological or chemical source, at any stage of production.

In the US there is greater focus on the concept of food sanitation defined, for example, as the ‘hygienic practices designed to maintain a clean and wholesome environment for food production, preparation and storage’ (Marriott, 1999). This second definition links hygiene more specifically with maintaining a clean working environment during food processing. However, even here hygiene as a subject can be seen as extending beyond the practice of cleaning itself to incorporate those elements which make cleaning possible. As an example, good plant, process and equipment design is critical to effective sanitation. Similarly, a hygienic processing environment depends on a broader range of measures including the right working practices for personnel involved in handling food, the control of insect and other pests, and the prevention of non-microbial contaminants such as foreign bodies.

This volume can be seen as part of a series of studies that look at hygiene in its broadest sense, including the control of chemical contaminants (Watson, 2001), measures to control particular pathogens (Blackburn and McClure, 2002), the application of HACCP systems to manage such hazards (Mayes and Mortimore, 2001), and the use of risk assessment to set objectives for HACCP and other food safety management systems (Brown and Stringer, 2002). The book begins by looking at the regulatory context. Chapter 2 provides an overview of the range of legislation in this area, from the international arena to application at national level. It also places hygiene in the broader context of

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HACCP systems and risk management. The following two chapters then consider the regulatory framework in the EU and USA.

Part II looks at the key issue of hygienic design. It is prefaced by an introductory chapter on the range of physical, chemical and microbiological contaminants that must be dealt with to maintain a hygienic food processing environment. The chapter concludes with a case study on the broad range of measures required to control a particular pathogen, *E. coli*, at the various stages of the food chain from 'farm' to 'fork'. The next two chapters look at hygienic plant design, including the particular control of airborne contamination. They are followed by a sequence of four chapters on hygienic equipment design, looking at general principles, construction materials, piping systems and the design of equipment for cleaning in place. A final chapter reviews methods for verifying the bacterial tightness and cleanability of equipment and certification schemes in Europe and the USA.

The final part of the book reviews the practices required to maintain a hygienic environment during food processing operations. Chapter 13 reviews the types of cleaning chemical and disinfectant and their use, sanitation programmes and methods for assessing their effectiveness. The following chapter discusses how to ensure that sanitation does not itself become a source of contamination. Since the personnel working in a food processing environment are a major potential source of contamination, Chapter 15 reviews the key topic of personal hygiene. The book then concludes with chapters on the prevention of foreign bodies and insect pests.

The reader may perceive that the focus of the book is on Europe and the USA. This focus is the result of the rather intensive communication between the USA and Europe on questions of hygienic manufacture, in particular between EHEDG and 3A/IAFIS. Nevertheless, the recommendations given in this book apply equally well to any other area in the world. It may be of interest to know that currently EHEDG Regional Sections are under development by interested organisations in several Asian countries. For more information please contact the EHEDG Office or look at the EHEDG website (www.ehedg.org).

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Part I

Hygiene regulation

2

The regulation of hygiene in food processing: an introduction

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2.1 Introduction

There is a steady increase in the involvement of regulatory and advisory bodies in the area of food process hygiene. Major programmes are underway to revise the nature of regulatory intervention, together with supporting educational and accreditation programmes. There are a number of reasons for this, especially highly publicised incidents such as BSE, Foot and Mouth outbreaks in Europe, and a myriad of problems with individual products. Examples include benzene in water, insecticide in soft drinks, dioxins in olive oil, spent lubricant oil in animal feed, the offering of condemned chicken meat for human consumption, ethylene glycol in white wine, and deaths and hospitalisation caused by food poisoning. Many of these incidents are given a high profile because they happen to international brands. Another factor can be the political fallout as nation states impose import bans. The use of pesticides, antibiotics, genetically modified organisms and hormones in farming has also been causing concern amongst consumers and experts. The sale of foods classed as organic has been rising quickly as people attempt to exercise choices they feel may protect them. Food scares have dented consumer confidence in the food industry.

We are starting to see 'Farm to Fork' approaches that consider the food process to include the whole chain from supply of animal feeds, and the farming of animals and crops, to industrial food processing and retail and restaurant outlets. This is supported by moves in the developed countries of the world to unify and consolidate control strategies and agencies, in order to shift the balance towards prevention and to increase the effectiveness of food safety programmes. In response to these and other concerns, in 1998 the US

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government commenced its coordinated 'Food Safety Initiative', with a budget of \$43 million in 1998 with a further \$101 million in 1999. Australia and New Zealand have, for example, pooled their efforts since 1995 in the Australia and New Zealand Food Authority (ANZFA). This has led to the new Joint Food Code, which became the sole ANZFA Food Standards Code by late 2002. The first parts of this code became legally enforceable in February 2001. In the European Union, concerns about food safety have led to the reorganisation of the European Commission's responsibilities and the formation of a centralised food safety authority, The European Food Safety Authority (EFSA). In the UK, a new centralised Food Safety Agency, mandated to protect the consumer, is increasingly setting policy and requiring action.

Much of the new legislation and supporting instruments are based on the internationally developed United Nations Food and Agricultural Organisation (FAO) *Codex Alimentarius*, contributing to a national and international trend towards harmonisation. Trading blocs as well as individual nations may exert an influence on hygiene legislation beyond their geographical boundaries by controlling hazardous imports. Europe and the USA may also have a significant influence beyond their jurisdiction because of the fact that they have highly developed legislation in the area of food safety. In the case of the EU, states aspiring to membership may adopt the EU directives 'off-the-shelf' as part of their own commercial, legislative and political strategies. Other neighbours such as Switzerland implement adaptations of EU legislation to ensure they can trade freely with the EU.

2.2 Risk management and HACCP

The most important international trend, supported by the FAO *Codex Alimentarius*, has been towards methodologies based on risk management, such as the Hazard Analysis and Critical Control Point (HACCP) system. Legislative and regulatory implementation is at various stages around the world. The EU took the initiative in 1993 (Council Directive 93/43/EEC) by making HACCP mandatory across the food industry. Implementation of the Directive since then has proceeded considerably faster in some member states than in others. In Australia, New Zealand and the USA, the pattern has been one of introducing HACCP laws by industry sector. The Food and Drug Administration (FDA) in the USA has made it abundantly clear that it sees risk management via HACCP rather than increased frequency of inspection as the way forward. A key challenge has been making the conceptual change from fixed rules and threshold values to one of risk assessment and critical control point methodologies. As an example, in The Netherlands, the application of HACCP in various food-processing sectors is supported by hygiene codes produced by Industry Associations under the control of the Ministry of Health, Welfare and Sport (VWS). In a recent survey, it was noted

that key definitions such as *Critical Control Point* did not agree between the various hygiene codes, leading to potential problems for operators who might be affected by a number of different codes (de Vreeze, M.E.J. and Bosboom, M.M.M., '*Harmonisatie van Nederlandse Hygienecodes*', Nederlands Normalisatie-Instituut, March 1998).

Even within the EU, member states have been taking different approaches to their duty under Directive 93/43/EEC Article 5 to provide guidelines and support for HACCP implementation. As an example, Ireland has implemented the directive in its mandatory standard I.S.342: 1997, *Guide to Good Hygiene Practice for the Food Processing Industry*, setting minimum standards of hygiene practice, and has supported this by establishing the voluntary standard I.S.343-2000 *Food Safety Management incorporating Hazard Analysis and Critical Control Point* as a basis for HACCP implementation. In addition to a legal requirement for there to be a person with appropriate hygiene training at each retail premises, the Dutch government has provided codes of practice for small businesses such as food retailers. After a serious outbreak of *E. coli* food poisoning, the UK has implemented a full HACCP programme using a small army of consultants to cover retail butchers' premises.

HACCP implementation has occurred in various stages. At the highest and earliest level, EU directives, just like ANZFA acts and FDA Codes, mandated member states to implement corresponding state laws and regulations. These were often introduced before being supported by relevant standards and guidelines. Further support has been provided by guidelines and standards produced in the first instance by voluntary bodies, but which, in some cases, are promoted to the status of national or international standards. In the European Union, the trend is towards guidelines for good practice together with performance standards and tests. An important principle of approaches based on risk management is that of verification and validation of systems to ensure they are effective. This is an area which requires much more development by legislators, inspectors, auditors and QA staff in the food industry.

Some countries have seen the need for 'route maps' as exemplified by the UK Industry Guide to Good Hygiene Practice – Catering Guide ISBN 0-11-321899-0, available from Her Majesty's Stationery Office (HMSO). This gives information about whether certain procedures are a legal requirement (in the UK) or just good practice. EU member states such as The Netherlands have an accreditation scheme for independent auditors such as TNO, Bureau Veritas and SGS, who work to maintain the standards of risk management carried out by individual operators and their advisors (in the same way that these organisations also perform accreditation services to ISO 9001 and ISO 14001, etc.). Similarly, Ireland supports the application of I.S.343-2000 within its borders. An overall summary of the mix of laws and standards in the European Union, covering hygiene issues, is given in Table 2.1.

Table 2.1 Legislation, official and voluntary standards on hygiene in food processing (adapted from de Vreeze, M.E.J. and Bosboom, M.M.M., ‘*Harmonisatie van Nederlandse Hygienecodes*’, Nederlands Normalisatie-Instituut, March 1998)

Jurisdiction	Authority	Laws	Official standards	Voluntary standards
International	World Trade Organisation	SPS-Code Agreement on Sanitary and Phytosanitary Measures	—	—
	International Standards Organisation	—	ISO/TC 199 Safety of Machinery (SC 2 Hygiene Requirements for the Design of Machinery)	ISO/DIS 15161 Guidance on the Application of ISO 9001/9002 to the Food and Drink Industry ISO/CD 14159 ‘Hygienic Requirements for the Design of Machinery’
	FAO/WHO Codex Alimentarius Commission	—	—	Codex Alimentarius (Alinorm 97/13, Alinorm 97/13A)
	Codex Committee on Food Hygiene			
	Codex Committee on Meat Hygiene (CCMH)			
	Codex Committee on Milk and Milk Products (CCMMP)			
	International Dairy Federation			Code of Hygienic Practice for Unripened Cheese and Ripened Soft Cheese (in preparation) Code of Hygienic Practice for Dried Milk (CAC/RCP 31:1983) Code of Hygienic Practice for Milk and Milk Products (in preparation)
Europe	European Council	93/43/EEC Food Hygiene	—	—
		89/392/EEC Machinery Directive and its amendments 91/368/EEC, 93/44, 93/68		

Comité Européen Normalisation	EEC 92/59/EEC Council Directive Concerning General Product Safety	—	EN 1672 1 and 2 and for specific machines; EN 453, EN 1673, EN 1974, EN 12505, EN 12505, EN 12331, EN 12853	Guidelines and standards (in association with 3-A and International NSF); see text
	EEC 93/465/EEC Conformity Assessment and Rules for Affixing the CE Mark			
	EEC 93/68/EEC Amending Directives on CE Marking: 87/404/EEC, 88/378/ EEC, 89/106/EEC, 89/336/EEC, 89/ 392/EEC, 89/686/EEC, 90/85/EEC, 90/ 384/EEC, 90/385/EEC, 90/396/EEC, 91/263/EEC, 92/42/EEC, 73/23/EEC			
	EEC 94/62/EEC Packaging and Packaging Waste – Amended by 97/ 129/EEC and 97/138/EEC			
CEN TC 153 Food Processing Machinery European Hygienic Design Group, EHEDG	Directive 98/83/EEC 'Potable Water'	—	Production Quality Arrangements (PQA) for meat processing Approved Quality Arrangement (AQA) for meat processing Meat Safety Quality Assurance (MSQA)	
	90/679/EEC Worker Safety Pathogenic Organisms			
	90/220/EEC Deliberate Release of Genetically Modified Organisms			

2.3 International hygiene regulation

2.3.1 FAO/ WHO *Codex Alimentarius*

The FAO/WHO *Codex Alimentarius* committee specifically concerned with food hygiene is the Codex Committee on Food Hygiene (CCFH). It has produced the following standards:

- Draft Revised Recommended International Code of Practice – General Principles of Food Hygiene ALINORM 97/13
- Draft Revised Guidelines for the Application of the Hazard Analysis and Critical Control Point (HACCP) System ALINORM 97/13A.

The approved forward standards programme for the FAO/WHO *Codex Alimentarius* Committee on Food Hygiene (CCFH) includes:

- Code of Hygienic Practice for Milk and Milk Products
- Hygienic Recycling of Processing Water in Food Processing Plants
- Application of Microbiological Risk Evaluation to International Trade
- Revision of the Standard Wording for Food Hygiene Provisions (Procedural Manual)
- Risk-based Guidance for the Use of HACCP-like Systems in Small Businesses, with Special Reference to Developing Countries
- Management of Microbiological Hazards for Foods in International Trade.

2.3.2 Codex Committee on Milk and Milk Products (CCMMP)

One of the earliest food sectors to see legislation on hygienic practice and product safety has been the dairy industry. Over 40 years ago, the International Dairy Federation (IDF) was already active in drafting compositional standards for milk and milk products. The Joint FAO/WHO Committee of Government Experts on the Code of Principles concerning Milk and Milk Products produced the Code of Principles concerning Milk and Milk Products in 1958 at the initiative of the IDF. The standards that the IDF elaborated as a non-governmental body missed, however, official recognition by governments, as there was no structure to obtain government approval. To establish regulatory status for compositional standards, IDF requested the FAO and WHO to convene a meeting of government experts to initiate a code of principles and associated standards for milk and milk products. In 1993 the resulting Milk Committee was fully integrated into the Codex system as the Codex Committee on Milk and Milk Products (CCMMP)

IDF maintained its role as technical adviser to the new Codex Milk Committee and its formal status is specified in the revised Procedural Manual of the Codex Alimentarius Commission (ninth edition, 1995): 'In the case of milk and milk products or individual standards for cheeses, the Secretariat distributes the recommendations of the International Dairy Federation (IDF).' Most of the standards concern composition of dairy products, but a few are concerned with hygienic practice:

- Code of Hygienic Practice for Unripened Cheese and Ripened Soft Cheese (in preparation)
- Code of Hygienic Practice for Dried Milk (CAC/RCP 31:1983)
- Code of Hygienic Practice for Milk and Milk Products (in preparation).

The International Dairy Federation is at <http://www.fil-idf.org> and its publications, including a number of processing standards, are to be found at <http://www.fil-idf.org/catalogue.pdf>.

2.4 European hygiene regulation

The laws applied by the national authorities have been harmonised at EU level by a framework directive (see Chapter 3). This lays down the law for general principles for the inspection, sampling and control of foodstuffs. It also provides for inspectors to be empowered to examine, record and seize or destroy foodstuffs which are unsafe or otherwise non-compliant. Offending premises and traders can be prevented from continuing to produce food for human consumption and fines can be levied. The framework Directive requires the member states to inform the Commission of their control activities and provides for EU-wide coordination through annual control programmes. In addition, the Karolus programme provides for exchange of control officials. Some controls are also undertaken at EU level. These are targeted at ensuring the adequacy and equivalence of the controls applied by the national authorities and involve teams of officials from the Commission in checking that the national systems are capable of meeting these goals. However, as in Australia, New Zealand and the United States, direct control is the responsibility of individual states.

The particular dangers arising from zoonotic diseases, like salmonellosis, tuberculosis and viral contaminants, have led the Commission's veterinary inspectorate to control and approve establishments in countries which produce food of animal origin for export to the European Union. Such products are also controlled at the point of entry into the European Union. However, in the main, food of non-animal origin has not been subject to this type of control, nor is the importation of these foodstuffs into the EU restrictive.

In recent years food policy at international level has been moving in a new direction, towards industry taking the responsibility for the control of the foodstuffs it produces, backed up by official control systems. The European food industry has been at the forefront of the development of preventive food safety systems, in particular the Hazard Analysis and Critical Control Point (HACCP) system, which requires the industry itself to identify and control potential safety hazards. Control measures are decided and applied by industry, with a view to producing safe food. The national authorities check that the controls are adequate. Although initially introduced by industry and employed in a non-mandatory manner, the success of this approach has led to it being included in several directives.

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Thirteen product-specific hygiene directives cover products of animal origin, from production to the point of distribution, and lay down detailed requirements. On the other hand, one horizontal hygiene directive covers all other products, with requirements based on good hygiene practices and HACCP principles. This directive covers products throughout the food chain. It imposes the responsibility for the safety of food and the prevention of unacceptable risks to the consumer on the food industry. At the same time, it allows industry the flexibility to meet its obligations by the most appropriate means available, and to respond quickly to new pathogens or contaminants. This challenges industry, particularly smaller businesses, to maintain a good technical understanding of food safety. The production of voluntary business sector guidelines on hygiene practices and HACCP, produced by industry in conjunction with the competent authority in each country, provides the basis for common understanding. Backed up by effective controls, this approach is intended to ensure a high level of health protection. However, some standardisation of approach between sectors and states as provided for in 93/43/EEC would be beneficial. Examples of the implementation of national standards in support of EU directives are shown in Table 2.2. EU directives which impact on food hygiene include:

- EEC 89/392/EEC Council Directive on the Approximation of the Laws of the Member States Relating to Machinery – Amended by 91/368/EEC
- EEC 91/368/EEC Council Directive amending Directive 89/392/EEC on the approximation of the laws of the Member States Relating to Machinery – Amended by 93/44 and 93/68
- EEC 92/59/EEC Council Directive Concerning General Product Safety
- EEC 93/44/EEC Amendment to 91/368 – Council Directive on the Approximation of the Laws of the Member States Relating to Machinery – Amended by 93/68
- EEC 93/465/EEC Council Directive Concerning the Conformity Assessment and Rules for Affixing the CE Mark
- EEC 93/68/EEC Amending Directives on CE Marking: 87/404/EEC, 88/378/EEC, 89/106/EEC, 89/336/EEC, 89/392/EEC, 89/686/EEC, 90/85/EEC, 90/384/EEC, 90/385/EEC, 90/396/EEC, 91/263/EEC, 92/42/EEC and 73/23/EEC
- EEC 94/62/EEC Council Directive on Packaging and Packaging Waste – Amended by 97/129/EEC and 97/138/EEC.

The trend in the management of risk in the food processing chain is increasingly towards 'Farm to Fork' initiatives. Amongst issues being addressed are:

- The exclusion of endemic animal disease which may affect humans, notably BSE, scrapie and *Salmonella*. Sweden and Finland have laws and procedures that have eliminated *Salmonella* from the animal and human food chain. Sweden has been lobbying vigorously for the adoption of their approach at EU level.
- The control of antibiotic-resistant bacteria by banning the routine use of antibiotics in animal feedstuffs. It has been argued that feeding antibiotics to

Table 2.2 Selected national standards on hygiene in food processing

Member country	Reference number	Title
Ireland	I.S. 342: 1997	Guide to Good Hygiene Practice for the Food Processing Industry
	I.S. 343-2000	Food Safety Management incorporating Hazard Analysis and Critical Control Point
	I.S. 3219	Code of Practice for Hygiene in the Food and Drink Manufacturing Industry
	I.S. 340	Hygiene for the Catering Sector
	I.S. 341 (Draft)	Hygiene for the Retail and Wholesale Sector
Britain	ISO/DIS 15161	Guidance to the Application of ISO 9001 and ISO 9002 in the Food and Drink Industry
	Alinorm 97/13A	Draft Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application
Germany	DIN 10503	Food Hygiene – Terminology
	DIN 10514	Food Hygiene – Hygiene Training
	Draft	Food Hygiene HACCP System Standardisation of Flow Diagram Symbols
	DIN 10500, DIN 10500/A1, DIN 10501 supplement, DIN 10501-1, DIN 10501-2, DIN 10501-3, DIN 10501-3 supplement, DIN 10501-4, DIN 10501-5, DIN 10502-4, DIN 10504, DIN 10505, DIN 10507, DIN 10510	Various standards for equipment, including testing
France	FD V 01-001	Hygiene and Safety of Foodstuffs Methodology for Drawing up of Guides to Good Hygiene Practice

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animals will lead to an increased prevalence of resistant genes in the intestines of the animals. At slaughter, the carcass will inevitably be contaminated with bacteria containing these genes. The genes can be transmitted to microbes in humans when the food is prepared or consumed and, in the end, humans can get infections from microbes harbouring these genes, causing treatment to fail. Several EU member states have in the past banned routine feeding of certain antibiotics in addition to those not permitted at EU level. Some such as Sweden have banned the routine non-therapeutic use of antibiotics entirely, and following representations by the Swedish, Finnish and Danish governments to, for example, the *Report from the Commission on Antimicrobial Feed Additives*, SOU 1997:132, the Commission removed four out of eight antibiotics from the list of authorised products. The four (spiramycin, tylosin, virginamycin and bacitracin) all belong to groups of antibacterials that are used in human medicine.

In Europe, three initiatives in particular address hygienic equipment manufacture.

2.4.1 The EU Machinery Directive

The European Community Machinery Directive 89/392/EEC and its amendments 91/368/EEC, 93/44/EEC and 93/68/EEC made it a legal obligation for machinery sold in the EU after 1 January 1995 to be safe to use, provided the manufacturer's instructions were followed. Design of food machinery must comply with EN1672-2. This requirement has vital implications for those supplying all types of machinery, including that described as suitable for food applications. In cases of breaches of food safety legislation, inspectors in the EU can confiscate and destroy products and also close down operations that threaten public health.

2.4.2 The European Hygienic Engineering and Design Group (EHEDG)

The European Hygienic Engineering and Design Group (EHEDG) develops design criteria and guidelines on equipment, buildings and processing. They have also developed equipment performance tests to validate compliance with the design criteria. The emphasis on guidelines is in the spirit of avoiding prescriptive, individual design specifications. The EHEDG is an independent group currently with 23 specialist subgroups dealing specifically with issues related to the design aspects of the hygienic manufacture of food products. Research institutes, equipment manufacturers, food manufacturers and government bodies are all represented (www.ehedg.org). It has also secured a major EU grant under the Quality of Life Program (Fifth Framework) to provide guidelines and training material (HYFOMA).

The EHEDG has formed links with ISO and CEN (the international and European standards organisations), Japanese groups and, in the USA, the 3-A

Table 2.3 Some organisations and bodies represented in the EHEDG

Research and government institutes	Equipment manufacturers	Food manufacturers
Biotechnological Institute, Denmark	Danfoss	BSN
Bundesanstalt für Milchwissenschaft, Germany	Südmo	Cargill
Technical University of Munich, Germany	Tetra Pak	H.J. Heinz & Co.
Bundesgesundheitsamt, Germany	GEA Tuchenhausen	Italgel
Campden and Chorleywood Food Research Association, UK	APV	Kraft Foods
Food Standards Agency, UK	Clextal	Suchard
College of Biotechnology, Portugal	Serac	General Mills
Institut National de la Recherche Agronomique, France	CMB	Nestlé
TNO, The Netherlands	Fristam	Rank Hovis
ATO BV, The Netherlands	Gasti	McDougall
University of Lund, Sweden	Robert Bosch	Unilever
UTT Biotechnology, Finland	Hamba	Danisco
Technical University of Gdansk, Poland	Huhnseal	Quest International
Institute Tecnológico Agroalimentario, Spain	KSB Amri	Pepsi Cola
	CFS	
	Stork	
	Definox	

Symbols Council and NSF International (formerly National Sanitation Foundation). In the case of the 3-A Symbols Council, the link is now a formal one. Standards are now being produced jointly with the FDA and USDA having an effective say via the 3-A input. The first result was a joint guideline on the passivation of stainless steel for hygienic use. The Executive Committee of EHEDG has a seat on the Steering Committee of 3-A and vice versa.

The work of developing guidelines is undertaken via subgroups which publish both clear recommendations for the hygienic and aseptic design and operation of equipment, along with the best methods to confirm that the equipment fulfils these requirements. These groups are drawn from equipment manufacturers, technical organisations and manufacturers, chiefly from the food and engineering industry. While such a list will inevitably be incomplete because of the growth in membership, an impression of the composition of EHEDG is given in Table 2.3. A series of guidelines have been or are being published in various languages. Extended summaries are published in *Trends in Food Science and Technology* published by Elsevier (Table 2.4) (journals@elsevier.co.uk).

An example of the contribution made by the participants in EHEDG has been the development of a new standard for hygienic/aseptic seals. Elastomeric seals are one of the more common sources of failure in aseptic processing. After very detailed study involving finite element analysis of the interaction of elastomeric components and different seal and housing geometries, plus extensive cycles of testing for cleanability and sterilisability, two superior new designs have been produced and have been published via the German DIN standards organisation as follows:

Table 2.4 Summaries of EHEDG guidelines in *Trends in Food Science and Technology*

Title	Reference
European Hygienic Equipment Design Group (EHEDG)	3 (11) 1992 277
The EC Machinery Directive and Food-Processing Equipment	4 (5) 1993 153–154
Hygienic Equipment Design Criteria	4 (7) 1993 225–229
Welding Stainless Steel to Meet Hygienic Requirements	4 (9) 1993 306–310
Hygienic Design of Closed Equipment for the Processing of Liquid Food	4 (11) 1993 375–379
Hygienic Pipe Couplings	8 (3) 1997 88–92
Hygienic Design of Valves for Food Processing	5 (5) 1994 169–171
Hygienic Design of Equipment for Open Processing	6 (9) 1995 305–310
A Method for Assessing the In-place Cleanability of Food-Processing Equipment	3 (12) 1992 325–328
A Method for Assessing the In-place Cleanability of Moderately-Sized Food-Processing Equipment	8 (2) 1997 54–57
A Method for the Assessment of In-line Pasteurisation of Food-Processing Equipment	4 (2) 1993 52–55
A Method for the Assessment of In-line Steam Sterilisability Food-Processing Equipment	4 (3) 1993 80–82
A Method for the Assessment of Bacteria-Tightness of Food-Processing Equipment	4 (6) 1993 190–192
Microbiologically Safe Continuous Pasteurisation of Liquid Foods	3 (11) 1992 303–307
Microbiologically Safe Continuous-Flow Thermal Sterilisation of Liquid Foods	4 (4) 1993 80–82
The Continuous or Semi-Continuous Flow Thermal Sterilisation of Particulate Food	5 (3) 1994 88–95
Hygienic Packing of Food Products	4 (12) 1993 406–411
Microbiologically Safe Aseptic Packing of Food Products	4 (1) 1993 21–25
Experimental Test Rigs are Available for the EHEDG Test Methods	6 (4) 1995 132–134
Passivation of Stainless Steel	9 (1) 1998 28–32
A Method for Assessing the Bacterial Retention Ability of Hydrophobic Membrane Filters	12 (1) 2001 36–38
Hygienic Design and Safe Use of Double-seat Mixproof Valves	12 (5/6) 2001 203–206
General Hygienic Design Criteria for the Safe Processing of Dry Particulate Materials	12 (8) 296–301
Challenge Tests for the Evaluation of the Hygienic Characteristics of Packing Machines for Liquid and Semi-liquid Products	12 (2001) 244–248
The Prevention and Control of <i>Legionella spp</i> (including Legionnaires' Disease in Food Factories	13 (2002) 380–384
Production and Safe Use of Food Grade Lubricants	In press
Hygienic Design of Pumps, Homogenisers and Dampening Devices	In press

- DIN 11864-1, Publication: 1998-07 Fittings for the food, chemical and pharmaceutical industry – Aseptic connection – Part 1: Aseptic stainless steel screwed pipe connection for welding
- DIN 11864-2, Publication: 1998-07 Fittings for the food, chemical and pharmaceutical industry – Aseptic connection – Part 2: Aseptic stainless steel flanged pipe connection for welding

Both can be found and ordered at: http://www.din.de/www_din/owa/bn_f_einstieg.init?z_sprache=EN

2.4.3 CEN TC233 Safety in Biotechnology

The European Committee for Standardisation (CEN) Technical Committee 233 on Safety in Biotechnology sets standards for equipment and procedures concerning the processing of recombinant and hazardous organisms. This is likely to benefit food process hygiene through the availability of additional CEN-approved components. This committee has been funded by the European Community to produce new European standards relating to safety in biotechnology. The intention is to support and guide the (European) biotechnology industry in the implementation and regulation of activities governed by the European biotechnological safety Directives 91/219/EEC, 90/679/EEC, 93/88/EEC and 90/220/EEC. Participants in the formulation of draft standards have included academics, equipment manufacturers, consultants, and manufacturers from process industries including pharmaceuticals, food and fine chemicals, research organisations and national standards bodies. Representatives have included EFTA countries, for example Switzerland. The emphasis has been on performance rather than prescription and on an approach based on hazard assessment and risk management.

The agreement of standards between parties with such a wide group of perspectives and interests has taken considerable time and effort on the part of those involved. This in itself is of substantial potential value as a platform for improved safety and for greater freedom of trade and international activities in biotechnology. In many cases, these standards have values beyond those connected solely with safety. In the case of equipment, it will be possible for components such as valves, couplings, separators, pumps, sampling devices, etc. to be type-approved according to their cleanability, sterilisability and leak-tightness. These hygiene-related performance ratings will have to be obtained by recognised laboratories using documented test procedures and conditions (e.g. for a mechanical seal: operating temperature, rotational speed, pressure, number of hours of operation, sterilisation conditions and frequency, etc.). Equipment that carries the CEN biosafety mark will have to be manufactured to a recognised quality management system. Again, there is an emphasis on type testing and certification of equipment, with similar control and documentation requirements to those of the EHEDG tests. The idea of these tests is not to guarantee that a particular type of equipment will pass validation in every installed circumstance, but to give relative comparisons that can inform design choices.

2.5 National hygiene regulation: the case of Scandinavia

Although Sweden and Finland are covered above as part of the EU, the Scandinavian group of Norway, Sweden and Finland is covered here specifically because of their distinctive and important approach to regulating the problem of *Salmonella* at source in the animal and human food chains. The Scandinavian approach is widely seen as setting an example for other countries to follow. It is also vital for companies wishing to export animal or human feed to these countries to be aware of the compulsory controls that are involved, if they are not to incur a risk of substantial losses.

In many countries, the endemic presence of pathogens such as *Salmonella* and *Campylobacter* in domesticated animals and birds is accepted as inevitable. In Sweden, *Salmonella* control was introduced for the first time in 1961, following a serious epidemic of *S. typhimurium* in humans in 1953, in which some 90 people died and approximately 9000 were taken ill. The source was discovered to be contaminated meat and meat products from a slaughterhouse. This forced the introduction of new legislation. Since 1961 notification of all kinds of *Salmonella* isolated in animals or animal feedstuffs has been compulsory in Sweden. Continuous surveillance and control programmes were initiated and animals from infected herds were banned from sale. In the case of Sweden, the *Salmonella* Control Programme in farm animals is the responsibility of the SBA (Swedish Board of Agriculture) and the NFA (National Food Administration), who must be notified if *Salmonella* is detected in animals or foodstuffs. Specially appointed veterinarians are responsible for official inspection and sampling. The law considers food from which any *Salmonella* bacteria have been isolated to be unfit for human consumption. Detection of *Salmonella* always triggers a number of compulsory measures with the intent to trace and eliminate the infection and its sources. Norway and Finland have similar laws and systems. Today fewer than 1% of all animals and animal products for human consumption are contaminated with *Salmonella*. Contamination in slaughtering and processing plants and retail outlets is rare, in contrast to most other countries in Europe and in the USA, where it is not at all uncommon to find *Salmonella* bacteria in raw chicken, beef, pork and eggs. In Sweden, Norway and Finland the incidence of human infections is about 0.04% of the population per annum of which approximately 85% acquired the disease while travelling abroad. In other European countries the situation is reversed. This success has been achieved by measures:

- to monitor and control the feed and water used in all types of holdings where animals are kept, to prevent and exclude *Salmonella* contamination of all parts of the food production chain
- to monitor and control the animal breeding stock at all levels, to prevent *Salmonella* from being transmitted between generations in the food production chain
- to monitor and control all other parts of the food production chain from farm

to retail outlets, at critical control points where *Salmonella* can be detected, and to prevent *Salmonella* contamination in every part of the chain

- to undertake the necessary action in case of infection. This includes sanitation of infected flocks or herds.

Neither antibiotics nor hormones are permitted for prophylactic treatment or growth promotion in any farm animal, regardless of species. Such substances can only be used for treatment of specific diseases, after prescription by a certified veterinarian, and must be followed by a withdrawal period according to legislation, during which meat, milk and eggs are considered unfit for human consumption. In a survey in 1997 no illegal substances were found out of the 20 000 meat samples from cattle, swine, sheep and horses that were analysed from every slaughterhouse in Sweden.

In the case of pigs and cattle the aim is to monitor the animal population in order to identify *Salmonella*-infected herds, to minimise the spread of infection and to eliminate *Salmonella* from infected herds. The programme is officially supervised, and consists of two parts:

1. Monitoring the situation by official sampling in slaughterhouses and processing plants, the number of samples being decided by the number of animals slaughtered.
2. Testing on the farms, in health programmes monitored by the Swedish Animal Health Services, or when there is clinical suspicion of *Salmonella* in sick animals.

If *Salmonella* is detected on a farm, the herd is put under official restrictions which include specific hygienic measures in the herd, prohibition of the movement of animals to and from the farm, and restricted contact with the herd. Chronically infected animals are eliminated from the herd, with such slaughter taking place only with special permission and according to special rules. An official investigation to find the source of the infection is undertaken.

During 1997 close to 30 000 samples were collected and analysed in slaughterhouses and processing plants. In slaughterhouses a total of only three *Salmonella*-positive lymph nodes from cattle and five from pigs were found, and none were found in processing plants. That is a frequency of 0.08% for the country as a whole. In processing plants, surface swabs from the carcasses are analysed to detect whether the plant had been contaminated by *Salmonella*. Only two positive samples, from pigs, were found in 1997.

The five basics of *Salmonella*-free production of poultry are:

1. The day-old chick has to be *Salmonella* free.
2. Feed and water must be *Salmonella* free.
3. The environment has to be, and remain, *Salmonella* free.
4. The entire production chain has to be checked regularly.
5. Immediate action has to be taken wherever *Salmonella* is detected, regardless of serotype.

There are two control programmes for birds while living on the farms, a voluntary and a mandatory one, with identical testing schemes. Both of them include production birds such as broilers, layer hens and turkeys, as well as breeder birds and egg production. The voluntary programme started in the 1970s, while the compulsory programme was started about 10 years later. Participation in the voluntary system is only possible if the higher levels of the production chain for that farm (parent and grandparent flocks) are also members. Farms not participating in the voluntary scheme are covered by the mandatory scheme. Participation is obligatory if producers are to deliver poultry to the slaughterhouse, or eggs to packing centres for retail sale.

The farms participating in the voluntary programme benefit from higher compensation in the case of an outbreak (up to 70% in the voluntary programme compared with up to 50% in the mandatory). In 1998 about 96% of the broiler farms (counting for 98.5% of the produced poultry meat) and close to 25% of the layer farms were members. All breeder flocks are members today, except a few small ones. The high frequency of participation can be explained by the fact that the government no longer pays the costs associated with an outbreak of *Salmonella* in broiler flocks, and the insurance companies demand participation to compensate the farmers. The industry also makes demands on their members through their organisation Svensk Fågel.

Sampling of slaughter and processing plants for poultry is a substantial element of the programme. The volume and frequency of sampling depends on the size of the plant. In broiler farms, sampling is organised in combination with an inspection of the farm, two weeks prior to slaughter. The birds are not admitted to normal slaughter procedures unless proven negative for *Salmonella*, to avoid contamination of the plant, but are destroyed if *Salmonella* is detected. From 1998 this system is also compulsory for unusual birds such as ostriches.

If *Salmonella* is found, the infected flock, broilers and layer hens alike, as well as turkeys and ostriches, are immediately destroyed, strict hygienic measures are enforced on the farm and the source of infection is traced and eliminated. Eggs where an invasive (that is transmitted within the eggs) serotype of *Salmonella* is detected are destroyed. On farms where non-invasive *Salmonella* is present, the eggs can be heat-treated and then sold. The layer hens where non-invasive *Salmonella* is found, after special permission from the NFA, can be slaughtered according to a special procedure, instead of being destroyed. Out of nearly 4000 yearly samples of poultry taken from slaughterhouses and processing plants during 1996 and 1997, only two were positive each year, indicating a detected frequency of *Salmonella* as low as 0.05%.

Feed companies must apply strict testing for *Salmonella* both on raw materials and on finished feedstuffs, as well as a strict hygiene programme, the principles of which have existed for nearly 50 years. According to legislation it is compulsory to heat-treat all industrial poultry feed, including the concentrates. A strict separation between processed feed and unprocessed raw materials is compulsory in all plants. In 1996 *Salmonella* was found in only 0.5% and in 1997 in 0.6% of the approximately 6000 analyses performed in the process

control. This control system for animal feed is the strictest in Europe and probably in the world.

The National Veterinary Institute, The Swedish Board of Agriculture and the National Bacteriological Laboratory undertook a cost-benefit analysis of the *Salmonella* programme in 1994. It compared the annual costs arising from human salmonellosis and the annual cost of control measures in order to prevent and/or minimise the extent of *Salmonella* infection in domestic and imported animals (poultry, cattle and swine) and in animal products. The analysis concluded that the cost of control in most instances would be much lower than the financial cost of treating human salmonellosis cases, should the controls cease. Total annual costs, at 1992 prices, were estimated at between 112 and 118 million SEK with a control programme in effect, whereas the costs would be between 117 and 265 million SEK without one. Costs for investigating outbreaks and control by local and regional authorities were not estimated. If these and other losses for pain and suffering, loss of leisure time, and productivity losses in factories and establishments due to *Salmonella* outbreaks were included, the estimated benefits would increase considerably. Sources for the Swedish programme include:

- Swedish *Salmonella* Control Programmes for Live Animals, Eggs and Meat, 1995-01-16
- WHO/Zoon./94.171, sid 16-32: A. Engvall, Y. Andersson, F. Cerenius: 3. The Economics of Swedish *Salmonella* Control: a Cost/Benefit Analysis
- Jordbruksverkets rapport 1998:10. *Salmonella* och andra zoonoser hos djur
- Livsmedelsverkets rapport 6/98: Examination of residues in fresh meat and live animals
- Livstecknet nr 3/98, sid 6: Catharina Berge, Ingrid Nordlander: 20 000 köttprover analyserade 1997
- Commission of the European Communities XXIV/1252/97: Draft report on a Veterinary Inspection Mission in Sweden concerning the *Salmonella* Control Programme in Poultry and the Implementation of Council Directives 90/539/EEC and 98/117/EEC
- Livsmedelsverkets rapport till EG-kommissionen 1998: Rapport om de erfarenheter som vunnits från kontroll av *Salmonella* ifråga om kött från djurslagen nöt, svin och fjäderfä och ifråga om levande fjäderfä för slakt, och tillämpningen av *Salmonella*garantier inom handeln.

3

Hygiene regulation in the EU

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3.1 Introduction

A series of food scares has reduced consumer confidence in food safety even though the risk from food is generally extremely low. It is important to reassure consumers and restore their confidence. This requires elimination of the basis for their concern, by the industry promising and providing safe food with the application of quality management systems that will guarantee this. The industry is achieving this, and independent auditing of these systems to demonstrate their performance is becoming increasingly common. Appropriate hygiene must be applied as necessary during all stages preceding the consumption of food to ensure that it is safe. It is apparent that this, and improved public awareness of it, are fundamental to the maintenance of consumer confidence. It also aids business profitability by reducing losses. Such efforts will not, however, prevent illness caused by subsequent unhygienic consumer activities. There must be an adequately equipped and controlled environment and appropriate hygiene procedures for the production, handling, storage, distribution and supply of food ingredients, packaging materials and foods. This may be based on detailed prescriptive controls providing a rigid guarantee of safe working, or a more flexible management system based on the control of objectively assessed risk, or a combination of these. In each case, implementation must be under the control of food business operators, who are responsible for ensuring that the products they supply are safe. A regulatory regime with effective enforcement is also necessary to deal with residual errors, failures and especially abuses.

* This chapter expresses the personal views of the author and must not be attributed to MLC.

The nature and application of this regime is the topic of this chapter. It covers the structure of the control system, before examining the EU legal requirements. There is legislation generally applicable to retailing and catering for all foods, and to the whole supply chain for many foods. There are also specific requirements applicable only to the production of foods of animal origin on an industrial scale and in those smaller businesses that are caught by these rules and therefore require similar controls to be in place. The chapter then considers future trends before providing a short list of sources of further information. Other chapters also include hygiene-related information.

3.2 Hygiene regulation in the EU: key themes

From early in the development of the European Community, its member states moved towards harmonised food hygiene control through Community laws. Attention was given initially to the more perishable commodities, particularly when they cross frontiers between those states.

3.2.1 Horizontal and vertical control measures

The European Commission developed legislation for products of animal origin within the Common Agriculture Policy, in a set of ‘vertical’ directives, each covering a restricted range of foodstuffs, usually in considerable detail and including some non-sanitary matters. They contain numerous inconsistencies, often for no obvious technical reasons (Fogden, 1994–96).

The existing Community hygiene controls on products of animal origin were reconsidered during the period around 1990 when the single market was being created. With the elimination of border controls, there was concern that food obtained under less stringent national rules could enter other states without further checks or controls. It was decided to harmonise the national production and trade requirements to a similar standard to eliminate this, so existing directives were updated. A ‘horizontal’ directive providing general hygiene rules for matters and foods not covered by the vertical legislation was added.

Hygiene rules cannot be considered satisfactory unless those concerned in their application and enforcement can interpret them effectively and consistently. They must be capable of ensuring the protection of public health and should be adequately flexible to satisfy diverse but essential needs. In many cases this is the situation, but improvements are possible. Thus a group of directives was adopted to ensure hygienic production and marketing of all foods. There were difficulties (e.g. with proposals for minced meat hygiene controls – see Section 3.6), but most vertical measures were adopted by September 1992 and the horizontal directive on the hygiene of foodstuffs (93/43/EEC) followed in June 1993 (Table 3.1). The latter is enforced under national food control systems while the vertical rules are under veterinary control. Legislation also covers the importation of foodstuffs from third countries into the Community,

Table 3.1 EEC/EC food hygiene directives and decisions

Number	OJ	Date	Pages
<i>Directives</i>			
64/433/EEC	L 21	29 July 1964	2012
71/118/EEC	L 55	8 March 1971	23
77/99/EEC	L 26	31 January 1977	85
80/778/EEC	L 229	30 August 1980	11
85/374/EEC	L 210	7 August 1985	29
88/657/EEC	L 382	14 December 1988	3
89/397/EEC	L 186	30 June 1989	23
90/667/EEC	L 363	27 December 1990	51
91/67/EEC	L 46	19 February 1991	1
91/492/EEC	L 268	24 September 1991	1
91/493/EEC	L 268	24 September 1991	15
91/495/EEC	L 268	24 September 1991	41
91/497/EEC	L 268	24 September 1991	69
91/498/EEC	L 268	24 September 1991	105
92/5/EEC	L 57	2 March 1992	1
92/45/EEC	L 268	14 September 1992	35
92/46/EEC	L 268	14 September 1992	1
92/48/EEC	L 187	7 July 1992	41
92/118/EEC	L 62	15 March 1993	49
93/43/EEC	L 175	19 July 1993	1
94/65/EC	L 368	31 December 1994	10
98/83/EC	L 330	5 December 1998	32
1999/34/EC	L141	4 June 1999	20
2000/13/EC	L109	6 May 2000	29
<i>Decisions</i>			
93/51/EEC	L 13	21 January 1993	11
94/371/EC	L 168	2 July 1994	34
2001/471/EC	L 165	21 June 2001	48

with a series of decisions listing the individual establishments that have been approved.

3.2.2 The scope of regulation: what is hygiene?

Article 2 of the horizontal 'General Food Hygiene Directive' (93/43/EEC) defines 'food hygiene' as 'all measures necessary to ensure the safety and wholesomeness of foodstuffs' and applies during 'all stages after primary production', this including harvesting, milking and slaughter. Circuitously and somewhat unhelpfully, it then defines 'wholesome food' as that 'which is fit for human consumption as far as hygiene is concerned'.

A draft replacement Regulation (see Section 3.5.3) for this Directive defines 'food hygiene' as 'the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use'. This document (ref. 9240/2/02 REV2, of 24

June 2002) was agreed politically but has not yet been adopted (August 2002).

The vertical hygiene directives are primarily aimed at controlling hygiene but include other rules that target the control of quality and the provision of information to a purchaser through labelling. Such aspects are certainly important in their own right in ensuring good product quality and in providing information and assurance to consumers about the foods that they intend to consume, but they do not always fit within 'hygiene' as defined above. The juxtaposition of these elements can be confusing (Fogden, 1994–96, Part 7), especially as they were developed by specialist veterinary officials with a limited understanding of general food law. Some of these initiatives are worthy, but if specific controls are needed, they would be better placed outside these hygiene directives. Many are already covered in principle in horizontal directives, for example in the Food Labelling Directive (2000/13/EC), which requires food to be labelled appropriately and in accordance with general and/or detailed rules. A review has addressed these concerns (see Sections 3.5.3 and 3.7.1).

3.2.3 Rigid control systems or risk management

Hygiene rules must be applied broadly to the production of food and its supply chain to provide effective protection against food safety problems. Moreover, operators should not confine themselves to compliance with legislated generic hygiene measures but should also consider whether additional precautions or control systems are required in the particular circumstances of their businesses. Increasingly, risk management systems are being introduced. These are commonly based on the Hazard Analysis and Critical Control Points (HACCP) system developed originally for microbiological control of foods intended to be consumed in American space missions. A comprehensive, properly implemented risk management system based on HACCP can make a very significant contribution to ensuring food safety (see Sections 3.2.4 and 3.5.3).

Some hygiene directives demand risk management, to different extents, but many vertical directives rely on rigid requirements specified in considerable detail. These cover all businesses in that category, rather than permitting controls that are adequate and sufficient for particular circumstances. These provide no encouragement to an operator to introduce appropriate risk management systems with different and probably less onerous controls, since these must be introduced in addition to the prescribed requirements. Other directives apply an HACCP-based procedure on top of prescriptive controls specified to varying levels of detail and complexity.

Hygiene deals with the preservation of health, and a hygienic business should control the risk of illness resulting from the operations carried out on its premises. Implementation of the necessary controls also gives advantages in maintaining product quality. There are three main requirements:

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1. Avoid contamination of the food in the first place.
2. Avoid the spread of contamination.
3. Eliminate harmful contamination.

3.2.4 Hazard Analysis and Critical Control Points (HACCP)

HACCP is recommended by leading health authorities including the WHO/FAO Codex Alimentarius Commission ('Codex') as the basis for hygiene risk management. Specialist texts and advice on HACCP are readily available. It is a seven-stage system which examines the production process and determines the critical points that need to be controlled in order to ensure food safety. The seven principles of HACCP are as follows (Codex Alimentarius, 1997b):

1. Conduct a hazard analysis.
2. Determine the critical control points (CCPs).
3. Establish critical limit(s).
4. Establish a system to monitor control of the CCPs.
5. Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
6. Establish procedures for verification to confirm that the HACCP system is working effectively.
7. Establish documentation concerning all procedures and records appropriate to these principles and their application.

The Codex HACCP Code gives further guidance. This includes the following:

- A food chain sector should already be operating according to Codex General Principles of Food Hygiene (Codex Alimentarius, 1997a), other appropriate Codex Codes of Practice and food safety legislation before the application of HACCP.
- Management commitment to HACCP is essential for the implementation of a HACCP system.
- Redesign of an operation may be necessary if a hazard requiring control is identified but no CCP can be found.
- Each operation should be subject to HACCP, and reviewed as necessary.
- Be flexible in applying HACCP, taking account of all the circumstances.

Until recently, HACCP was not formally required as such by any EU food hygiene legislation, although substantial parts of the principles of HACCP were incorporated in some areas, including the General Food Hygiene Directive (Section 3.4.2) and the directives controlling meat preparations and products. Commission Decision 2001/471/EC, however, required the introduction by 8 June 2002 of risk management procedures developed in accordance with the HACCP principles in fresh meat and poultry meat establishments subject to the vertical control mechanisms, although this could be delayed for a year in small establishments. This Decision also laid down procedures for microbiological

checks in such premises. In general, however, vertical EU controls are based on prescriptive detail rather than self-control. The attitude and/or knowledge required for effective self-control of hygiene risks is lacking in some food businesses, and it is likely that at least some prescriptive rules will continue to form the basis of legislated requirements for some time.

However, the global trend is towards self-regulation, and it is appropriate to provide a legislative system that permits this for businesses that can demonstrate relevant competence and effectiveness. These could then profit from derogations from the prescriptive requirements, giving them flexibility in the system they introduce and avoiding unnecessary expense occasioned by redundant measures. It is easier to enforce detailed rules than to assess individual systems of control, so inspectorates need to be trained to ensure that they are able to satisfy themselves that food hygiene standards are being met (Section 3.7.3). This is already a problem, since there is a requirement in the General Food Hygiene Directive for an HACCP-based system to be in place. Such systems are currently weak at best in many premises where there is an apparent lack of understanding, competence or application. There is still a considerable need for education and encouragement, probably before resorting to strong enforcement (except in dangerous situations). The so-called 'honeymoon period' cannot, however, go on forever.

The experience of a successful British initiative may provide a slightly cautionary note. As a result of the 1996 fatal *E. coli* O157:H7 outbreak in Scotland, the government introduced legislation in 2000/01 requiring all shops handling unwrapped raw meat and also supplying ready-to-eat foods to implement an HACCP system or, in Scotland only, to introduce stringent physical separation of the two types of food. In England, the Meat and Livestock Commission managed a government-funded project costing almost 10 million euros, which trained about 6000 butchers in HACCP techniques in 18 months, employing a large proportion of the HACCP trainers in the country. Proportionate amounts were provided to Scotland, Wales and Northern Ireland, although these were used for enforcement activities (including training) rather than being ring-fenced for training. Clearly the introduction of HACCP across the EU in all food businesses, whether simultaneously or over an extended period, would have extensive resource implications and certainly could not be fully achieved within a couple of years.

3.3 Enforcement of hygiene regulations

The nature of EU directives is that they have to be implemented through national legislation, unlike its regulations and decisions which apply automatically. Each member state must introduce its own measures to implement each directive within a specified period, to achieve the objectives agreed and set out in the directive. So, for example, in Britain the General Food Hygiene Directive has been implemented by the Food Safety (General Food Hygiene) Regulations

1995 which largely repeat the directive's provisions but are drafted according to the national legal tradition.

The vertical directives were originally proposed as regulations. However, the member states decided not to control food hygiene in this inflexible manner but as directives, the form proposed for the horizontal measure. These allow governments to implement the controls, meeting the objectives, in ways that suit national or cultural preferences. There are, however, opportunities for inconsistencies. Harmonised rules can be introduced effectively through directives, but the result is less uniform than when regulations are introduced directly and simultaneously into each state. This, with possible variability of enforcement, can result in unfair competition and protectionism. The Commission monitors the position to avoid this.

3.3.1 Official control

National governments are required by the Official Control Directive (89/397/EEC) to enforce food hygiene legislation. This is devolved in many states to a local level through municipal or regional authorities, indicating that a coordinating system should be in place to improve consistency. National enforcement officials interact on a European basis through the Food Law Enforcement Practitioners' forum. Official inspections of production and supply establishments are often supplemented by audits by customers or specialist inspection bodies. These may apply stricter standards than are required by law, and the consequences of failure may be painful and immediate, through loss of business rather than an extended enforcement procedure. In such cases, the official control system can be almost redundant.

3.3.2 Veterinary and non-veterinary enforcement

As indicated previously, the vertical directives are based on veterinary supervision whereas the horizontal directives are not. This can cause difficulties, even friction, where the two systems are controlled by separate national or local authorities. Improved cooperation and administrative coordination would help in some states and it is desirable that legislators improve the interface by reducing some differences between the requirements, which can be confusing.

3.3.3 Civil liability for hygiene failure

It is the responsibility of every business proprietor active in the food chain to ensure that they provide products that will help to ensure consumer safety, whether these be equipment, ingredients or final products. It is worth remembering that the Product Liability Directive (85/374/EEC) places strict liability on suppliers of all goods, previously excluding primary agricultural products in most member states but now extended to these (Directive 1999/34/EC). This legislation assists injured persons to make a claim for damages in civil

law. Claimants need only prove damage to themselves (or their property, subject to a minimum value), and that the damage was caused by a defective product for which the producer was responsible. They do not have to show that there was any fault in what the producer did, or did not do, or that there was any negligence on the part of the producer. Moreover, that liability begins at the end of the chain, with the business supplying the injured person, and passes back down the chain to the original producer of the goods only if each link is able to state from whom they obtained the defective product. Effective traceability is therefore essential for every item purchased by a food business, to transfer liability to the person who is properly responsible for the defect. Appropriate insurance may also be helpful, in case such transfer is impossible.

3.3.4 Consumer aspects

Customer expectations must be met, if food businesses are to thrive. Since hygiene is one of their fundamental demands, satisfying this is clearly high in the list of priorities for business success. It is believed that a consumer seeks both safe food and confidence that this is being provided. Given that confidence, most will not ordinarily concern themselves with production hygiene. They may well, on the other hand, rightly react strongly against visibly poor hygiene where food is supplied to them. That does not provide any excuse for poor hygiene where consumers are not able to see what is going on; nor is it acceptable to apply hygiene in such places only when an official control inspector is performing an inspection. In any case, expert inspectors are usually able to perceive this.

Regrettably, nowadays consumers in some states are less aware of and less competent in hygiene than previous generations because they have not received sufficient relevant instruction at home or education at school. It is therefore essential that sufficient hygiene instructions are presented in the labelling of food, although manufacturers of food products often properly argue that it is not their task to compensate for lack of general instruction. It is then the responsibility of the consumer to read that information – but regrettably many fail to do so. Better consumer education is necessary in hygiene and in the need to recognise their responsibility in maintaining the hygiene put into the foods and food ingredients they purchase.

Criminal legislation requiring consumers to prepare and serve food hygienically would generally be impractical to enforce and undesirable, except perhaps where gross faults cause serious illness or death (although civil remedies do already exist). It would most probably not reduce significantly the enormous amount of minor food poisoning caused every year by consumers, resulting in discomfort, pain and inability to work.

3.4 The General Food Hygiene Directive (93/43/EEC)

This directive follows the vertical directives' format in comprising a number of articles providing general requirements together with annexed detailed provisions on particular control areas (see Table 3.2).

3.4.1 Essential requirements

These are set out in Article 3 of the directive. Fundamentally, Article 3(1) requires 'preparation, processing, manufacturing, packaging, storing, transportation, distribution, handling and offering for sale or supply of foodstuffs [to] be carried out in a hygienic way'. In practice, the General Food Hygiene Directive controls most retailers, caterers, the production and supply of all foods that are not of animal origin, and all other food businesses that are not controlled under the vertical directives. Put simply, every part of the food supply chain must be hygienic. Article 3(2) deals with risk management (see Section 3.4.2) and Article 3(3) requires food businesses to meet the specific hygiene rules laid down in the annex to the directive (see Section 3.4.3).

Table 3.2 Structure of the General Food Hygiene Directive

Article	Principal areas covered
1	Scope
2	Defines 'food hygiene', 'food business' and 'wholesome food'
3	Requires hygiene and risk management throughout the food chain
4	Allows for microbiological and temperature control criteria
5	Industry hygiene guides
6	EN 29000 standards
7	Additional national hygiene requirements
8	Official control
9	Enforcement
10	Third country imports – safeguard measures
11	National prevention of health risks
12	Competent authorities
13	Adoption of international standards
14	Adoption of additional requirements
15	Review of implementation
16	Entry into force
17	Applicability to all member states Annex – detailed requirements
I–III	Various types of premises
IV	Transport
V	Equipment
VI	Food waste
VII	Water supply
VIII	Personal hygiene in food handling areas
IX	Raw materials, intermediates and finished foods
X	Training

Article 5 allows for the development by the industry of guides to good hygiene practice, in collaboration with interested parties. Codex principles may be applied. If a national competent authority believes that such a guide meets the requirements of Article 3, it must forward it to the European Commission which will make it available to the other member states. These guides do not have the force of law, for there is quite properly no requirement to follow such guidance, since any other means of complying with the legislation is just as acceptable. However, they have strong persuasive value, and proof of compliance with a recognised guide would be very helpful against an enforcement challenge. European guides may be developed in due course, which would take account of existing national guides but apply throughout the EU.

Article 7 allows member states to introduce national hygiene legislation that exceeds the requirements in the directive provided they do not restrict, hinder or bar intra-Union trade in relevant food. This has been done in some states, which have, for example, introduced temperature controls. National temperature/time hygiene legislation has not yet been harmonised by the Community. The horizontal directive provides for this in Article 4. Currently it specifically requires such control only for microbiologically perishable foods and hot-processed foods which are to be held or served chilled (Annex, IX).

3.4.2 Risk management

Article 3(2) requires all food business operators controlled under this legislation to carry out a risk analysis based on the following HACCP principles (it omits the verification and documentation stages):

- Analysis of the potential food hazards in a food business operation
- Identification of the operational points where food hazards may occur
- Decision as to which of the points are critical to food safety (thus establishing the critical control points – CCPs)
- Identification and implementation of effective control and monitoring procedures at those CCPs
- Review of the analysis and risk management system periodically and when the food business operations change.

This has been a legal requirement since 1996. The law does not currently specifically require documentation of the risk assessment and management system, or of the results of reviews. However, it is suggested that this is in fact a requirement wherever a food business could not reasonably maintain an effective system in place in the absence of documentation. This is thought to be the case in all businesses of any substantial size or operational complexity. Moreover, the presentation of a documented record to an enforcement authority or court is likely to be more persuasive that the requirement had been complied with than unsupported statements. Food businesses are therefore urged to make a reasonable effort to record their assessments, systems and reviews; such

documentation may be required in future, and this is already the case in many British butchers' and other shops (see Section 3.2.4).

3.4.3 Annex

This provides limited specific controls concerning the structure and facilities in food premises (Chapters I–III). Chapter I provides rules applicable to food premises other than movable and temporary ones, which are subject to the rules in Chapter III. Chapter II specifies rules that apply to all rooms where food is prepared, treated or processed except dining areas and rooms covered by Chapter III. These chapters require appropriate design and construction of premises to permit good hygiene practices, with temperature control (if necessary), sufficient washbasins and lavatories, ventilation, lighting, drainage and changing facilities. There must be protection against risks of contamination and cross-contamination. The premises, including working surfaces and equipment, must be kept in a sound condition and be easy to clean and disinfect. Additional requirements may result from the application of Articles 3(1), 3(2) or 7 (see Sections 3.4.1 and 3.4.2).

Chapter IV deals with transport, requiring vehicles and containers to be suitable, with temperature control where appropriate, and in sound condition. They must be able to be cleaned where necessary, especially between loads of different foods, or between foods and non-foods. Mixed loads must be properly separated to avoid contamination. Dedicated receptacles, containers or tankers marked 'for foodstuffs only' must be used to transport food in bulk. Chapter V similarly requires articles, fittings and equipment that come into contact with food to be kept clean, properly maintained and in good condition.

Chapter VI prohibits the unavoidable accumulation of waste in food rooms, and requires food waste and other refuse to be stored in closed or approved containers, again clean, sound, easy to clean and disinfect. Chapter VII requires potable water to be supplied; this must be used wherever necessary to ensure food hygiene, including in the preparation of ice. Other water may be present in the premises (e.g. for steam generation and fire control) but must be kept separate from the potable supply and clearly identified as non-potable.

Personal hygiene is essential. All the other controls will not ensure food safety if the staff contaminate the food because they are dirty, do not wear protective clothing or are liable to transmit diseases. Chapter VIII deals with this, with the second paragraph banning specified people from being allowed to work in food handling areas in a way that could lead to direct or indirect contamination of food with pathogenic micro-organisms. These are people who are known or suspected to suffer from, or be a carrier of, a disease likely to be transmitted through food and also people with infected wounds, skin infections, sores or diarrhoea. It is essential that food business proprietors persuade their staff to declare such incapacities so that they can be put onto tasks where there is no risk of contaminating food. It is important to note that the rule applies to

anybody, not just those employed as food handlers, whose presence working in any food handling area puts the food at risk.

Chapter IX prohibits acceptance of raw materials or ingredients that are, or are likely to be, 'so contaminated with parasites, pathogenic micro-organisms or toxic, decomposed or foreign substances' that they would still be unfit for human consumption after passing through normal hygienic sorting, preparatory and processing procedures. Raw materials and ingredients that do enter the premises must be properly stored, handled and used to prevent harmful deterioration and contamination. Food must be protected from contamination that is likely to make it unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state. Pests must be controlled. Temperature controls must be in place where this is necessary to prevent a risk to health from the growth of pathogenic micro-organisms or the formation of toxins, although brief periods outside such control are permitted for practical reasons. As mentioned previously, hot foods to be held or served chilled must be cooled as quickly as possible to a safe temperature. Hazardous and inedible substances, including animal feedstuffs, must be adequately labelled and separated in secure containers. In essence, this chapter requires all reasonable precautions to be taken to prevent food being put at risk by contamination during its preparation, storage and handling.

Chapter X is as important as the other provisions. It requires that 'food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity'. There is no point in having a set of safety rules in place if those working in the premises do not know what is expected of them, and adequate supervision is essential to trap potential failures and other problems. If appropriately carried out, training can instil a sense of ownership into the workforce, and this can be very effective in ensuring that a correct attitude and approach is maintained at all times.

3.5 Specific (vertical) hygiene directives applicable to particular foodstuffs

These directives apply to the industrial-scale production of foods of animal origin but also to some smaller businesses, such as butchers who prepare meat products and sell them to other retailers for onward sale. This can cause problems because of the inflexibility of the requirements.

3.5.1 The legislation

Most EU hygiene and other legislation can be accessed on the Internet (through <http://europa.eu.int/eur-lex/>). A selection of the principal hygiene directives is listed in Table 3.3 (excluding specialised measures such as those on veterinary residues and transmissible spongiform encephalopathies). These directives are

Table 3.3 Vertical hygiene directives

Product	Directive	Date adopted
Fresh red meat	64/433/EEC	26.6.1964
Fresh poultry meat	71/118/EEC	15.2.1971
Meat products	77/99/EEC	21.12.1976
Egg products	89/437/EEC	20.6.1989
Aquaculture animals/products	91/67/EEC	28.1.1991
Live bivalve molluscs	91/492/EEC	15.7.1991
Fishery products	91/493/EEC	22.7.1991
Rabbit meat and farmed game meat	91/495/EEC	27.11.1990
Wild game meat	92/45/EEC	16.6.1992
Milk and milk products	92/46/EEC	16.6.1992
Fishery products on vessels	92/48/EEC	16.6.1992
Other products of animal origin	92/118/EEC	17.12.1992
Minced meat and meat preparations	94/65/EC	14.12.1994
Animal waste	90/667/EEC	27.11.1990

supplemented by Decisions such as those relating to cooked crustacea and molluscs (93/51/EEC) and eggs (94/371/EC).

3.5.2 Areas of control: an example

In general terms, the vertical directives apply to the food chain up to primary processing, which includes harvesting, milking and slaughter. They apply to the industrial production, processing, treatment, inspection, marking, labelling, storage, supply, transportation and related operations, i.e. to the production and 'placing on the market' of various foods of animal origin, but not to their retail sale nor to their supply to consumers by way of catering.

How do the vertical controls apply to the production and placing on the market for human consumption of products of animal origin? The Fresh Meat Directive (64/433/EEC) provides an example. This directive was adopted in 1964 but its text was updated and replaced from 1993 (Directive 91/497/EEC). Temporary derogations were available in the discretion of national authorities (Directive 91/498/EEC) for premises that were unable to comply with the new requirements. Those derogations applied only to structural aspects, not hygiene, and the meat from such establishments had to be distinguished from meat from fully compliant premises.

This directive applies only to the supply of meat from domestic bovine animals, swine, sheep, goats and solipeds. 'Meat' here means all parts of such animals that are suitable for human consumption. 'Fresh meat' means any 'meat' that has not been treated; applying cold treatment to preserve meat, whether or not it is wrapped under vacuum or under a controlled atmosphere, does not count as treating it for these purposes. It is believed that many of the requirements of this and similar directives could be replaced by a risk analysis and management procedure supplemented by veterinary recommendations.

Premises

The Fresh Meat Directive applies throughout the supply chain, from lairage preslaughter, veterinary inspection of the animals through the various stages of production (including cutting, packaging and health marking), to the storage and transportation of the product. It applies to slaughterhouses (abattoirs), cutting plants and cold stores but not to the cutting and storage of fresh meat 'performed in retail shops or in premises adjacent to sale points, where the cutting and storage are performed solely for the purpose of supplying the consumer directly on the spot'. This effectively eliminates most independent butchers' shops from the controls unless they also sell meat to anyone except domestic purchasers and caterers.

A feature of the vertical directives is that they require the national competent authority to approve the premises, equipment and activities carried out there before the product can be supplied for human consumption. The General Food Hygiene Directive has no such requirement for prior approval. Structural requirements for establishments producing fresh meat are contained in Annex I. Derogation is permitted by Article 4 for some establishments based on their limited throughput. This is measured in 'livestock units' (LU) for slaughterhouses (adult bovines and solipeds = 1 LU; other bovines = 0.5 LU; pigs over 100 kg liveweight = 0.2 LU; other pigs = 0.15 LU; sheep and goats = 0.1 LU; lambs, kids and piglets below 15 kg liveweight = 0.05 LU). Slaughterhouses are generally categorised as 'low throughput' if they handle less than 20 LU/week and less than 1000 LU/year, as are cutting plants producing not more than 3 tonnes of meat per week.

Annex I, Chapter I, provides detailed structural requirements covering the quality, cleanliness and condition of walls, floors, drains, changing rooms with lavatories and washbasins, doors, ceilings, insulation, refrigeration, ventilation and lighting, water, hand cleansing and disinfection; taps must not be hand-operable. Tool cleansing and disinfection facilities must be provided, in convenient positions and supplied with water at not less than 82°C. Protection of meat during loading and unloading is necessary, as are pest control and secure containers or a lockable room to store meat not intended for human consumption – and a lockable room for the exclusive use of the supervising veterinary service. Chapters II, III and IV of Annex I provide further requirements for slaughterhouses, cutting plants and cold stores respectively.

Raw materials

The controls on the raw material for the production of fresh meat, animals intended for slaughter, in an approved slaughterhouse are extensive. They are found in Articles 3, 4, 5, 6 and 8 and Annex I. Article 3(1) controls the production of carcasses, half carcasses, quarters and smaller cuts, including offal. These must have been obtained from an animal that has satisfied both ante-mortem and post-mortem inspection and is thus shown to be fit for human consumption, while Article 5 lists 15 categories that must be declared unfit for human consumption by the official veterinarian. Article 7 requires meat unfit for

human consumption to be clearly distinguished from meat fit for human consumption and to be treated according to the Animal Waste Directive, 90/667/EEC. Article 6 provides various special controls. Article 8 provides additional controls on veterinary residues. Article 9 requires the presence of a veterinarian in slaughterhouses and cutting plants. Annex I provides detailed specific requirements to ensure the hygiene of raw materials, including structural and storage provisions, and Chapter VI deals with ante-mortem inspections.

Operations

Animals must be slaughtered hygienically and under veterinary supervision immediately they are brought into slaughter premises, and thereafter a raft of detailed measures come into effect, intended to guarantee that the meat is fit to eat and protected from contamination. Cutting must take place in an atmosphere that has a temperature not exceeding 12°C; during cutting, boning, wrapping and packaging, the temperature of meat must ordinarily not exceed 7°C. Carcasses fit for human consumption must be stamped in ink or branded with a health mark under veterinary control in a prescribed manner. Cut meat and offal must be treated similarly, although the mark may be applied to its packaging in certain cases. Only specified colours can be used for health marking.

Products

There are no compositional or labelling controls exceeding hygiene requirements in this directive.

Temperature control

Chapter XIV requires meat to be chilled immediately after post-mortem inspection and kept at a constant internal temperature not exceeding 7°C for carcasses and cuts and 3°C for offal during storage and transportation. Derogations are available from the competent authority for transportation to cutting plants or butchers' shops in the immediate vicinity of the slaughterhouse, provided the meat reaches these within an hour. If meat is to be frozen, this must be done in the slaughterhouse or cutting plant, or in a cold store to which it was transported directly. It must be cooled without delay to below -12°C and stored below that temperature.

Storage and transport

Conditions are laid down to ensure hygienic storage and transportation. Cut meat and offal must ordinarily be wrapped and packaged unless the wrapping provides sufficient protection, unless it is to be suspended throughout its transport. The veterinarian must ensure that conditions are hygienic, with protected loading and unloading and transport by clean, closed vehicles or containers.

Staff

Annex I requires sufficient changing rooms, with showers, lavatories and wash-basins with taps not operable by hands or arms. There must be suitable facilities

to wash and disinfect hands near workstations; their taps must not be operable by hand and there must be some hygienic means for drying the hands. It requires 'absolute cleanliness' of staff, and people likely to contaminate meat are prohibited from working on it or handling it. Those working where exposed or wrapped meat is being handled, packaged or transported must wear clean headgear, footwear and working clothes and, where necessary, neck shields or other protective clothing. They must wear clean clothes at the beginning of each working day, renewed during the day as necessary. They must wash and disinfect their hands at each resumption of work and several times during the day. Smoking is prohibited where meat is worked on, handled, stored or transported. Article 10(3) requires a hygiene training programme to be in place, involving the official veterinarian. Annex III lays down professional qualifications required by auxiliaries assisting the veterinarian.

Management and supervision

The management of the food business is responsible for all aspects of the hygienic operation of the premises. See also the note (Section 3.2.4) on HACCP implementation and microbiological checks. The competent authority, through official veterinarians, is responsible for supervising the operation of the premises and ensuring that it operates hygienically.

3.5.3 Review

The European Commission instituted a consultation exercise on the consolidation and simplification of the vertical directives in April 1996, with a second stage in February 1997 which included a draft directive to replace the existing legislation. Draft proposals for four regulations and a directive covering the hygiene of foodstuffs and certain animal health rules have since passed through several stages of discussion between the European and member states' authorities. It remains unclear (in August 2002) how quickly these will proceed towards formal adoption, although the complex and inevitably lengthy process has made significant progress and is considered a matter of some priority. It is appropriate to mention the imminent enlargement of the EU, which is expected to result in a significant number of new member states. These are working hard to ensure their hygiene practices comply with the Community standards.

The proposals would base the revised EU hygiene legislation on the General Food Hygiene Directive model (see Section 3.2.2), supplemented by specific provisions in areas where additional or more detailed controls are deemed necessary. Specific requirements for the documentation and verification of risk management systems, again based on principles of HACCP, would strengthen this area (see Section 3.7.1). They would effect a significant measure of consolidation and simplification, although some observers are likely to remain dissatisfied with the extent of this.

3.6 Case study: controversy over minced meat (and meat preparations)

It is essential that meat and foods containing meat be supplied hygienically, to ensure public safety. Regional populations consume minced beef ('mince') in different ways; some invariably cook it thoroughly but elsewhere a significant proportion is consumed lightly cooked or even raw. The use of pork and lamb varies. It was not surprising, therefore, that specific national hygiene requirements varied. Some member states had little legislation; others were restrictive, some limiting mincing to 'on the spot' following a purchaser's request.

Stringent French requirements, developed to restore consumer confidence after hygiene scandals in the 1960s, had formed the basis of a directive applicable in inter-state trade, in 1988. Proposals later that year to extend this to domestic markets were controversial. Four main issues were isolated that were not directly linked to hygiene and were irrelevant for mince that was to be thoroughly cooked (Fogden, 1991). These would increase product costs, affect product quality and cause manufacturing burdens. They involved the following requirements:

- Mince must be prepared from meat less than six days old, preventing use of trimmings from matured beef, thus increasing prices and restricting practical production periods.
- Mince must be chilled within an hour to 2°C, requiring investment in equipment, risking damage to surface tissues and causing significant problems in its transportation – hygiene does not require such stringency.
- Only certain parts of the carcass, excluding shin meat (a traditional source), could be minced – this would have increased prices and affected nutritional quality.
- Frozen meat must be excluded from the production of chilled mince, which made temperature control more difficult and eliminated a traditional practice, causing significant supply problems and increasing prices.

These issues caused special concern in some member states, including the UK and The Netherlands, but the measures were demanded by others, particularly France. British estimates suggested an increase of 25% in the price of its mince, primarily affecting vulnerable groups in society. This led to a strenuous debate, eventually resolved in 1994 by permitting certain national derogations from the requirements of a replacement directive (94/65/EC) provided that product safety was not compromised.

3.7 Future trends

The EU hygiene directives are in the process of being reviewed, which should lead to improved consistency and controls.

3.7.1 Review of the directives

There were early calls for the hygiene legislation to be reviewed to eliminate inconsistencies, and the European Parliament called for the vertical controls to be subordinated to the horizontal directive. The latter recognised this, requiring the Commission to examine the relationship and, if necessary, make proposals by June 1996. It also had to report and make any appropriate proposals before 1999 on the experience gleaned from the implementation of the horizontal directive.

It seems probable that the horizontal text will become the foundation for a more consistent package of hygiene legislation (see Section 3.5.3), although this is taking time. The substitution of risk management techniques into the vertical legislation, which is currently based on prescriptive controls, is unlikely to take place soon, although some requirements have been introduced as an addition to the previous controls (see Section 3.2.4). The legislators have to satisfy sometimes-irrational public demands as well. There are great hurdles to be overcome to achieve the desirable solution based on an integrated approach, but eventually a more consistent and scientific approach must surely come to fruition, encouraged by the transfer of many responsibilities to DG Sanco of the European Commission and by the creation of the European Food Safety Authority.

It is unclear what compromise will be found. However, the current proposals envisage a number of common requirements based on the provisions in Directive 93/43/EEC and including HACCP principles, with specific controls in annexes where these are deemed necessary (whether on hygiene or political grounds). It is hoped that the quality and composition requirements of the vertical directives would be revoked, or transferred to more suitable legislation. It is thought unlikely that the hygiene directives will be revised into consistent texts and implemented into national legislation before the beginning of 2006.

3.7.2 Discussion

As always, it is essential to refer to the legislated texts to know what is required of any business operator in a particular situation. In the case of EU hygiene legislation, this is more difficult because it is necessary not only to look at the law as enacted in the member state where an operation is taking place, but also to consider the objectives as laid down in the original EU directive which were agreed to by the relevant government as part of that measure when it was adopted. The two usually agree, more or less. But that uncertainty, magnified where more than one state implementation is involved because of trans-frontier activity, can cause problems.

This could have been alleviated by the adoption of regulations having immediate effect rather than directives – but this was politically unacceptable because the governments valued flexibility of approach. The current proposals are for regulations, but these may yet be adopted as directives, as happened to the proposals that led to the current legislation. Various problems therefore remain, and some issues could have been resolved better.

Improvement of scientific basis

The detailed requirements of the vertical provisions (see Section 3.5) contrast with the essential rules in Directive 93/43/EEC (see Section 3.4), which require adherence to the principles of good hygiene management, although some particular requirements are also specified. It is not obvious that the use in the vertical texts of the risk management approach of the General Food Hygiene Directive would result in risk to health. That would have eased the task of updating plants and provided flexibility to new establishments. The detail in the vertical directives perhaps suggests a lack of faith by the EU authorities in animal product industry operators and/or in those charged with the official control of this sector. There are grounds for prudence where any perishable foods are being produced, distributed and supplied, but it is strange that such caution is shown during the initial stages of the chain of supply of products of animal origin, whereas later stages, for example in retail outlets, are generally controlled less repressively, as are other microbiologically sensitive foods.

Consistency, necessity and proportionality

It is essential that hygiene controls are practicable. The current ones are inconsistent, leading to confusion and sometimes to difficulties where more than one applies in an establishment. This requires attention, preferably resulting in technically justifiable controls. These controls must satisfy their purpose, to control hygiene so that public safety can be assured. This is generally the case, but sometimes excessive requirements have been introduced, breaching the EU principle of proportionality that should apply to prevent legislation in excess of what is required to solve a problem. These often just satisfy political needs by enabling governments to avoid reducing unjustifiable controls, because of their fear of alarming consumers. In an EU context, politics often outweighs science when legislative compromises have to be agreed.

Elimination of other measures

It is suggested that there is no place in hygiene legislation for non-hygiene controls. There are many that should be moved elsewhere, or preferably eliminated in some cases, to ensure proper attention to others that do ensure food safety. Moreover, these often seem to have been introduced in the existing vertical texts without understanding that existing horizontal controls, for example in food labelling directives, are adequate. In this context, it may again be noted that the current proposals define ‘food hygiene’ as ‘the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use’.

3.7.3 Outcome: self-regulation or prescription

Risk analysis and management provide a mechanism that can ensure food safety equally as well as prescriptive legislation. Both approaches require commitment and/or enforcement to be effectively implemented. What is required is a

positive, competent and thorough attitude and implementation of good hygiene standards by everyone involved in every business in the food supply chain. This cannot be instituted by legislation, nor is it likely. It can be improved by educating people into understanding why it is essential, and what consequences can follow failure.

Confidence in industry management

At present, there is reason to lack faith in some food businesses. Their hygiene control is inadequate, putting consumer safety at risk. Consequently there is, and there will remain, a need for prescriptive legislation supported by effective enforcement and penalties. Many businesses, however, are being run well. There is scope for these to benefit from relaxation of prescriptive detail, allowing them to improve their performance and profitability in a more flexible manner. It is suggested that this should only be done where the enforcement authority is satisfied that the attitude and technical competence in the business are such that it will maintain high hygiene standards. It should be possible for all businesses to benefit from this, in principle, and the authorities would clearly need to maintain an adequate level of surveillance to ensure that the situation remains acceptable.

Ease of enforcement

However, complementation of risk management systems is more difficult to enforce than complying with detailed requirements. There is a need to employ thorough and thoroughly competent officials with a good understanding of hygiene as it applies in the particular businesses that they inspect. Even then, problems arise because hygiene practices are often debatable and faults can be difficult to challenge objectively so as to satisfy a court. It is therefore probably wise to err slightly on the side of caution in the public interest for all businesses handling any perishable foods, not just those that handle such products of animal origin. However, those able to demonstrate a history of good attitude and control should be permitted to manage their hygiene in a business-efficient way.

3.8 Sources of further information and advice

3.8.1 Trade associations

The selected organisations in Table 3.4 perform representative functions for national associations and individual companies at European level. See also the European Public Affairs Directory.

3.8.2 Consumer groups

- European Bureau of Consumers' Unions (BEUC), tel. +32 (0)2 735 31 10
- European Federation of Consumers' Co-operatives (Eurocoop), tel. +32 (0)2 230 32 44.

Table 3.4 European trade associations

Sector	Organisation abbreviation	Telephone
Agriculture	COPA and COGECA	+32 (0)2 287 27 11
Aquaculture	EAS	+32 (0)59 32 38 59
Bakery and confectionery	CEBP	+32 (0)2 230 34 16
Butchers	IBC	+32 (0)2 230 38 76
Butter	TRANSBEUROP	+32 (0)2 230 44 48
Milk and dairy products	EUCOLAIT	+32 (0)2 230 44 48
Eggs, game and poultry	EUWEP	+31 (0)30 69 67203
Fish	EUROPECHE	+32 (0)2 230 48 48
Fish processors	AIPCEE	+32 (0)2 743 87 30
Food and drink	CIAA	+32 (0)2 514 11 11
Fruit and vegetable nectars	AIJN	+32 (0)2 743 87 30
Ice cream	EUROGLACES	+33 (0)1 53 42 13 38
Livestock and meat	UECBV	+32 (0)2 2304603
Mayonnaise and sauces	CIMSCEE	+32 (0)2 743 87 30
Meat processors	CLITRAVI	+32 (0)2 203 51 41
Poultry and game	CDVGP	+32 (0)2 512 61 78
Poultry and poultry processing	AVEC	+45 (0)33 25 41 00
Processed cheese	ASSIFONTE	+49 (0)228 95 96 90
	EUROCOMMERCE	+32 (0)2 230 58 74
Retailing	FEMGED	+32 (0)2 734 32 89
	GECODE	+49 (0)221 936 55770
Soft drinks	UNESDA	+32 (0)2 743 40 50
Tomato products	OEICT	+32 (0)2 743 87 30

3.8.3 Other contact points

- European Commission, Rue de la Loi 200, B-1049 Brussels, Belgium, tel. +32 (0)2 299 11 11
- Food Law Enforcement Practitioners' Forum, tel. +31 (0)70 340 50 60
- Meat and Livestock Commission, tel. +44 (0)1908 677577 or +32 (0)2 230 86 68
- National Agriculture, Consumer Protection and Health authorities.

3.9 References and bibliography

(For EU legislation, see Table 3.4.)

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4

Hygiene regulation in the United States

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4.1 Introduction

From the beginnings of civilization there have been concerns about the quality and safety of food. The Jewish dietary laws are found in the Book of Leviticus in the Old Testament. The dietary laws of Islam are found in the Koran. These religious practices were partly based on practical knowledge of known food safety concerns of the times. And there was the folklore concerning what was safe to eat, such as '*don't eat the red berries*' type of advice. In 1202, King John of England proclaimed the first English food law, the Assize of Bread, which prohibited adulteration of bread with such ingredients as ground peas or beans. Most are familiar with the German Spaten-Reinheitsgebot-Purity law of 1516, the standard of purity for beer.

Regulation of food in the United States (US) dates from early colonial times. The following chronology describes some of the milestones in US food regulation. Adulteration constituted much of the early concerns about food safety. In 1880 President Hayes appointed chemist C.M. Wetherill to the recently established US Department of Agriculture (USDA). This was the beginning of the Bureau of Chemistry, the predecessor of the Food and Drug Administration (FDA). Peter Collier, chief chemist, USDA, recommended passage of a national food and drug law in 1883. The bill was defeated, but this brought attention to food safety, resulting in 100 bills being introduced in Congress during the next 25 years. Dr Harvey W. Wiley became the Bureau's chief chemist after Collier and expanded the Bureau's role in protecting the food supply. Wiley is called the 'Crusading Chemist' and 'Father of the Pure Food and Drug Act'.

The original Food and Drug Act was passed by Congress and signed into law by President Theodore Roosevelt in 1906. The Meat Inspection Act was passed

on the same day. Shocking disclosures of unsanitary conditions in meat processing plants, the use of poisonous preservatives and dyes in foods and cure-all claims for worthless and dangerous patent medicines written about in *The Jungle*, a novel by Upton Sinclair, were the driving forces leading to these two new laws. There were numerous further regulations and US Supreme Court rulings on adulteration, misbranding, false and misleading claims, and food additives. In 1930 the McNary-Mapes Amendment to the 1906 Act authorized FDA standards for quality and quantities in containers. In 1933 the FDA recommended a complete revision of the obsolete 1906 Act. After five years of legislative battle, the Federal Food, Drug, and Cosmetic (FD&C) Act of 1938 was enacted. The 1938 FD&C Act established the FDA as the controlling federal authority for food safety. In 1940 the FDA was transferred to the Federal Security Agency, which in 1953 became the Department of Health, Education and Welfare (now Health and Human Services).

From the passage of the FD&C Act of 1938 to the present there have been a number of changes to the Act, the most notable being as follows.

- The 1948 Miller Amendment affirming that the FD&C Act applies to goods in interstate commerce
- The 1954 Factory Inspection Amendment
- The 1958 Food Additive Amendment that requires manufacturers to establish the safety of new food additives, and which includes the Delaney clause that prohibits approval of any food additive shown to induce cancer, when used at any level, in humans and animals
- The FDA publication of the first list of 200 substances generally recognized as safe (GRAS)
- The 1960 color additive amendment which requires manufacturers to establish their safety
- The FDA began administration of sanitation programs for milk, shellfish, food service and interstate travel facilities
- The low-acid food processing regulations now recorded in Title 21 of the Code of Federal Regulations, Part 113 (21 CFR 113)
- The Infant Formula Act of 1980
- The Tamper Resistant Regulations
- The Bioterrorism of 2002.

4.2 The Food and Drug Administration (FDA)

The FDA touches the lives of virtually every American every day. It is their job to see that the food we eat is safe and wholesome, the cosmetics we use won't hurt us, the medicines and medical devices we use are safe and effective, and that radiation-emitting products such as microwave ovens won't cause harm. Food and drugs for pet and farm animals also come under the purview of this agency. The FDA ensures that all of these products are labeled truthfully with

the information necessary for proper use. The FDA is one of the oldest consumer protection agencies. Its 9000 employees monitor the manufacture, import, transport, storage and sale of about one trillion dollars' worth of products each year. The FDA is a public health agency, charged with protecting American consumers by enforcing the FD&C Act and other related public health laws. To carry out this mandate of consumer protection, the FDA has about 1100 investigators and inspectors who cover the nation's 95 000 FDA-regulated businesses. These employees are located in offices in 157 cities across the USA.

The United States Department of Agriculture (USDA) is also part of the US food safety system. USDA investigators and inspectors visit more than 15 000 facilities a year, seeing that products are properly manufactured and truthfully labeled. As part of their inspections, they collect 80 000 domestic and imported samples for examination by FDA scientists for label checks.

If a company is found violating any laws the FDA enforces, the FDA can encourage the firm to voluntarily correct the problem or recall a faulty product from the market. A recall is usually the fastest and most effective way to protect the public from unsafe products. When a producer can't or won't correct a public health problem with one of its products voluntarily, the FDA has legal sanctions it can use. The agency can go to court to force a manufacturer to stop selling a product and to have products already produced seized and destroyed. When called for, criminal penalties are sought against manufacturers and distributors. Almost 3000 products a year are found to be unfit for consumers and are withdrawn from the market, either by voluntary recall or by court-ordered seizure. In addition, nearly 30 000 import shipments a year are detained at the port of entry because the goods seem to be unacceptable.

The FDA's 2100 scientists, including 900 chemists and 300 microbiologists stationed in the 40 laboratories around the country, prepare the scientific evidence needed to back up the agency's legal cases. Some of these scientists analyze samples to see, for example, whether products are contaminated with illegal substances. Other scientists review test results submitted by companies seeking approval for drugs, vaccines, food additives, coloring agents and medical devices. The National Center for Toxicological Research, at Jefferson, Arkansas, which investigates the biological effects of widely used chemicals, is operated by the FDA. The agency also runs the Engineering and Analytical Center at Winchester, Massachusetts, which tests medical devices, radiation-emitting products, and radioactive drugs.

Assessing risks and weighing risks against benefits is at the core of the FDA's public health protection duties. By ensuring that products and producers meet certain standards, the FDA protects consumers and enables them to know what they're buying. The agency requires that drugs, both prescription and over-the-counter, be proven safe and effective and that food additives (indirect, secondary direct, and direct) are also safe and effective. In deciding whether to approve new drugs or food additives, the FDA does not do research, but rather examines the results of studies done by the manufacturer. The agency must determine that the new drug produces the benefit that it is supposed to produce

without causing side-effects that would outweigh those benefits and that food additives are safe for their intended use. A major FDA mission is to protect the safety and wholesomeness of food. The agency's scientists take samples to see whether any substances, such as pesticide residues, are present in unacceptable amounts. If contaminants are identified, the FDA takes corrective action. The FDA also sets labeling standards to help consumers know what is in the foods they buy.

The FDA and USDA are the primary agencies of the federal government in the United States responsible for safeguarding the food consumed by its citizens domestically, and overseas in US-controlled establishments, as well as in US regulated modes of transportation. Hygienic concerns are policed by 'factory' and food service inspections. These inspections are one of the tools made available through the FD&C Act of 1938 (FDCA) in Sections 301, 703 and 704. The Factory Inspection Amendment of 1953 clarified this authority. Plant inspection is an enormous task and requires full industry and state cooperation. The USDA has the overall responsibility for meat, poultry and egg processing facilities and, through a memorandum of understanding (MOU) with the FDA, provides voluntary inspection for dairy plants processing non-Grade A dairy products, i.e. dry milk products, cheese, and butter. The FDA also has an MOU with the states for state regulatory inspections of Grade A dairy plants. The legal basis for USDA plant inspections is provided by the following Acts:

- The Poultry Product Inspection Act of 1957
- The Federal Meat Inspection Act of 1967
- The Egg Products Inspection Act of 1970.

The 1946 Agricultural Marketing Act provides the basis for the USDA Agriculture Marketing Service, which is responsible for the voluntary, fee-for-service dairy plant and equipment reviews carried out by the USDA Dairy Grading Service.

4.3 Regulation in practice: the case of dairy processing

In the United States, the safety and quality of milk and dairy products are the responsibility of two federal and 50 state regulatory agencies. Local jurisdictions may also regulate. On the federal side, these responsibilities are assumed by the FDA, which is part of the US Department of Health and Human Services, and by the USDA. The FDA has the ultimate regulatory authority and monitoring responsibility over the dairy industry, while the USDA involvement with this industry is voluntary and service-oriented. Each state is empowered by state laws to carry out certain regulatory functions with respect to the dairy industry within that state.

In dealing with the safety and quality of milk and dairy products, the US dairy industry identifies two grades of milk: Grade A and manufacturing grade (commonly called Grade B). Grade A milk is produced and handled in

accordance with strict sanitation requirements and is intended for use in fluid milk products. Grade B milk may be used in manufactured dairy products such as ice cream, frozen desserts, and cheese (excluding cottage cheese). Less stringent sanitation requirements apply to the production and handling of Grade B milk, and this milk may be used only in manufactured dairy products such as butter, cheese and powdered milk except Grade A powder. Approximately 90% of milk produced in the US is sold to plants and dealers as Grade A.

In the 1920s and 1930s, the shipment of milk and milk products from one political jurisdiction to another was restricted by the availability of producer milk to a point of processing and marketing. Exceptions occurred in large metropolitan areas contiguous to one or more political sub-divisions, which made it necessary for milk to be shipped across political (or regulatory jurisdiction) boundaries. A second and equally important impediment to the movement of milk was differences in state and local public health regulations, which often made it difficult, if not impossible, to ship milk between geographical areas. If movement was necessary, it was often done under the supervision of multiple local regulatory authorities, requiring compliance with their differing public health regulations. It was with this background that dairy industry leaders and government regulatory authorities initiated action that led to the formation of the National Conference on Interstate Milk Shipments (NCIMS) in the early 1950s. The goals of the Conference are as follows:

1. To provide sanitary regulations to protect public health.
2. To ensure uniformity and enforcement of milk regulations, and reciprocity.
3. To ensure that milk is produced under regulations which would safeguard public health.

In short, their objective was and remains to provide ‘the best possible milk supply for all people’.

The NCIMS is a voluntary organization consisting of representatives from each state, FDA, USDA, and the dairy industry. This organization maintains the federal/state milk certification program (Interstate Shippers Program) to facilitate the movement of Grade A Milk in interstate commerce. The program relies on the *Grade A Pasteurized Milk Ordinance* (PMO) for uniform sanitary standards, requirements and procedures. This program provides the state and federal agencies and the dairy industry with reliable data on sources of acceptable high-quality milk. These sources are published quarterly in the *IMS List Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers*. The *IMS List* is available from the FDA-Milk Safety Branch. 3-A Sanitary Standards are referenced in the PMO as appropriate sanitary design criteria for equipment and are used to evaluate the compliance of equipment with established hygienic standards.

The *Grade A Pasteurized Milk Ordinance* (PMO) is a model milk ordinance and code produced by the US Public Health Service (PHS), the FDA, state regulatory agencies and industry representatives. The PMO has been developed not as a federal law but as a uniform standard recommended for state adoption.

The advantages of the PMO for the NCIMS cooperative programs are:

1. The PMO as a model ordinance and code discourages the use of public health regulations to establish unwarranted trade barriers against the acceptance of high-quality milk from one jurisdiction to another. It provides for full reciprocity, which allows free US interstate movement of IMS-listed milk and milk products.
2. The model ordinance and code allows the establishment of effective and well-balanced milk sanitation programs throughout the USA.
3. The Conference stimulates the adoption of adequate and uniform state and local milk-control legislation and encourages the application of uniform enforcement procedures through appropriate legal and educational measures.

In addition to participating in preparing the PMO, the responsibilities of the PHS and FDA to the NCIMS include:

1. Standardizing, for uniformity, the rating procedures of state and federal personnel at least every three years.
2. Publishing a list of Regional Milk Specialists and State Milk Sanitation Rating Officers whose rating methods and interpretations of the PMO have been evaluated and certified by the PHS and FDA.
3. Standardizing the evaluation procedures of State Milk Laboratory Evaluation Officers and State Sampling Surveillance Officers.
4. Publishing a list of State Milk Laboratory Evaluation Officers whose competence in interpreting and evaluating milk laboratory methods has been evaluated and certified by the PHS and FDA.
5. Publishing quarterly the *Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers* (IMS List). The IMS List contains a state-by-state enumeration of all current listed milk and milk product shippers, along with their products' sanitation and enforcement rating scores.
6. Extending to state regulatory agencies and educational institutions assistance in the training of representatives of state and local governmental units, including milk sanitation rating, milk laboratory evaluation, sampling surveillance officers, and dairy industry personnel.
7. Conducting check ratings of the sanitation compliance status of listed interstate shippers.
8. Evaluating and approving the laboratory facilities and publishing a list of approved laboratories.
9. Assisting in development of sanitary standards for the fabrication of single-service containers and closures for milk and milk products and publishing a list of acceptable single-service plants.

The FDA has an arrangement with the USDA under which the latter assists the states in developing safety and quality regulations for the manufacturing milk industry within their local areas. The FDA periodically inspects ice cream, frozen dessert and cheese manufacturing plants for compliance with the Food,

Drug, and Cosmetic Act using the PMO or the current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. FDA also promulgates standards of identity and labeling, quality, and fill-of-container requirements for milk and dairy products moving in interstate commerce.

4.4 Inspection in the dairy industry

The FDA has the responsibility under the Food, Drug, and Cosmetic Act, the Public Health Act, and the Milk Import Act to assure the public that the nation's milk supply and imported dairy products are safe and wholesome. The FDA has the regulatory authority to require processors of both Grade A and Grade B milk to take remedial action when conditions exist that could jeopardize the safety and wholesomeness of milk and dairy products being handled. Normally, the FDA limits its compliance activities to Grade A milk and dairy products moving in interstate commerce. To lessen its regulatory compliance burden, the FDA has entered into a cooperative arrangement with the states. Through a Memorandum of Understanding with the NCIMS, which comprises all 50 states, the FDA and the states share the responsibility for ensuring the safety and wholesomeness of Grade A milk and dairy products.

Under the authority of the Agricultural Marketing Act of 1946, the United States Department of Agriculture (USDA) is directed to carry out certain voluntary service functions to aid in the efficient marketing of American agricultural products. These services include developing inspection and grading services, and recommending standards to encourage uniformity and consistency in commercial practices.

The USDA also inspects dairy manufacturing plants to determine whether good sanitation practices are being followed. Only after an inspection shows that the plant has met the requirements in the *General Specifications for Approved Plants* can that plant qualify for services such as grading, sampling, testing, and certification of its products. The USDA has no regulatory authority regarding dairy plant inspections and cannot require a plant to change its operations. It can only withhold approval and decline to provide inspection and grading services. The grading and inspection services are offered on a voluntary basis. Those wishing to use the services must request them and pay a fee. The USDA Dairy Programs are totally funded by fee for service – no tax dollars are used. The USDA/Agriculture Marketing Service (AMS) publishes a quarterly list of *Dairy Plants Surveyed and Approved for USDA Grading Service*. The USDA inspects the dairy plants listed in this publication periodically.

USDA plant approval is determined by unannounced inspections, conducted at least twice yearly and covering more than 100 items, including milk supply, plant facilities, condition of equipment, sanitary practices, and processing procedures. The inspection and grading criteria are outlined in *General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service of Manufactured or Processed Dairy Products* (7CFR 58.101 to 58.938)

administered by the Dairy Programs of USDA. The Dairy Grading Branch of the USDA-AMS Dairy Programs also provides service under its full-time resident grading and quality control program. Plants using this service are listed in *Dairy Plants Surveyed and Approved for USDA Grading Service* with an asterisk. This full-time program offers on-the-spot official grading of the plant's manufactured products, laboratory testing and quality control, and plant inspection services. The resident program also makes available to the plant manager the technical know-how and experience of the Dairy Grading Branch's supervisory staff for help in solving product quality problems. Plant inspection services and the Resident Grading and Quality Control Programs are available on a voluntary basis, and fees are charged to cover costs.

Additionally, the USDA Dairy Grading Branch conducts equipment sanitary design reviews. The USDA Dairy Grading Branch fully supports and utilizes established 3-A Sanitary Standards and 3-A Accepted Practices. When equipment or systems for which 3-A Standards or Practices have been developed are presented for USDA review, the document will be used as the sanitary criteria. When USDA review of equipment is requested for which there are no 3-A Standards, the USDA will use the general criteria found in their publication titled *USDA Guidelines for the Sanitary Design and Fabrication of Dairy Processing Equipment*. These guidelines are consistent with the sanitary criteria found in the 3-A Sanitary Standards.

Under an arrangement with the FDA, the USDA assists individual states in establishing safety and quality regulations for manufacturing-grade (Grade B) milk. In this regard, the USDA has developed model regulations for state adoption that relate to the quality and sanitation aspects for producing and handling such milk. These regulations are set forth in the *Recommended Requirements for Milk for Manufacturing Purposes and Its Production and Processing*. USDA officials monitor the state programs to determine compliance with the Recommended Requirements and also can, upon request, provide training to state inspectors. The 29 states that have Grade B milk have adopted these model regulations.

Fifty states have enacted safety and quality regulations for Grade A milk, and 29 states have enacted regulations for Manufacturing Grade (Grade B) milk, which are essentially identical to those contained in the PMO and the USDA Recommended Requirements. The enforcement of these regulations is normally the responsibility of the state departments of health or agriculture. The states' authority comes from their state statutes. The states are the primary regulatory agencies and generally have the first right of refusal when regulatory action is needed. In practice, states make most of the day-to-day decisions.

Specifically with respect to equipment, approval can only come from state regulatory authorities. Most states have adopted the PMO for their basic Grade A milk sanitation document. Some have adopted 3-A Sanitary Standards and 3-A Accepted Practices as regulation, while others use 3-A criteria as guidance during plant inspections. The states may look to the Public Health Service/Food and Drug Administration (PHS/FDA) for guidance on some issues. This may

involve equipment for which there are no 3-A Standards, or application and/or interpretation of specific requirements of the PMO. The PHS/FDA publishes coded memoranda on selected issues not covered by existing regulations or standards and to clarify existing regulations. Even though the states are the primary enforcement authority, if there is imminent public health danger, the PHS/FDA will enter directly into the regulatory process by the authority granted them by the Food, Drug, and Cosmetic Act. However, the PHS/FDA's usual stature is one of cooperation, assistance and advice.

The states' role is of course much more detailed than is described here; but the enforcement procedures for certifying interstate milk shippers are uniform in all 50 states. The regulations may vary slightly from state to state, but they will have as a minimum requirement those found in the PMO and the 3-A Sanitary Standards. Under the National Labeling and Education Act, states must also have uniform labeling requirements. States desiring deviations must have special permission to require product standards in excess of federal standards of identity.

4.5 Regulation of particular processes

There are three sets of regulatory requirements for food safety applicable to aseptic food processing and packaging operations. Aseptic systems can fall under the regulatory jurisdiction of either the FDA or the USDA. The processor and/or equipment supplier will need to determine which regulatory requirements are pertinent based upon the type of product being processed. When milk or milk products as defined in the PMO are involved, the aseptic operation must comply with the provisions of the PMO, in addition to the FDA Low-Acid Canned Food Regulations. Since 1983 the PMO has included aseptically processed milk products and serves as a code of practice for the production and processing of these products.

Low-Acid and acidified food products that contain little or no meat or poultry are covered by the FDA regulations on 'Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers', and for 'Acidified Foods'. These regulations are found in Title 21 of the *Code of Federal Regulations* (CFR), parts 108, 113 and 114. Section 113.40(g) lists specific requirements for low-acid aseptic processing and packaging systems, including specifications for equipment and instrumentation.

The FDA requires registration of aseptic processing plants and filing of thermal processes and sterilization procedures before product can be distributed in interstate commerce. The FDA regulations rely upon aseptic processing and packaging authorities to establish adequate parameters for sterilization of product, packages and equipment, so that commercial sterility of the end-product is assured. The FDA exerts its influence over the types of aseptic processing and packaging systems that can be utilized to produce foods for distribution into interstate commerce by its review and acceptance or rejection of process filing forms from individual companies. When a company files

processing schedules for new aseptic processing or packaging systems, the FDA's technical staff request sufficient information from the processor to evaluate the adequacy of the equipment and procedures to produce a commercially sterile product. Usually, the equipment manufacturer(s) and the processing authority are involved in the presentation of this information to the FDA. The FDA relies upon periodic inspections of processing plants to monitor compliance with these regulatory requirements.

The FDA must accept food contact surfaces of aseptic packaging materials, and package sterilization media, including hydrogen peroxide and irradiation, for their intended purpose before they may be used in FDA or USDA regulated food establishments. Present accepted uses are listed in 21 CFR 174 through 179. For new uses a petition must be submitted to FDA to amend the food additive regulations. Procedures and types of data necessary to support such a petition are described in 21 CFR 171.

The dairy regulatory situation in the US may involve the FDA, USDA and state regulatory authorities. Although the FDA has overall responsibilities for ensuring the safety and quality of milk and milk products, it is the individual state that has the primary responsibility for regulation of dairy farm and milk plants and equipment approval. The USDA-Dairy Programs is not a regulatory agency, but offers voluntary inspection services. However for a dairy product to receive a USDA Grade it must be manufactured in a USDA-inspected plant.

4.6 Regulation of equipment: the 3-A Sanitary Standards

The 3-A Sanitary Standards are used throughout the US as the source of hygienic criteria for food and dairy processing, packaging, and packaging equipment. 3-A Standards are referenced in the PMO, adopted or referenced in most state dairy regulations and required by USDA dairy regulations as containing suitable hygienic criteria. Within the US other sectors of the food industry use 3-A Standards in whole or in part. For example, the biopharmaceuticals industry, the juice and carbonated beverage industry, and especially the egg processing industry use 3-A. 3-A criteria have also been successfully applied to the dry cereal products processing industry. The Canadian milk producing and processing industry also use the PMO and 3-A Standards. Additionally, the 3-A Secretary receives many requests for Sanitary Standards from Europe, Australia and New Zealand. In short, 3-A Standards are useful for equipment design where minimizing microbial risk is important, where clean-in-place is desirable, or where both are important. Applications for equipment and systems used for aqueous-based chemical processing are found in 3-A Sanitary Standards.

Criteria found in the 3-A Sanitary Standards are applied to equipment and machinery. 3-A Accepted Practices are applied to systems. The 3-A Sanitary Standards and 3-A Accepted Practices consist of seven parts:

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1. A finite scope is important because it covers, in terms of the piece of equipment or system, where the standards are to be applied; i.e., it is a statement of intent.
2. Definitions of terms used in standards define the products, product contact surfaces, non-product contact surfaces, and any specific terms of the equipment under consideration as well as specific terms covered by the standard.
3. Descriptions of permitted materials consider the self-limiting characteristics of materials that compose the equipment. Sanitation specifications specify this with the ultimate criterion being based on the environment of its intended use. In 3-A, the metal of choice is AISI 300 series or equivalent stainless steel or metals equivalent to or better than 300 series.
4. Details of fabrication of the equipment for sanitary design as affected by the fabrication process may include finish, limitation of radii, self-draining characteristics, and accessibility for cleaning and inspection, as well as the design for mechanical cleaning (CIP), floor and wall clearance, the integrity of product contact surfaces and any other factors for the construction of the equipment to meet necessary sanitary design criteria.
5. The Appendix is an advisory section of the standards that includes references to stainless steel materials and product contact surface finish, plus other information unique to the construction and installation of the equipment. The Appendix may also contain special considerations needed for cleaning and sanitizing the equipment.
6. The effective date is generally six months after final approval for equipment.
7. 3-A Accepted Practices usually contain at least one additional section concerned with proper installation requirements to satisfy public health concerns.

The development of 3-A Sanitary Standards and 3-A Accepted Practices occurs by orderly and prescribed protocols. The 3-A Sanitary Standards Committees include membership from three stakeholder groups representing regulatory, processor and equipment suppliers. The decisions on acceptable hygienic criteria are reached by consensus and are scientifically based. The 3-A Sanitary Standards Committees cooperate with the European Hygienic Engineering and Design Group (EHEDG) and the International Standards Organization (ISO) Technical Committee 199 on hygienic guidelines and standards development. The goal is to produce non-conflicting criteria and, if possible, documents that will produce equivalent results when applied. 3-A and NSF International work together to develop hygienic standards for machinery used by the non-pumpable food industry. To date, the partnership has co-adopted ISO FDIS 14159 Machinery Safety-Hygiene Requirements for the Design of Machinery and a family of three ANSI/NSF/3-A standards for meat and poultry processing equipment. The ANSI/NSF/3-A family of meat and poultry standards has been chosen for use by the USDA/AMS for use in its voluntary, fee-for-service meat and poultry equipment review program.

4.7 Regulation of the meat and seafood industries

The Food Safety and Inspection Service (FSIS), a public health agency in the United States Department of Agriculture (USDA), protects consumers by ensuring that meat and poultry products are safe, wholesome, and accurately labeled. The FSIS regulates meat and poultry products that account for a third of consumer spending on food, with an annual retail value of \$120 billion. It regulates all raw beef, pork, lamb, chicken, and turkey, as well as sausage, soups, stews, pizzas, and frozen dinners (any product that contains 2% or more cooked poultry or 3% or more raw meat).

Under the Federal Meat Inspection Act and the Poultry Products Inspection Act, the FSIS inspects all meat and poultry sold in interstate and foreign commerce, including imported products. Approximately 7400 federal inspectors carry out inspection laws in about 6200 plants. Inspectors check animals before and after slaughter, visually examining over six billion poultry carcasses and 125 million livestock carcasses, including beef, pork, and lamb, each year. They prevent diseased animals from entering the food supply and examine carcasses for visible defects that can affect safety and quality. The FSIS also inspects products during processing, handling, and packaging to ensure that they are safe and truthfully labeled. To address specific concerns, inspectors can test for the presence of pathogenic microorganisms and violative drug and chemical residues. There are mandatory Hazard Analysis Critical Control Point (HACCP) requirements for all federally inspected plants and a zero tolerance for *Salmonella*.

Consumption of seafood is up 60% over the past decade, and the trend is continuing. The US seafood industry is broad and varied. There are at least 1000 types of fish harvested from the ocean or raised by aquaculture. There are more than 4100 US seafood processors and handlers. Much of the fishing industry is old-fashioned, especially compared to other major food industries. Production is still dominated by individual, independent boat operators, which can give rise to insufficient control over the fish from catch to delivery at dock. In addition, there is limited control over the handling of seafood by seafood wholesalers and processors. Although most fish are free from chemical and biological contaminants and disease when caught, they can spoil during the sometimes long trip from harvest to table. Once seafood is purchased, poor storage, handling or cooking can render it unfit to eat.

The FDA's present fish inspection program involves collecting samples of fish to monitor their quality and to inspect fish processing facilities. To enhance this mandatory program, the FDA, along with the National Marine Fisheries Service (NMFS), is piloting a new, voluntary, fee-for-service fish inspection program. The program is based upon the HACCP system of ensuring food quality and safety. HACCP involves identifying and then monitoring the critical points in handling and processing food where risk of contamination is greatest. The FDA first used HACCP in the early 1970s to control microbiological hazards in the mushroom canning industry. After considerable refinement, the system was made mandatory for the low-acid/acidified canned food industry.

Under the new inspection program, seafood plants design their own HACCP plans and submit them to the FDA and the NMFS for approval. The two agencies then monitor the plants' implementation of the plans. HACCP controls everything critical to the production of a safe, wholesome, properly labeled product. The aim of the new inspection program is to prevent problems before they start.

4.8 Trends in US regulation

The FDA has issued a revised version of its *Food Code*, a reference that guides retail outlets such as restaurants and grocery stores, and institutions such as nursing homes, on how to prepare food to prevent food-borne illness. The updated edition includes updated recommendations based on the latest findings in food safety science. The new recommendations cover such critical areas as raw eggs, juices, raw sprouts, ready-to-eat foods, hamburgers, pork and poultry. The *Food Code* is updated every two years, to coincide with biennial meetings of the Conference for Food Protection. The conference consists of representatives from regulatory agencies at all levels of government, the food industry, academia, and consumer organizations that work to improve food safety at the retail level.

The future of food and dairy hygiene regulation will be less one of command and control by federal and state regulators and more one of self-determination by the food and dairy processing industries. Pathogen control and application of HACCP will replace command and control. This change has already occurred in the USDA–Food Safety and Inspections (FSIS) Service for the meat and poultry industry. USDA–FSIS eliminated its prior approval before use programs in the areas of facilities and equipment review sanitation, ingredients and labeling in favor of microbial reduction regulations and mandatory HACCP. To replace prior equipment approval, NSF International and 3-A have cooperated in developing hygienic equipment standards for meat and poultry equipment. NSF/3-A are planning to develop standards for facilities. The seafood industry is following the same model. NSF/3-A have industry and regulatory support to develop equipment standards. Also, under the US NCIMS, there are several dairy plants in an HACCP pilot program. If these pilot programs are successful and acceptable to the NCIMS and USPHS, HACCP and self-determination by the dairy industry could replace the current command and control regulatory approach now used. The food industry is well advanced in using an HACCP approach to ensure food safety. This is due in part to lack of human resources by the states and federal government to do the routine inspections for processing plants other than those mentioned above. Also, the federal regulations for foods, other than dairy, meat and poultry, infant formula and low/high acid foods in hermetically sealed containers, are rather general and not well suited for command and control regulation. Global trade will ultimately drive food safety regulation to be universal, at least to the extent that country or regional regulations achieve

equivalent levels of public health safety. Certainly, good manufacturing practices, HACCP and SSOPs will be central to a universal system. The road to food safety is global and is one we must all take using the same routes.

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Part II

Hygienic design

5

Sources of contamination

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5.1 Introduction

The three main types of food contaminant are physical, chemical and microbiological. Foods can become contaminated during growing and harvesting of raw materials, storage and transport to the factory and processing into finished products. Finished products may then be contaminated during subsequent storage and transport to shops, and during storage and preparation by the consumer. The main routes of contamination are through surfaces, air, water, people and pests (Holah, 1999).

Processing, transport and packaging equipment may also contribute. The passage of food material over a surface leaves residual food debris which encourages the growth of microorganisms. Over time these can multiply to sufficient numbers that they affect the safety or quality of the food. The build-up of food debris, which may deteriorate when out of the main product flow, will also have an impact on product quality if it subsequently returns to the main product flow. Chemical contamination may also result from these contact surfaces if they are not adequately rinsed after cleaning and disinfection regimes. Lubricants, often unavoidable in equipment with moving parts, may contribute to chemical contamination (Steenard *et al.*, 2002). Non-product contact surfaces, such as floors, walls, ceilings, overhead beams and equipment supports, are also important. As well as being reservoirs of microbial contamination, they can also be a source of physical and chemical contamination (e.g. from flaking plaster and the chemical residues within it). They need to be designed so that they are durable and can be effectively cleaned.

Air can be a significant medium for the transfer of contamination to food products (Brown, 1996). Unless the air is treated, microorganisms will be

present, and the air is also a contamination route for 'light' foreign bodies such as dust, straw-type debris, and insects. Chemical taints can enter the production area through airborne transmission. Water is used in the food industry as an ingredient, as a production process aid and for cleaning. Its use as an ingredient and as a processing aid can give rise to potential microbial or chemical contamination problems, and so it is important to use water of a high microbiological and chemical quality (i.e. of potable quality). Water used in handwashing facilities also poses a potential problem. Unwanted water, such as from steam or water vapour, condensation, leaking pipes or drains, or rainwater, can also be a vector for contamination. Stagnant water is particularly hazardous, as microbial levels can multiply rapidly under favourable conditions. The water used in cleaning and sanitising regimes also needs to be of adequate quality. See Holah (1997) and Dawson (1998, 2000) for further information on the quality and use of water in the food industry.

People are a large reservoir of microorganisms. Gastrointestinal infections, for example, can be transferred to food (e.g. via aerosol droplets resulting from coughing near the process line) (Guzewich and Ross, 1999). Pathogens on hands are also a major potential source of contamination (Taylor and Holah, 2000). People can also be a vector for contamination of food with physical hazards such as hair or fingernail fragments, earrings, plasters and small personal belongings. Pests such as birds, insects and rodents are potentially a major contamination problem, and particular care needs to be taken to prevent their entry into food production areas. Buildings need to be designed to keep them out. Floors, ceilings and walls need to be designed so that they do not allow insects and other invertebrates the chance to live and breed.

5.2 Physical contaminants

Food can be contaminated by physical objects commonly known as foreign bodies. There is a huge range of foreign bodies reported in foods, arising from many different sources:

- Leaves, stalks and other extraneous pieces of plant material associated with fruit and vegetables
- Soil and stones associated with harvested fruit and vegetables
- Bone or organ tissue associated with raw meat
- Insect and animal parts or residues in raw materials or resulting from infestation during processing
- Glass, metal and plastic fragments associated with either raw materials or the processing environment.

Foreign bodies can be either present in raw materials or introduced during food processing operations. Their prevention depends in part on good agricultural practices on the farm, particularly in the way crops are harvested and cleaned prior to dispatch, or how well cattle are maintained as well as the

quality of slaughtering operations. Good practices amongst raw material suppliers can substantially reduce the number and range of foreign bodies which a food processor has to deal with.

Food processors can ensure a minimum standard for raw materials through a supplier quality assurance scheme. The EU, for example, has minimum standards for horticultural product quality (Anon., 1996a, 1996b, 1996c). Many companies issue their own individual company specifications which are normally more stringent than the EU standards. They also enable the company to be more specific in their individual requirements. The following categories covering foreign bodies are often included (Bedford, 2000):

- Foreign Matter (FM) – material of non-plant origin. This includes stones, soil, wood, glass, insects, etc. and any other material such as plastic which may have become included in the load. This category also includes any toxic material of plant origin such as potato or nightshade berries in vegetable crops. There is usually a nil tolerance for all these items, with the possible exception of insects. It may be impossible to achieve complete absence of insects, as even after chemical treatment they may remain in the dead state often hidden within the leaves of such items as lettuce and calabrese.
- Extraneous Vegetable Matter (EVM) – parts of the crop plant other than that to be consumed, e.g. bits of stem in a consignment of Brussels sprouts or leaf in green beans. Small amounts may be allowed.
- Foreign EVM (FEVM) – parts of plants other than the crop species. Small amounts may be allowed. This category does not include any toxic material (see FM above).

There are two priorities in dealing with foreign bodies in a factory setting. The first is adequate procedures for identifying and removing any remaining foreign bodies contaminating raw materials coming into the factory. The second is to ensure that the processing environment itself does not become a source of foreign bodies. It can do so in a number of ways:

- Through personnel handling food (hair, fingernails, plasters for cuts, or jewellery, for example)
- Through badly designed or maintained equipment (metal or plastic fragments, rust or loose nuts or screws)
- Through poorly designed or maintained buildings (for example, peeling paint, glass or wood splinters)
- Through inadequate design and procedures for the control of pests, whether insects, animals or birds.

Methods for detecting and removing foreign bodies are discussed in Chapter 16. The control of the air supply and water quality to prevent contamination is discussed in Chapter 7. Personal hygiene is discussed in Chapter 15. The hygienic design of buildings and equipment is covered in Chapters 6 and 8 respectively. The control of insect pests is discussed in Chapter 17.

5.3 Chemical contaminants

The main groups of chemical contaminants that can be found in food share the following characteristics:

- They are not intentionally added to food.
- Contamination can happen at one or more stages in food production.
- Illness may result if consumers ingest enough of them.

The first of these points distinguishes chemical contaminants from other chemicals in food, e.g. vitamins and additives. The wide range of possible sources of chemical contamination has major resource implications, particularly in controlling chemicals that find a wide range of uses, for example pesticides. In order to ensure consumer and worker protection, very careful attention must be given at all stages in food production.

There are various types and sources of chemical contaminants:

- Pesticides and veterinary residues arising from agricultural production
- Naturally occurring toxicants
- Environmental contaminants
- Hazardous chemicals formed during processing
- Migration from packaging
- Contamination during processing.

A wide range of practical steps can be taken to control pesticide and veterinary residues in food, including the following:

- Providing clear guidance and setting appropriate limits for use
- Effective surveillance and enforcement regimes by government
- Including these procedures and limits in supplier quality assurance schemes
- Testing incoming supplies of raw materials.

It is important to recognise that the use of pesticides near crops and farm animals, and in factories concerned with food production, can also lead to residues in food (Shaw and Vannoort, 2001). This can be particularly difficult to detect if surveillance for residues looks mainly for those pesticides used directly on crops or farm animals. The remedy is to extend surveillance and to enforce national standards in the use of these chemicals.

There are three basic types of naturally occurring toxicants (Watson, 1998):

- Toxins produced by microbial contamination of food and raw materials used in food production
- Toxins produced by crops (in some cases at least to protect the plants from insects)
- Toxins ingested by food-producing animals.

The first category includes toxins produced by fungi (mycotoxins) and bacteria. The second group includes a wide range of food-producing plants. The third is a small group of marine toxins, mostly produced by dinoflagellate algae, that find

their way up the food chain and to the consumer. Considerable progress can be made in protecting consumers from many of the natural toxins in food by applying good agricultural practices and through the careful handling of food. As an example, crop rotation can reduce mycotoxin contamination, as can keeping stored grain and seeds dry (Moss, 2002). Bacterial toxins are much less likely to be found in food if HACCP systems are applied in food production. Plant breeding can lead to higher as well as lower levels of toxins.

Polychlorinated biphenyls (PCBs) and dioxins have been perhaps the most widely studied environmental contaminants in food. PCBs were used in a wide variety of industrial applications and are very persistent contaminants, both in the general environment and in human fat (Steering Group on Food Surveillance, 1983). In theory the routes of entry into food are:

- Uptake from the environment by food-producing animals, particularly those with high fat content (as PCBs are lipophilic)
- Direct contamination of food or animal feed
- Migration from packaging into food, just as other chemicals in packaging can migrate into food.

Known sources of dioxins now also include vehicle exhausts, domestic coal fires, manufacture and use of organic chemicals, and metallurgical processors. Two main types of contamination of food appear to be involved: atmospheric deposition and spreading of sludge, in both cases on farmland (Harrison, 2001a). Other environmental contaminants in food include metals and a yet to be defined number of the organic chemicals used in industry (Harrison, 2001b). Metal contamination of food can occur in a wide variety of ways, including environmental and other sources such as canning. Control depends on effective surveillance of food for environmental chemical contaminants. Toxicological standards can be used to define whether or not surveillance results show there is a hazard to consumer health. Both of these types of approaches are now standard in the best surveillance programmes.

It has been very difficult to predict which chemicals might be formed during food processing and might pose a hazard to consumers. There are already a few established examples:

- There is evidence that carcinogenic N-nitrosamines can be formed during the production of alcoholic beverages, fermented foods and cured meats (Steering Group on Chemical Aspects of Food Surveillance, 1992).
- Carcinogenic polycyclic aromatic hydrocarbons can contaminate smoked food (Bartle, 1991), although the main dietary sources of these compounds in the UK appear to be early in food production.
- 3-Monochloropropane-1,2-diol (3-MCPD) and ethyl carbamate have both also proven to be unwanted contaminants that are formed during food processing (JFSSG, 1999a; Food Standards Agency, 2000).
- Acrylamides are formed when food is processed or prepared at high temperatures, if the product contains both fats and carbohydrates and/or proteins. Acrylamides are potentially carcinogenic (FAO/WHO, 2002).

Early work on phthalate esters and several monomers such as styrene used to make plastics demonstrated that chemical migration can occur from packaging into food. There has been a huge amount of practical work on this over the last 30 years (various authors, 1997), much of it on plastics. Thus there are now in place detailed controls on this aspect of plastics in the European Union (EU) and the USA (FCM Unit, 2000). Less is known about chemical migration from other packaging materials. Paper and board have been subjected to surveillance which so far has shown that some chemicals can migrate from it into food (e.g. diisopropylnaphthalenes; JFSSG, 1999b).

Contamination during processing can come from a range of sources, including the following:

- Machinery lubricants
- Cleaning detergents and sanitisers
- Floor, wall and ceiling coatings and resins (including paint)
- Pesticides used in the factory.

The first of these can be avoided by use of appropriate lubricant (see Chapter 8). Procedures for the use of cleaning and sanitising agents are discussed in Chapter 13 and methods for assessing potential contamination in Chapter 14. Hygienic building design is discussed in Chapter 6.

5.4 Microbiological contamination

Pathogenic microorganisms are the major safety concern for the food industry. The vast majority of outbreaks of food-related illness are due to pathogenic microorganisms, rather than to chemical or physical contaminants. As they are generally undetectable by the unaided human senses (i.e. they do not usually cause colour changes or produce off-flavours or taints in the food) and they are capable of rapid growth under favourable storage conditions, much time and effort is spent in controlling and/or eliminating them. Even if microorganisms in a food are destroyed by a subsequent cooking process, they may have previously produced toxins, so the prevention of contamination through good hygienic regimes remains vital. As well as pathogenic microorganisms, spoilage organisms either can be naturally present or can gain access to food. Whilst not a food safety concern, increased levels of spoilage organisms will usually mean a reduction in the length of time that the food remains fit to eat. This can affect product quality and so also influence the consumer's perception of the product.

Growth of microorganisms will depend on a number of factors, such as temperature, humidity/water activity (a_w), pH, availability of nutrients, presence or absence of oxygen and inhibitory compounds such as preservatives. Different organisms require different conditions for optimal growth (e.g. some grow only in the absence of oxygen, others prefer either warm or cool conditions). Bacterial growth is by simple division of one cell into two (binary fission), and their number will increase exponentially under favourable conditions.

The effects that factors such as temperature, oxygen, pH and a_w have on microbial activity may be dependent on each other. Microorganisms generally become more sensitive to oxygen availability, pH and a_w at temperatures near growth minima or maxima. Often, bacteria grow at higher pH, higher a_w and lower temperature under anaerobic conditions than when aerobic conditions prevail. Microorganisms that grow at lower temperatures are usually aerobic and generally have a high a_w requirement. Lowering a_w by adding salt or excluding oxygen from foods (such as meat) that have been held at a refrigerated temperature dramatically reduces the rate of microbial spoilage. Normally, some microbial growth occurs when any one of the factors that controls the growth rate is at a limiting level. If more than one factor becomes limiting, microbial growth is drastically curtailed or completely stopped. Effective control of pathogenic and spoilage bacteria thus depends on a thorough understanding of the growth conditions favouring particular pathogens. This understanding can be used to minimise contamination of incoming raw materials, to inactivate bacteria during processing and prevent decontaminated food from becoming recontaminated.

It is also important to know where and how, if growth conditions are favourable, microorganisms can become established. They are particularly attracted to surfaces which provide a stable environment for growth. Surfaces exposed to the air are always vulnerable unless frequently and effectively cleaned and sanitised. However, surfaces within closed equipment may also be vulnerable. There are usually places in process lines, even if correctly designed, where some product resides longer than desirable. Even if dead areas have been designed out, some product will attach to equipment surfaces, even at high liquid velocities. Microorganisms may reside on such surfaces long enough to multiply. With the increase in the number of microorganisms, the numbers washed away with the product increase as well, leading to eventual contamination. The problem is exacerbated if a process includes dead spaces where product can stagnate. As an example, if a cell of *E. coli* is trapped in a dead space filled with 5 ml of a lightly viscous low-acid food product at a temperature of approximately 25°C, it may take less than 24 hours for the number of *E. coli* cells to increase to a concentration of 0.2×10^9 per ml, assuming they double every 40 minutes (Lelieveld, 2000). If every hour just 1 ml is washed out from the dead space by the passing product, by the end of the first day of production the product is infected with 200 million *E. coli* cells each hour. If the production capacity of the line is 5 million ml per hour, the average *E. coli* contamination will be $200/5 = 40$ per ml. Many traditional process lines have much larger (often very contaminated) dead spaces and growth rates can be higher if conditions such as temperature are favourable.

Microorganisms may also penetrate through very small leaks. There is considerable evidence that microorganisms may pass microscopic openings very rapidly and that pressure differences may retard but not prevent passage, even if the pressure difference is as high as 0.5 bar. *Serratia marcescens* may move at a speed of 160 mm per hour (Schneider and Dietsch, 1974). Motile bacteria may

therefore propel themselves against the flow of liquid through a leak. Microorganisms, motile or not, may also grow through a passage by forming a biofilm on the surface. Studies of the migration of microorganisms through microscopic passages show the passage of microorganisms through holes of a few micrometres in diameter in a metal plate of 0.1 mm thickness (Brénot *et al.*, 1995).

When attracted to a surface, microorganisms deposit, attach and initiate growth. As they grow and multiply, the newly formed cells attach to each other as well as to the surface, forming a growing colony of microorganisms. When this mass of cells becomes sufficiently large that it entraps debris, nutrients and other microorganisms, a microbial biofilm is established (IFT, 1994). Biofilms form in two stages. First, an electrostatic attraction occurs between the surface and the microbe. The process is reversible at this state. The next phase occurs when the microorganism exudes an extracellular polysaccharide, which firmly attaches the cell to the surface. The cells continue to grow, forming microcolonies and, ultimately, the biofilm.

These films are very difficult to remove during the cleaning operation. Microorganisms that appear to be more of a problem to remove because of biofilm protection include *Pseudomonas* and *L. monocytogenes* (Notermans *et al.*, 1991). Current information suggests that the application of heat appears to be more effective than that of chemical sanitisers, and Teflon appears to be easier to clear of biofilm than does stainless steel (Marriott, 1999).

Biofilm development may take place on any type of surface and is difficult to prevent if the conditions sustain the multiplication of microorganisms. Many microorganisms, including many pathogens (*Listeria monocytogenes*, *Salmonella typhimurium*, *Yersinia enterocolitica*, *Klebsiella pneumoniae*, *Legionella pneumophila*), form biofilms, even under hostile conditions such as in the presence of disinfectants. Adverse conditions may even stimulate microorganisms to grow in biofilms (van der Wende *et al.*, 1989; van der Wende and Characklis, 1990). Thermophilic bacteria (such as *Streptococcus thermophilus*) can form biofilms in the cooling section of milk pasteurisers, sometimes within five hours, resulting in massive infection of the pasteurised product (up to 10^6 cells per ml) (Driessen and Bouman, 1979; Langeveld *et al.*, 1995). On metal (including stainless steel) surfaces, biofilms may also enhance corrosion which may result in microscopic holes. Such pinholes allow the passage of microorganisms and thus may cause infection of the product. Like other causes of fouling, biofilms will also affect heat transfer in heat exchangers. On temperature probes, biofilms may seriously affect heat transfer and thereby the accuracy of the measurement. Reducing the effectiveness of heat treatment may itself help to stimulate further bacterial growth. On conveyor belts and on the surfaces of blanching equipment, for example, biofilms may infect cooked or washed products, which are assumed to have been made pathogen-free by the temperature treatment received.

Biofilms may be much harder to remove than ordinary soil. If the cleaning procedure is not capable of completely removing biofilms which may have

developed, decontamination of the surface by either heat or chemicals may fail as biofilms dramatically increase the resistance of the embedded microorganisms (IFT, 1994). It is thus imperative that product contact surfaces are well cleaned before disinfection. Krysiniski *et al.* (1992) studied the effects of a variety of cleaning and sanitising compounds on *L. monocytogenes* allowed to attach to stainless steel and plastic material used in conveyor belts for 24 hours. They found that sanitisers alone had little effect on the attached microorganisms even when the sanitiser exposure time was increased to 10 minutes. Unattached cells, on the other hand, showed a 5-log reduction in numbers in 30 seconds. In general, acidic quaternary ammonia, chlorine dioxide and peracetic acid were the most effective sanitisers on attached cells. Least effective were chlorine, iodophors and neutral quaternary ammonium compounds. When the attached microorganisms were treated with cleaning compounds prior to treatment with sanitisers, the bacteria were inactivated.

5.5 Controlling contamination: the case of *E. coli*

Some of the key issues in this chapter can be seen by looking at how one major pathogen, *Escherichia coli* (especially Vero cytotoxigenic types (VTEC) such as *E. coli* O157), contaminates food and the hygienic and other measures required to prevent it. The growth-limiting parameters for pathogenic *E. coli* are shown in Table 5.1. A contaminated raw material is one of the most common reasons why *E. coli* is present in a final product. Where a product receives no further process capable of eliminating the organism, these contaminants will inevitably result in potentially hazardous foods. VTEC outbreaks associated with cheese made from unpasteurised milk (Anon., 1999), unpasteurised apple juice (Besser *et al.*, 1993) and raw, fermented meats (Cameron *et al.*, 1995) have all implicated contaminated raw ingredients as significant contributory factors.

Effective control of the raw material to preclude or reduce the organism is absolutely critical to the safety of many food industry products (ILSI, 2001). The primary raw materials implicated in foodborne outbreaks include raw milk, raw beef and raw fruit. In all cases, the principal route of contamination to the material is from exposure to animal faeces, particularly cattle and sheep. In the

Table 5.1 Growth-limiting parameters for pathogenic *E. coli*

	Minimum	Optimum	Maximum
Temperature (°C)	6.5	37	44–45
pH	3.6	—	9.0
a_w	0.95	—	—
Sodium chloride	Grows vigorously in 2.5% NaCl Grows slowly in 6.5% NaCl Does not grow in 8.5% NaCl		

case of raw milk, for example, controls that can reduce the introduction of faecal pathogens into the milk supply centre on effective milking parlour hygiene which includes cleaning and disinfection of udders and teats, together with cleaning and sanitisation of the milking equipment used for milking itself and subsequent milk storage systems (Johnson, 2002). This should include all transfer pipes including portable hoses.

Meat, and beef in particular, have been frequently implicated in outbreaks of foodborne *E. coli* O157 infection. Meat becomes contaminated through the transfer of faecal pathogens to the muscle tissue from faeces on the hide or from the intestine itself during the slaughtering operation. Minimising this contamination through the prevention of dirty animals entering the abattoir via effective farm handling, transport and lairage control is essential. The preclusion of dirty animals entering the slaughter line is part of the formal process used, for example, at inspection in UK abattoirs. Animal hide removal, evisceration and the handling of other parts of the animal carrying contaminants such as the hooves must be carefully controlled to prevent transfer from these areas to the muscle meat. Subsequent thorough cleaning and sanitisation of product contact surfaces, particularly when cutting into primal joints, is absolutely essential to prevent spread of any contaminants entering the plant (Gill, 2000). Like raw milk, it is not possible to preclude contamination with enteric organisms during raw meat processing and it is important to regularly monitor the hygienic status of the carcass meat. This is particularly important where the raw meat is subject to processes not capable of significantly reducing levels of enteric pathogens such as in the manufacture of fermented meats. The inability to preclude such contamination has led many processors, particularly in the USA, to introduce steam pasteurisation plants, which reduce the concentration of microorganisms on the surfaces of the meat while maintaining the raw meat quality and appearance. These systems are capable of reducing contamination on the surface by up to 3 log units (Phebus *et al.*, 1997) and can make a significant contribution, together with effective animal husbandry and slaughter hygiene, to minimising the levels and frequency of contamination with these harmful organisms in raw meat.

In the case of fruit and vegetables, proper treatment of animal wastes prior to application to soil used for growing these crops, including long-term storage and composting, will help prevent crops becoming contaminated. Good agricultural practices that avoid the use of 'drop fruit' and ensure wastes are never applied to exposed crops intended for consumption without further processing, are simple, obvious but nevertheless effective control measures to reduce the chances of such materials being contaminated with VTEC.

Many production processes rely on simple washing stages to remove extraneous dust and soil and to reduce levels of contaminating organisms including pathogens, e.g. ready-to-eat salads and vegetables and fresh, unpasteurised fruit juices. A variety of outbreaks involving these products have highlighted the vulnerability of the minimal processing employed in their production. Salad vegetables and fruit are usually washed in chlorinated water

prior to further processing. Chlorine levels used in commercial practice have historically been at ≤ 200 mg/kg. Studies have shown this level to be capable of reducing levels of contaminating pathogens by 1–2 log units.

Outbreaks associated with salads in particular have, however, prompted processors to investigate much higher levels of chlorination or indeed the use of other sanitising agents in an attempt to achieve greater reductions (Taormina and Beuchat, 1999). Whatever method is used, it is important to ensure that the active ingredient, most often chlorine, is present in its active form on a continuous basis. Washing systems have just as much capacity to spread contamination as they have for reducing it if the wash water is not regularly changed or the levels of active ingredients are not properly maintained. In addition, it is important to recognise that washing efficacy will also be dependent on facilitating good contact between the contaminant and the antimicrobial agent, and the surface structures of many vegetables and fruits can offer significant protection to microorganisms. Washing systems that incorporate means for agitation will clearly be helpful in reducing microorganisms on these plant material surfaces.

The majority of food products are manufactured with some form of processing, and some processes are capable of reducing or eliminating VTEC, if present. In such circumstances, it is the application of effective controls at critical stages of the manufacturing process that, if properly and consistently applied, will generate a safe finished product. Products such as cheese made from pasteurised milk, cooked meats and ready meals are all subject to processes in which the organism should be effectively eliminated. Processes used to produce products such as prepared, ready-to-eat salads and raw, fermented meats together with some hard cheeses made from raw milk usually result in the reduction of contaminating pathogens, but survival may occur, particularly if initial contamination levels are high. There are some products such as soft cheese made from raw milk or sprouted seeds such as beansprouts or alfalfa sprouts where the production process can allow growth and lead to elevation of pathogen levels if present originally in the raw material. However, even with these products it is possible to identify production methods that, if applied correctly, can reduce the risk associated with their consumption.

The application of effective processes and, hence, process controls necessitates some understanding of the effect of different process stages of the growth and survival of potential pathogens that might be present. Once understood, it is then possible to introduce relevant systems for monitoring the processes. As the growth-limiting parameters outlined in Table 5.1 indicate, heat processing is a very effective way of eliminating pathogenic *E. coli*. Similarly, the rapid acid production and associated pH reduction that occur during fermentation, when combined with drying which affects water activity (a_w), also significantly reduce contamination levels.

A recurring factor often identified as a reason for outbreaks of *E. coli* O157 and VTEC infection is contamination of the product after application of the pathogen reduction process. Contamination usually arises from either exposure

of the finished product to raw materials or exposure of the product to contamination from the environment or people. Facilities and procedures must be in place to segregate raw materials and finished products and to prevent them from coming into contact. In the manufacture of cooked meat, ready meals or prepared salads this is usually achieved by separating the factory into two areas: low- and high-risk areas. The decontamination stage is used as the division between the two areas such as the building of an oven into a separating wall or the placing of a chlorinated wash water flume between high- and low-risk operations. Individuals on the low-risk side handle the raw product and then, after processing, it is removed by individuals dedicated to the high-risk side. These principles of segregation should be applied to all personnel moving from the low-risk side of the factory to the high-risk side, with appropriate coat and footwear changes and appropriate hand-washing procedures. An infectious disease policy must be in place for operatives handling ready-to-eat products, which should include notification of any instances of infectious disease and associated absence from work. These issues are discussed in detail in Chapters 6 and 15.

Effective cleaning and disinfection of all equipment is essential. It is particularly important to prevent organisms from building up in the equipment used for processing raw material. High levels at these stages may result in spread of contaminants to other batches or excessive levels that may exceed the capacity of the subsequent process, e.g. cooking or fermentation to reduce initial levels of any bacterial pathogens to those resulting in a safe finished product. Cleaning efficacy can be monitored using indicators of hygiene such as tests for coliform bacteria or ATP bioluminescence tests, which monitor the presence of residual levels of ATP from product residues and microorganisms (see Chapter 13). Improperly used, such methods may lead to incorrect conclusions. The use of these methods, therefore, also requires understanding of their limitations.

Effective segregation between raw products and those intended to be consumed as ready-to-eat must also be operated in both the retail and catering environments. This includes using separate counters for displaying raw and cooked foods or having Perspex/safety glass dividers in counters to keep them apart. Safe procedures for serving, slicing or weighing raw and ready-to-eat foods must be developed. Personnel carrying out such practices should be appropriately trained to understand the risk associated with cross-examination from raw foods and from items coming into contact with raw foods such as equipment, surfaces and hands. They should be provided with the appropriate facilities to undertake good hygienic practices such as regular and effective hand washing (see Chapter 15).

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Hygienic plant design

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6.1 Introduction

The decision to invest in a new or existing production facility always aims to improve the profitability of the enterprise. Investing in hygienic facilities is important because it provides the foundation for the production of food products which are safe for the consumer to eat and of an appropriate quality. Hygienic design needs, however, to be compatible with other essential requirements. Plant design or modification should provide an appropriate environment for processing operations, while ensuring compliance with all applicable building safety and environmental regulations. Layouts, for example, should allow ready access to equipment for both routine and non-routine maintenance. Materials selected should be sufficiently rugged to withstand likely service conditions or be easily replaced or repaired.

Planning is very much a multi-disciplinary process in which the architect, civil engineer, production manager, heating, ventilation and cooling experts are each specialists in the team. A quality assurance or hygiene manager will be a key member of the team. It is important to make use, as far as possible, of companies with experience and expertise in the design and construction of food processing facilities for both the planning and construction stages. Generally it is better to enlist local professionals who are well experienced in local legislation on building and planning, know the climate, and have extensive knowledge of the location, soil and groundwater conditions, for example.

The primary aim of hygienic plant design should be to set up effective barriers to microbial and other contamination. Factories should be constructed as a series of barriers to limit the entrance of contaminants. Within a plant there will be areas with differing levels of hygienic design and operational

requirements. Broadly there are three main types of area with ascending hygienic requirements:

- Level 1: non-production areas
- Level 2: food processing operations dealing with undecontaminated product or finished goods
- Level 3: food processing operations dealing with decontamination processes and decontaminated product before it receives its final protective packaging.

Non-production areas include office space for management and administrative staff, facilities for production staff such as canteens and rest rooms, car parking and storage facilities, for example. Hygienic design requirements and procedures will be less stringent than in other parts of the plant. However, hygienic design and operation will still be important. Non-production areas must be clearly segregated from production areas so that unauthorised staff, for example, are not allowed to move from one area to the other, contaminating production areas in the process. Toilet and washroom facilities must be sufficient to allow production staff to maintain appropriate levels of personal hygiene. Premises and storage areas must, for example, be designed to be easily maintained, and be kept in good order, if they are not to attract pests and become sources of contamination themselves. Poor hygienic design and operation will increase the contamination 'load' on barriers protecting production areas and make it more likely that they will be breached. Each level of hygienic design is therefore important.

Level 2 'hygienic areas' (sometimes referred to as 'low-risk or good manufacturing practice (GMP) areas') include food processing operations dealing with undecontaminated product. These include any food components of the final product that have not been decontaminated so that they are effectively free of bacteria prejudicing or reducing the microbiological safety or shelf-life of the finished product. Such starting materials should be handled in the factory so that numbers of contaminants are not increased and they cannot contaminate any other components that have already been decontaminated. As an example, the layout of processing areas should be designed on the forward flow principle to prevent cross-contamination. Undecontaminated material should not be handled by personnel also handling finished product (except with the appropriate hygiene controls and separation), or allowed to enter high-care areas (HCA: see below). Hygienic areas should be designed and constructed for easy cleaning so that high standards of hygiene can be achieved to prevent pathogens, for example, from becoming established and contaminating products. Areas conforming to this standard can also be used for the post-process handling of in-pack decontaminated products.

The final and most stringent level of hygienic design and operation is 'high-risk areas' (HRA). A high-risk area is a well-defined, physically separated part of a factory which is designed and operated specifically to prevent the recontamination of decontaminated ingredients and products after completion of the decontamination process and during assembly and primary packaging.

Usually there are specific hygiene requirements covering layout, standards of construction and equipment, the training and hygiene of operatives, engineers and management and a distinct set of operational procedures (especially covering the intake and exit of food components and packaging material), all designed to limit the chances of decontaminated product becoming recontaminated.

Care must be taken in using such terms as 'high-risk' or 'high-care'. Their use can imply to employees and other people that lower overall standards are acceptable in those areas where, for example, operations concerned with raw material reception, storage and initial preparation are undertaken. In practice, all operations concerned with food production should be carried out to the highest standard. Unsatisfactory practices in so-called low-risk areas may put greater pressures on the 'barrier system' separating the two areas. The advent of the use of more 'pharmaceutical' techniques in hygienic food manufacture may lead to the use of appropriate pharmaceutical terminology, e.g. 'clean' zones. Most of the requirements for the design of hygienic areas, HCA and HRA, and on preventing recontamination in HRA, are the same, with the emphasis on minimising contamination in hygienic areas (Anon., 1997a). In considering whether a high risk is present or high care is required and therefore what specifications should be met, food manufacturers need to carefully consider their existing and future product ranges, the hazards and risks associated with them and possible developments in the near future. If budgets allow, it is always cheaper to build to the highest standards for all three levels of hygienic area from the onset of construction rather than try to retrofit or refurbish at a later stage.

As well as differing types of hygienic area, each providing a barrier to the risk of contamination, there are three other basic barriers which are outlined in Fig. 6.1:

1. The first barrier represents the siting of the factory.
2. The second represents the factory building which should separate the factory from the external environment.
3. The third represents the internal barriers that are used to separate manufacturing processes of different risk, e.g. pre- and post-decontamination.

Each of these barriers has different types of hygienic design requirement which will be discussed in more detail in the following sections.

6.2 The factory site

The design, construction and maintenance of the site surrounding the factory provides an opportunity to set up the first outer barrier to protect production operations from contamination. The site should ideally be in an area with good air quality, no pollution problems (e.g. from other industrial plants) and uncontaminated soil. Well-planned and properly maintained landscaping of the grounds can assist in the control of rodents, insects and birds by reducing food

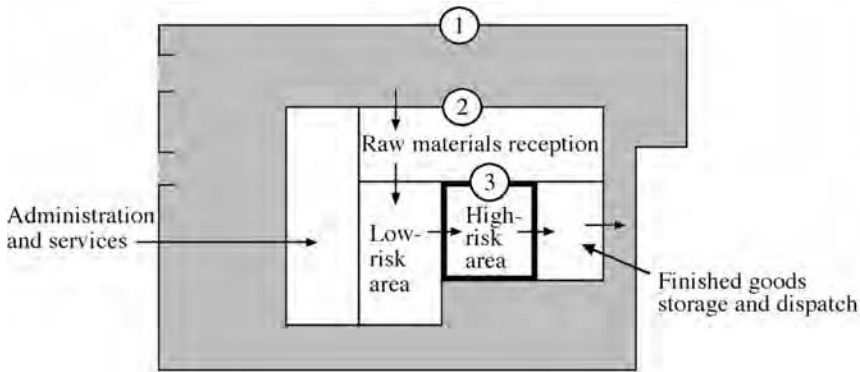


Fig. 6.1 Layout of a factory site showing key barriers against contamination:
1 – perimeter fence; 2 – main factory building; 3 – high-risk area.

supplies and breeding and harbourage sites (Shapton and Shapton, 1991). Katsuyama and Strachan (1980) and Troller (1983) suggest that the area immediately adjacent to buildings be kept free of trees and bushes, and that it also be kept grass-free and covered with a deep layer of gravel or stones (Fig. 6.2). The use of two lines of rodent baits located every 15–21 m along the perimeter boundary fencing and at the foundation walls of the factory, together with a few mouse traps near building entrances, is advocated by Imholte (1984).

Imholte (1984) advocates orientating buildings so that prevailing winds do not blow directly into manufacturing areas. Good landscaping of sites can also reduce the amount of dust blown into the factory, as can the sensible siting of any preliminary cleaning operations for raw materials which are often undertaken outside the factory. The layout of vehicular routes around the factory site can also affect the amount of soil blown into buildings. Shapton and Shapton (1991) suggest that for some sites it may be necessary to restrict the routes taken by heavily soiled vehicles to minimise dust contamination. They also stress the importance of ensuring that waste material is not left in uncovered containers and that any spillages of raw material are cleared up promptly so as not to attract birds, animal or insect pests. Some insects require water to support their life cycle, e.g. mosquitoes. All areas where water could collect or stand for prolonged periods of time need to be removed or controlled. Imholte (1984) also draws attention to lighting for warehouses and outdoor security systems attracting night-flying insects and recommends high-pressure sodium lights in preference to mercury vapour lamps. Entrances that have to be lit at night should be lit from a distance with the light directed to the entrance, rather than lit from directly above. This prevents flying insects being attracted directly to the entrance.

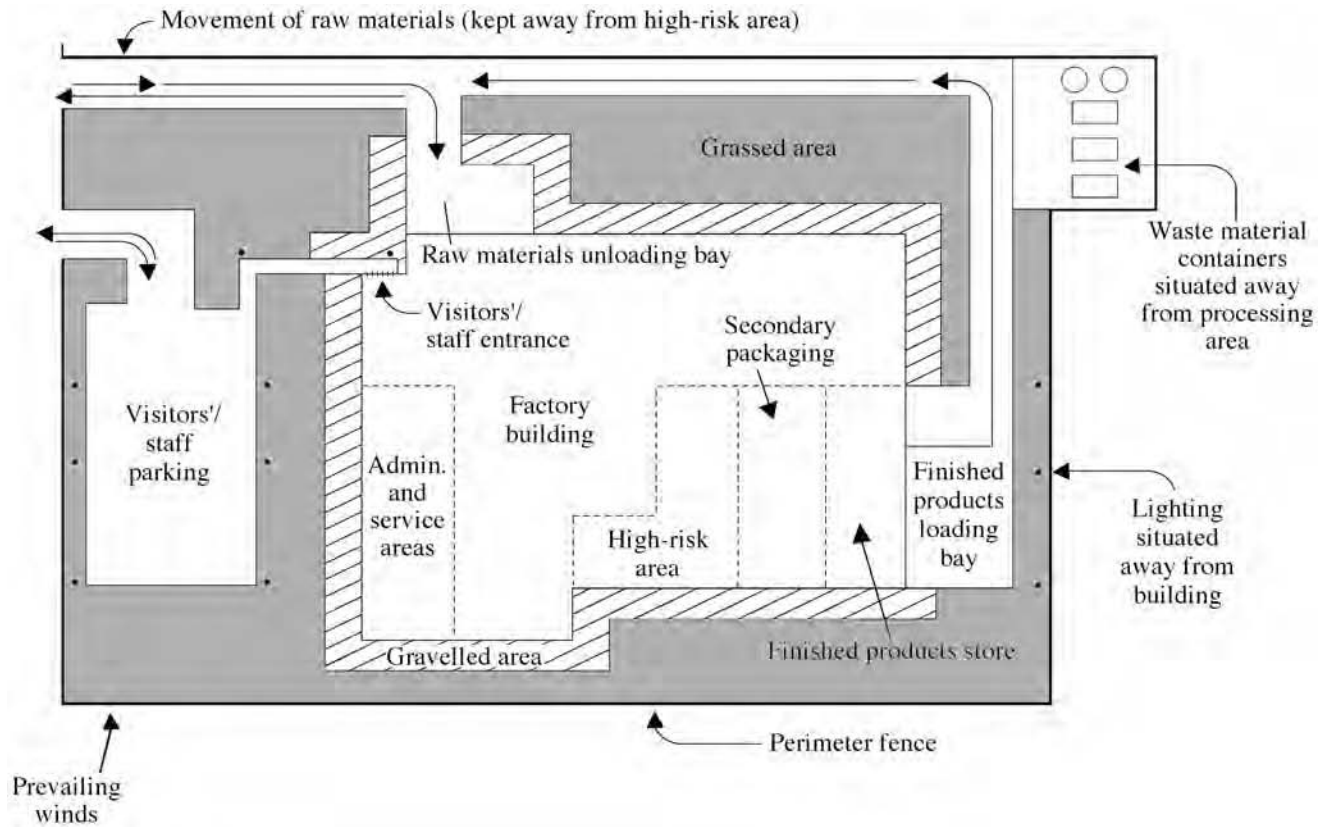


Fig. 6.2 Hygienic layout of a factory site.

6.3 The factory building

The building structure is the second, major barrier, providing protection for raw materials, processing facilities and manufactured product from contamination or deterioration. Protection is from potential sources of environmental contamination including rain, wind, surface runoff, delivery and dispatch vehicles, dust, pests and uninvited people. While protecting against these sources of contamination, the factory buildings should also be designed and constructed to suit the operations carried out in them and should not place constraints on the process or the equipment layout. If they do, they may compromise subsequent internal barriers against contamination.

Shapton and Shapton (1991), Imholte (1984) and Timperley (2003) discuss the various methods of forming the external walls. A typical example of a suitable outside wall structure is shown in Fig. 6.3. The diagram shows a well-sealed structure that resists pest ingress, provides nowhere for birds to perch or nest and is protected from external vehicular damage. The ground floor of the factory is also at a height above the external ground level. By preventing direct

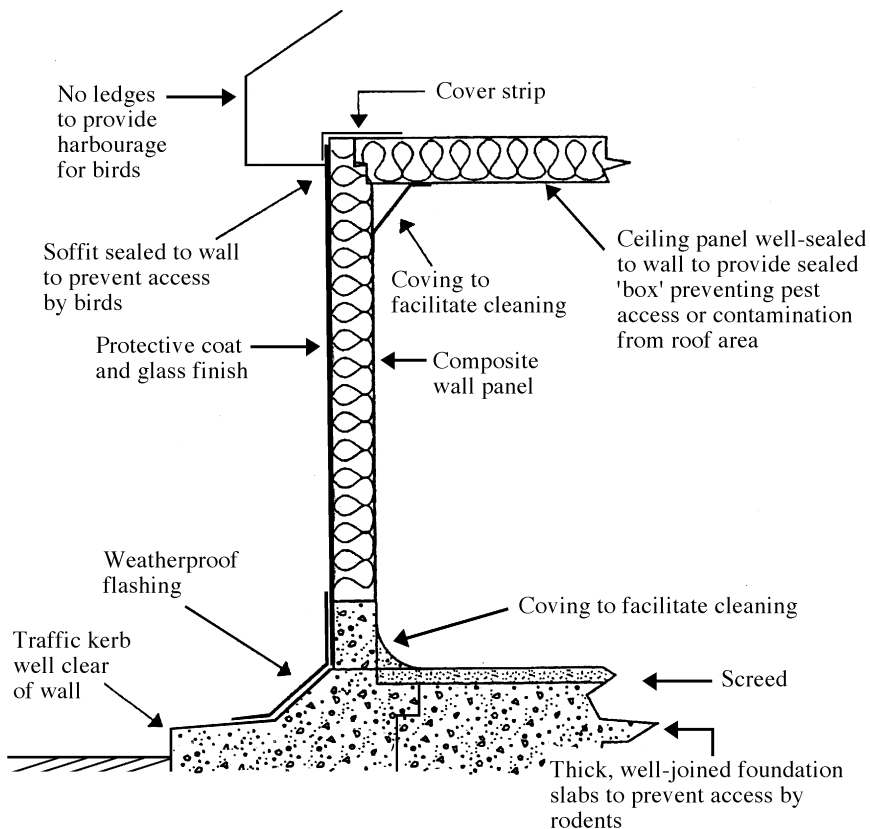


Fig. 6.3 Design of external walls for a food processing plant.

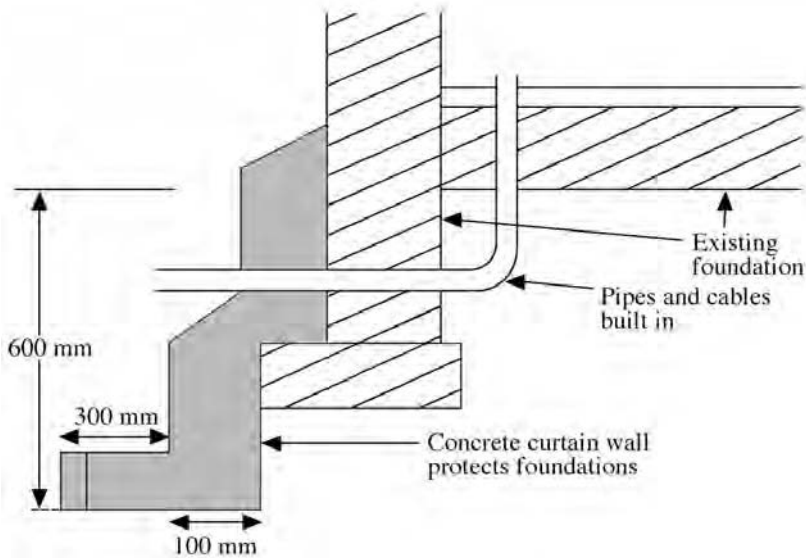


Fig. 6.4 Design of foundations for the external walls of a food processing plant (from Timperley, 2003).

access into the factory at ground floor level, the introduction of contamination (mud, soil, foreign bodies, etc.), particularly from vehicular traffic (forklift trucks, raw material delivery, etc.), is restricted. The wall is well sealed at both the top (to the ceiling and roof) and the bottom (to the foundations and flooring) to prevent dirt, dust and pests getting into the building. Weatherproof flashing provides protection at the bottom of the wall against damage and corrosion. A wide kerb provides further protection.

Figure 6.3 is complemented by Fig. 6.4 which looks in more detail at foundations. Some rodents can burrow over 1 metre vertically and foundations need therefore to drop a minimum of 600 mm below ground level. If the base of the building already has a kerb (as shown in Fig. 6.3), it should protrude by a minimum of 300 mm. In some older buildings, the foundations may be too shallow and will not prevent rodents from burrowing underneath. In these cases it is recommended that a curtain wall is built against the existing outside walls or footings to a depth of at least 600 mm below ground level with a bottom member turned outwards from the building to a distance of 300 mm to form an 'L' shape.

All points where cables, drains and services pass through foundation walls and floors must be sealed. Drains and sewers must be proofed and regularly maintained to prevent rodents gaining access and using them as harbourage or as a means of entry to buildings. Any defective drains must be located and repaired. Inspection chambers, covers, hatches and rodding caps must be inspected regularly and all disused lengths of drain either filled with concrete to the connection with the sewer or collapsed and the trench filled with dense hardcore. Any stormwater drains should be protected with top-hung flaps and

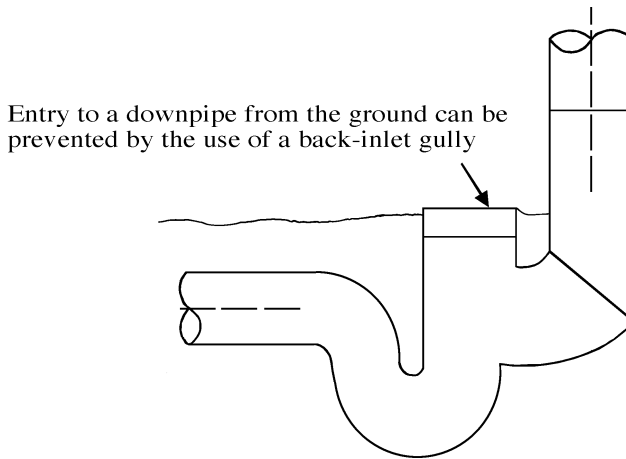


Fig. 6.5 Back-inlet gully to prevent access by rodents through pipes (from Timperley, 2003).

maintained regularly to remove silt and leaves. Back inlet gulley can be used to prevent rodents from entering and climbing the inside of rainwater pipes at ground level (Fig. 6.5). If these are not fitted, then rodent access can be controlled by means of wire mesh balloons fitted to the outlet from the gutter. These balloons must have a mesh size of 6 mm or smaller and should also be fitted at the top of any soil or ventilation pipes. Wire mesh should not be used at the bottom of downpipes because of the risk of blockage. External climbing of downpipes by rodents can be prevented by fitting flat or cone-shaped guards. These should be sited high enough to clear vehicular or pedestrian traffic but not above the level of any sills, mouldings or branch pipes which may provide alternative routes into the building.

Rodents are able to squeeze through small holes in order to gain access to buildings. A small rat can squeeze through a 10 mm crack and a mouse through one of 6 mm. Small holes in brick, stone or concrete walls and floors should be filled with mortar. Large holes should be filled with brick or stone set in mortar. If this is impractical then concrete can be used. To prevent rodents from re-opening holes during the setting period of the concrete or mortar, 25% rapid hardening cement can be used as part of the overall mixture. Alternatively, holes can be filled with crushed chicken wire prior to concreting. Repairs should be done early in the day to ensure that the concrete has set before nightfall.

Roofs should be kept in good repair, regularly inspected and any missing or damaged slates or tiles replaced. All holes formed at junctions with the eaves must be sealed either by fitting templates cut to shape or by the application of a suitable sealing material which cannot be pecked out by birds. Any ventilation opening should be proofed with 10 mesh monofilament nylon mesh mounted in a removable frame of metal or PVC to allow regular inspection and cleaning. Exhaust fans should be fitted with shutters which are self-closing when the fan is idle.

Rodents can climb rough brickwork or stone walls. This can be prevented by the application of a smooth coating of cement and painting it with a hard gloss finish. This coating should be applied below any dock leveller and a minimum of 2 metres either side of any sliding doors when they are fully open. Where composite metal wall panels are used, particular attention must be paid to sealing them effectively at the top and bottom junctions. Profiled metal capping strips should be welded to corrugated metal wall panels to prevent rodents from gaining access to the inner hollow core between the outer metal panel and insulation.

The type of building, either single- or multi-storey, needs to be considered. Imholte (1984) describes the advantages and disadvantages of both types of buildings. He also suggests a compromise may be achieved by having a single-storey building featuring mezzanine floors to allow gravity flow of materials, where this is necessary. Single-storey buildings are preferred for the majority of high-risk (e.g. chilled food) operations and generally allow the design criteria for high-risk areas to be more easily accommodated. However, it should be appreciated that where production is undertaken in renovated buildings, it may not be possible to capitalise on some of the advantages quoted by Imholte (1984). Of particular concern in multi-storey buildings is leakage, of both air and fluids, from areas above food-processing areas. Contamination can enter high-risk areas via leakage through both floor defects and badly maintained drains. Drainage systems can act as air distribution channels, with air from low-risk areas (both above and below) being drawn into high-risk areas. This can typically occur when the drains are little used and the water traps dry out.

In general, openings such as windows and doors should be kept to a minimum. A good case can be made for high-risk operations being in a windowless area. As Imholte (1984) observes: 'Regardless of the sophistication of the heating, ventilating and air-conditioning systems, there are always those who are uncomfortable with the surrounding temperature conditions and feel the need to open a window or a door.' If they are required, e.g. to allow visitor or management observation, windows should be glazed with either polycarbonate reinforced or laminated sheet. Ideally they should be double-glazed and permanently closed. A glass register, detailing all types of glass used in the factory, and their location, should be compiled. External windows that contain glass should be provided with a protective film to contain breakages. No glass should be permitted in a process area where breakage could contaminate the product. External windows may be tinted to assist solar control.

The material for window frames should be a low maintenance type such as UPVC or aluminium and sealed around the edges with a good quality filler such as two-part polysulphide. Internal sills should be sloped (20°–40°) to prevent their use as 'temporary' storage places, with external sills sloped at 60° to prevent birds roosting. Any opening windows in production areas must be screened and the screens be designed to withstand misuse or attempts to remove them. Screens should be constructed with insect mesh mounted in a removable frame of metal or PVC for cleaning. The mesh gauge may be stated as 5/7 strand

per cm (18/16 strand per inch) but the maximum hole size should be 1.4 mm. The mesh may be nylon, PVC-coated fibreglass, stainless steel or aluminium.

External doors may be one of the following types chosen for its security, hygienic and/or practical application:

- Swing
- Horizontal sliding
- Roller shutter
- Hinged
- Folding sliding
- Vertical sliding.

In all cases, the following design criteria should be met:

- A tight fit is achieved between the door and its frame.
- The correct material is used.
- Each door is self-closing.
- Opening and closing is smooth.
- Surfaces are cleanable.
- Door handles are easily cleaned and do not trap dirt.
- The design is hygienic, having a smooth finish, radiused edges and minimal seams.

The four materials in general used for door construction are steel, clad timber, rubber and plastic (e.g. PVC or GRP – glass-reinforced plastic). Steel doors are used extensively but tend to be insufficiently robust, easily distorted, heavy to operate and difficult to maintain. Exposed wood is vulnerable to rodent attack and is therefore an unsuitable material for door frames. Plastic coated timber may be used. This is more adaptable, easier to clean, operate and maintain, and is likely to suffer less from excessive damage.

All external doors should be self-closing and fit closely in the opening with no gaps exceeding 6 mm and preferably less than 3 mm. All external door frames should be sealed at the junctures with the walls and floors and kept in good repair. Doors should be provided with vision panels, kick plates and push plates. Vision panels should be made of a suitable material, e.g. polycarbonate. Where a fire-rated door is required the use of special wired laminated glass is recommended. This should be enclosed by plastic film or sheets of polycarbonate. External doors should not open directly into food production areas. If doors are to be used at night, it is good practice to position lights 9 to 12 metres from the door to attract insects away from the door area. Sliding and concertina doors should have all gaps between the door and the frame sealed with brush strips. Roller shutter doors should fit closely at the base and have a rubber strip fitted to ensure that no gap exceeds 6 mm. All doors which have to remain open for vehicle entry and/or loading can be proofed by installing 'rapid roll' PVC doors or heavy duty PVC strip curtains with the correct overlap, as specified by the manufacturers. The use of air curtains can be effective against insects but they should not be the only proofing measure used.

Access to processing areas from outside should be via double doors with an air lock or by use of a lobby with a door at each end (see, for example, Fig. 6.9 on page 99). An insect trapping device must be provided in the lobby. Large doors which are not in constant use may be equipped with a small personnel door. This facility should encourage employees to keep the large door closed. Air curtains or air doors can be used to keep out flying insects or condensation ingress to cold stores in areas under positive pressure. These must cover the total width of the opening and have adequate depth. The effectiveness of air curtains depends on the velocity of the air, the width, thickness and angle of the curtain, internal air temperatures and pressures together with the absence of strong winds. These doors are not very effective against strong wind. Chilled and frozen products require an air lock system to prevent an influx of ambient air during loading and unloading. A system of traffic signals and door interlocks must be incorporated into the building. The outer door may be a roller shutter door, with the inner door insulated to meet the temperature requirements. All trucking doors should be protected from damage by the use of guard rails or posts. Emergency exits must be fitted with 'out-only' operating bars. The doors must remain closed except in the case of an emergency. In order to avoid the inconvenience and restriction of movement which fire doors impose, electromagnetic catches may be fitted. These catches can be connected to the fire alarm system such that doors will be released in the event of fire. Approval for their use must be obtained from the fire authority.

6.4 General design issues for the factory interior

The main principles of hygienic design of the interior of a factory unit should be to remove any potential internal sources of contamination and to prevent any external contaminants from accumulating. The first principle can be achieved in a number of ways, including the following:

- Materials in the proximity of food processing operations should be non-toxic.
- Glass, wood and other materials that could present a serious hazard to consumers if fragments contaminate food should be avoided.
- Materials must be durable and able to withstand the operational environment, including extremes in temperature, physical impact vibration, moisture and corrosion from food materials (e.g. those containing organic acids).
- Services such as water or steam should be designed so they do not provide a growth medium for contaminants (e.g. through condensation) or become contaminated themselves.

The second principle can be achieved by such design features as the following:

- No inaccessible areas, cavities or seams where dirt can gather.
- All areas and corners easily accessible for inspection and cleaning.

- Surfaces should flow off (at $> 3^\circ$) to prevent dirt or fluid accumulating.
- No horizontal surfaces. If there is a possibility dirt can gather, a vertical gradient of 45° is recommended with a round or half-round profile.
- Joins such as welds should be continuous and smooth with the surrounding surface.
- No sharp corners or right-angles. Corners should be radiused with the use of coving.
- Materials should be easily cleaned, smooth and non-porous so that dirt cannot accumulate.

6.5 Walls

Hygiene standards for walls as defined in various EC Directives require that they must be constructed of impervious, non-absorbent, washable, non-toxic materials and have smooth crack-free surfaces up to a height appropriate for the operations. For high-risk areas the standard of construction and finish must apply right up to ceiling level. The same hygienic assessment techniques as described for flooring materials are also directly applicable to wall coverings and finishes. Guidelines for the design and construction of walls have been prepared by Timperley (2003).

A number of different types of materials may be used to construct walls forming the boundaries of a high-risk area and of the individual rooms within the area. When considering the alternative systems, a number of technical factors such as hygiene characteristics, insulation properties and structural characteristics need to be taken into consideration. Materials need to be resistant to corrosion from food materials (for example those containing organic acids). They should also be resistant to temperatures up to 85°C .

Modular insulated panels are now used very widely for non-load-bearing walls. The panels are made of a core of insulating material between 50 and 200 mm thick, sandwiched between steel sheets, which are bonded to both sides of the core. Careful consideration must be given, not only to the fire retardation of the wall insulation or coating material, but also to the toxicity of the fumes emitted in the event of a fire as these could hamper a fire-fighting operation. The steel cladding is generally slightly ribbed to provide greater rigidity and can be finished with a variety of hygienic surface coatings, ready for use. The modules are designed to lock together and allow a silicone sealant to provide a hygienic seal between the units. The modules can be mounted either directly (in a U-shaped channel) onto the floor or on a concrete upstand or plinth (Fig. 6.6). The latter provides useful protection against the possibility of damage from vehicular traffic, particularly fork-lift trucks. However, it should be appreciated that this arrangement reduces the possibility of relatively easy and inexpensive changes to room layout to meet future production requirements. Sections fixed directly onto the floor must be properly bedded in silicone sealant and coved to provide an easily cleanable and watertight junction.

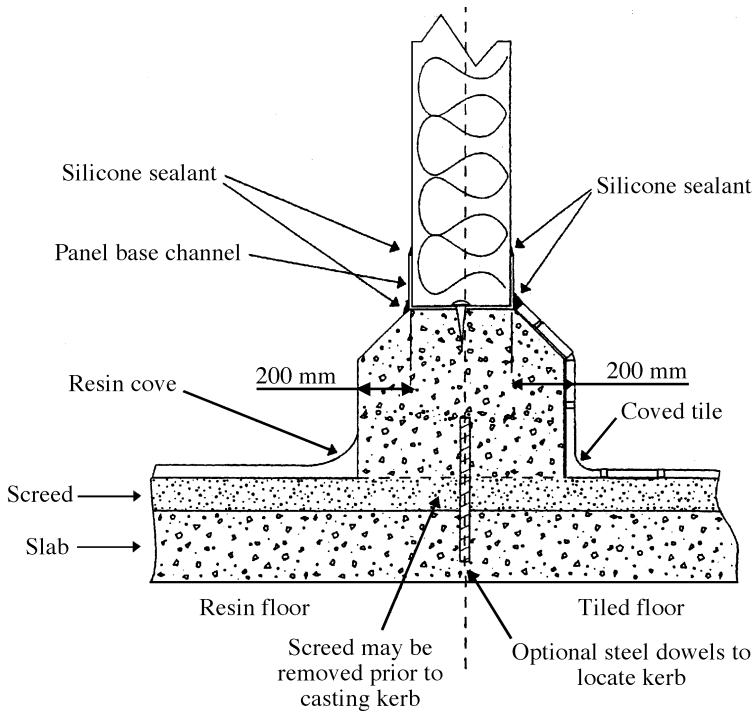


Fig. 6.6 Design and installation of internal walls and flooring.

Movement joints must be designed to allow for expansion and/or contraction of the wall structure and must coincide with existing movement joints in the base slab. It is essential that provision is made for movement joints to be built in as work proceeds and not cut into finished work. Movement and expansion joints should be filled with a suitable packing and/or sealant material and the joint covered with metal angle or cover strip to prevent rodent access to the joint. Fixing materials such as bolts and nuts, screws and nails should be smoothed away completely. If this is not possible, nut heads should fit smooth on the surface.

To ensure continuity in the appearance and surface characteristics of walling throughout a food processing area, thin sections (50 mm) of insulated panel are sometimes used to cover external or load-bearing walls. When such a practice is adopted, there is a possibility of introducing harbourage sites for pests between the two walling materials. The chances of problems occurring are greatly increased if openings for services are made in the insulated panels without effective sealing. Although it is preferable to form the internal finish as an integral part of the wall structure, various cladding systems of polypropylene, polyvinyl chloride or stainless steel can be used in some circumstances. However, great care has to be taken to prevent mould growth or infestation with pests such as spiders and insects, in areas where the cladding is not flush with the background wall.

Load-bearing and fire-break walls are often constructed from brick or blockwork. Walls made from such materials do not generally provide a smooth enough surface to allow the direct application of the various types of coating. A common practice is to render the brickwork with a cement and sand screed to achieve the desired surface smoothness for the coating layer. The walls may be covered by other materials such as tiles or sheets of plastics. The former is preferred, provided each tile is fully bedded and an appropriate resin is used for grouting. In very wet or humid areas, where there is a strong possibility of mould growth, the application of a fungicidal coating may be considered. There is evidence that some such coatings remain effective for many years.

Partition walls constructed from either hollow blockwork or composite panels must be sealed at the top and bottom to prevent rodents from entering the inner hollow core. This can be accomplished by laying a solid block course to cap hollow blockwork walls or welding a capping strip to composite panels. Cavity walls provide excellent harbourage for rodents and allow them access between different parts of a building. Rodents often gain access via air-bricks or ventilators and these should be proofed with metal mesh having openings of 6 mm or less. Internal ventilators should be constructed from metal or proofed with metal mesh if of plastic construction. Any damage to cavity walls must be repaired immediately.

The coating applied as the top layer must result in a finish that is smooth, easy to clean, durable and impermeable. Material used should also be non-toxic. Liquid paint-based systems comprise a primer, one or more undercoats and one or more finishing coats. The finishing coats may be emulsion paints, oil-based, epoxy or polyurethane paints, or chlorinated or acrylated rubber paints. In areas where high levels of humidity or condensation occur regularly, it may be necessary to apply a fungicidal paint system to control the growth of moulds. Some paint systems rely on leaching of chemicals from within the paint to control mould growth. These types of paint are not generally considered suitable for use in food processing areas because of the potential contamination and taint hazard. Reinforced liquid coatings, based on glass fibres mixed with an epoxy resin, can also be used to provide a smooth finish which is easy to clean, and also gives good resistance to many chemicals, impact damage, and abrasion, all of which are good hygienic features. However, taint problems can potentially arise during their application.

The overall shape of the wall is also important. The presence of ledges and similar features (e.g. around windows) can result in a significant hazard as regards accumulation of debris, and this has to be considered at the design stage. Having installed hygienically suitable floors and walls, it is important that floor-to-wall, wall-to-wall and wall-to-ceiling joints are hygienically constructed. Covings should provide an easily cleaned surface at wall, floor and ceiling junctions. A 50 mm radius curve or a 50 × 50 mm deep chamfer is generally considered to be large enough to enable easy cleaning (although extra consideration will have to be made to prevent damage from moving traffic such as trolleys and fork-lift trucks).

In floor-to-wall junctions, a 50 mm radius resin cove or a coved tile can be used, depending on the nature of the flooring material (tiles tend to be 30 mm in radius). Its upper join is terminated by a galvanised or stainless steel stop bead secured to the wall, with the wall render finishing above this bead. Silicone sealant is used between the tile or resin and the stop bead to allow for thermal or other movement of the wall and flooring. All spaces between floor joists or rafters should also be filled in order to prevent rodents gaining access to the tops of the walls.

6.6 Ceilings

Ceilings should be smooth with no seams. Seams should be sealed. If the ceiling is suspended the space above the ceiling should be accessible and cleanable. A minimum clearance of 1.5 m is advisable to allow access. Suspended ceilings can be constructed using suitable load-bearing insulation panels or suspending sections of insulated panels, as used for the internal walls, from the structural frame of the building. The use of such insulated panels meets legislative requirements by providing a surface that is easily cleanable and will not shed particles. It is important to ensure that drops from services passing through the ceiling are sealed properly to prevent ingress of contamination. Cables may be run in trunking or conduit but this must be effectively sealed against the ingress of vermin and water. All switchgear and controls, other than emergency stop buttons, should, whenever possible, be sited in separate rooms away from processing areas, particularly if wet operations are taking place.

Lighting may be a combination of both natural and artificial. Artificial lighting has many advantages in that, if properly arranged, it provides illumination over inspection belts and a minimum of 500–600 lux is recommended. Fluorescent tubes and lamps must be protected by shields, usually of polycarbonate, to protect the glass and contain it in the event of breakage. Suspended units should be smooth, easily cleanable and designed to the appropriate standards to prevent the ingress of water. It is suggested that lighting units are plugged in so that in the event of a failure the entire unit can be replaced and the faulty one removed from the processing areas to a designated workshop for maintenance. Ideally, recessed lighting flush with the ceiling is recommended from the hygienic aspect but this is not always possible and maintenance may be difficult.

6.7 Floors

The floor in a food factory forms the basis of the entire processing operation, and a failure in the floor often results in lengthy disruptions of production and financial loss while repairs are carried out. Unsatisfactory floors increase the chances of accidents, cause difficulties in attaining required hygiene standards

and increase sanitation costs (Timperley, 2002). Both its physical durability and hygienic qualities have to be considered. The overall design of the floor must be such that it can be effectively cleaned and disinfected, is safe in use (e.g. anti-slip) and that it is stable under these cleaning regimes and to normal processing activities (i.e. does not begin to disintegrate, which may result in microbial or physical contamination of the food being processed). Guidelines for the design and construction of floors have been prepared by Timperley (2002).

Design specifications for floors should cover the following:

- The structural floor slab
- The waterproof membrane, which should extend up walls to a height above the normal spillage level
- Movement joints in the subfloor and final flooring, around the perimeter of the floor, over supporting walls, around columns and machinery plinths
- Drainage, taking into account the proposed layout of equipment
- Screeds, either to give a flat enough surface to accept the flooring or to form the necessary falls when these are not incorporated in the concrete slab
- Floor finish, either tiles or a synthetic resin
- Processing considerations, including the following:
 - trucking
 - impact loads from proposed operations, and equipment and machinery to be installed
 - degree of product spillage and associated potential problems with corrosion, thermal shock and drainage requirements;
 - types of cleaning chemicals to be used and requirements for slip resistance.

Figure 6.6 shows a cross-section of a typical tiled, concrete factory ground floor, illustrating the various layers necessary to provide the required strength, stability and other properties (e.g. damp proofing). The structural floor slab (i.e. the base on which the top layer of flooring will sit) should be capable of withstanding all structural, thermal and mechanical stresses and loads which will occur during service, as a failure will compromise the hygienic properties of the top-layer flooring. In particular, allowances should be made for expansion, contraction and cracking, and where appropriate for problems arising from hydrostatic pressure and rising damp. This can, under certain circumstances, cause the adhesion between the floor slab and flooring to fail. In general, the floor slab should be free from contamination, dry, and finished with a strong, even surface.

All wet- or corrosion-resistant floorings need to be laid on a waterproof and acid-resistant membrane. This is particularly important in the design of suspended floors, where deflection due to heavy moving loads may cause cracks or fissures through which corrosive liquids (or water during cleaning operations) might pass to damage the structural concrete. Some of the main requirements of the membranes are that they should be:

- resistant and impermeable to specified liquids (depending on factory use)
- continuous

- strong enough to support imposed loads and resist damage during flooring repairs
- capable of flexing
- extended up the walls to a height above the normal spillage level
- carried over plinths or kerbs, below drainage channels and into drains.

The flooring material itself can be made of a number of different substances. Although concrete is resistant to chemical attack from alkalis, mineral oils and many salts, it is attacked by acids, vegetable and animal oils, sugar solutions and some salts. It is also porous and tends to crumble under impact or when abraded. As such, it is not generally considered to be suitable as a flooring material for most food processing areas. However, it can be improved by various means so that it can be used in some food storage and access areas.

The choice of flooring surfaces can be broadly grouped into three categories:

- Concretes
- Fully vitrified ceramic tiles
- Seamless resin screeds.

Concrete flooring, including high-strength granolithic concrete finishes, although suitable and widely used in other parts of a factory, is not recommended for food processing areas. This is because of its ability to absorb water and nutrients, allowing microbial growth below the surface where it is extremely difficult to apply effective sanitation programmes.

Pressed or extruded ceramic tiles have been used by the food industry for many years and are still extensively used in processing areas. In recent years they have been partially replaced on grounds of cost by the various seamless resin floors now widely available. Provided tiles of a suitable specification (fully vitrified ceramics) are selected and properly laid – an important prerequisite for all types of flooring – they are perfectly suitable for food production areas and give a long-life floor.

Tiles are laid on sand and cement mortar-bonded to the subfloor (thin bed), or on a semi-dry sand and cement mix (thick bed). A tile thickness of approximately 20 mm will provide adequate strength with either of the bedding methods. Thinner tiles (12 mm) are used for bedding into a resin bed by a vibratory method. Tile surfaces may be smooth or studded or may incorporate silicon carbide granules to improve slip resistance. Studded tiles are not recommended because of the greater difficulty of cleaning such surfaces. Ideally, surfaces that offer the greatest ease in cleaning should be used. However, in practice, the requirements for anti-slip conditions cannot be ignored and as a result the final choice should reflect a balance of the relevant factors and the emphasis placed on them.

Joints should be grouted as soon as practical, otherwise the joint faces may become contaminated. Cementitious grouts are not considered suitable for hygienic applications and resin grouts are normally used. These should not be applied for at least three days after the tiles have been laid, so that water from

the bed can evaporate. Epoxy resins are widely used for grouting but have limited resistance to very high concentrations of sodium hypochlorite and soften at temperatures above 80°C. Polyester and furan resins are more resistant to chemical attack. Shapton and Shapton (1991) cite data for the chemical resistance of different resins given by Beauchner and Reinert (1972). The grouting material should fill the joints completely to a depth of at least 12 mm and be finished flush with the tile surface. Thinner joints (1 mm) are achieved when the tiles are vibrated into a resin bed. The procedure ensures a flat plane and reduces the possibility of damage to the tile edges in use. One advantage of tiled floors that is not always fully appreciated is that sections or local areas of damaged surface can be replaced and colour-matched with relative ease, so that the overall standard and appearance of the floor can be maintained.

Resin-based seamless floors offer a good alternative means of attaining a hygienic surface provided they are laid on a sound concrete base. The choice of finish can be made either from various resin-based systems (primarily epoxy or polyurethane) or from polymer-modified cementitious systems. The resin-based systems can be broadly grouped under three headings:

- *Heavy duty*: heavily filled trowel-applied systems 5–12 mm thick. Such screeds are of high strength and are normally slip-resistant.
- *Self-levelling*: ‘poured and floated’ systems applied at 2–5 mm thickness. These systems are sometimes more correctly described as ‘self-smoothing’. They generally give smooth glossy surfaces.
- *Coatings*: usually 0.1–0.5 mm thick. They are not recommended for high-risk or other production areas because of their poor durability. Failures of such floors have been associated with microbial contamination, including *Listeria monocytogenes*, becoming trapped under loosened areas where the coating has flaked.

A further aspect that needs to be considered is whether the proposed floor meets legislative requirements. Statements in UK and EU legislation are of a general nature but do call for floors to be ‘waterproof’ or ‘impervious’ and ‘cleanable’. Taylor and Holah (1996) have developed a simple technique to assess the water absorption of flooring materials, and materials can be quickly accepted or rejected on any water uptake recorded. Water uptake is unacceptable because if fluids are able to penetrate into flooring materials, microorganisms can be transported to harbourage sites that are impossible to chemically clean and disinfect. Cleanability is more difficult to interpret but both Taylor and Holah (1996) and Mettler and Carpenter (1998) have proposed suitable test methods in which the cleanability of attached microorganisms is assessed. When considering the selection of flooring materials, therefore, evidence for imperviousness and cleanability should be sought. The floor should be coved where it meets walls or other vertical surfaces such as plinths or columns as this facilitates cleaning. As part of the design of floors, allowance has to be made for adequate drainage of water – that is, the physical shape of the floor should allow water to drain away easily. A slope (or ‘fall’) of 1 in 60 is normally adequate; 1

in 40 may be required for floors that are habitually very wet, whilst 1 in 80 may be sufficient for normally dry tiled floors.

6.8 Drainage

Ashford (1986) states that drainage is often neglected and badly constructed. Detailed consideration of the drainage requirements is an important aspect of floor design. Ideally, the layout and siting of production equipment should be finalised before the floor is designed to ensure that discharges can be fed directly into drains. In practice, this is not always possible, and in the food industry in particular there is a greater chance that the layout of lines will be frequently changed. Equipment should not be located directly over drainage channels as this may restrict access for cleaning.

Discharges from equipment, however, should be fed directly into drains to avoid floor flooding. Alternatively, a low wall may be built around the equipment from which water and solids may be drained. Where the channels are close to a wall they should not be directly against it to avoid flooding of the wall-to-floor junction. An indirect advantage of channels near a wall is that the siting of equipment hard up to the wall is prevented, thus providing access for cleaning.

Satisfactory drainage can be achieved only if adequate falls to drainage points are provided. A number of factors should be taken into consideration when establishing the optimum or practical fall, for example:

- *Volume of water:* wet processes require a greater fall.
- *Floor finish:* trowelled resin surface finishes require a greater fall than self-levelling ones. Otherwise 'puddles' created by small depressions in the surface may remain.
- *Safety:* falls greater than 1 in 40 may introduce operator safety hazards and also cause problems with wheeled vehicles.

Timperley (2002) states that floors should have a fall to drain of between 1 in 50 and 1 in 100, depending upon the process operation and surface texture, while Cattell (1988) suggests a compromise figure of 1 in 80 for general purposes and safety.

The type of drain used depends to a great extent upon the process operation involved. For operations involving a considerable amount of water and solids, channel drains are often the most suitable. For operations generating volumes of water but with little solids, aperture channel drains are more favourable (Fig. 6.7). In most cases, channels should have a fall of at least 1 in 100, have round bottoms and not be deeper than 150 mm for ease of cleaning. They must be provided with gratings for safety reasons. The channel gratings must be easily removable, with wide apertures (20 mm minimum) to allow solids to enter the drain. In recent years there has been a marked increase in the use of corrosion-resistant materials of construction, such as stainless steel for drain gratings.

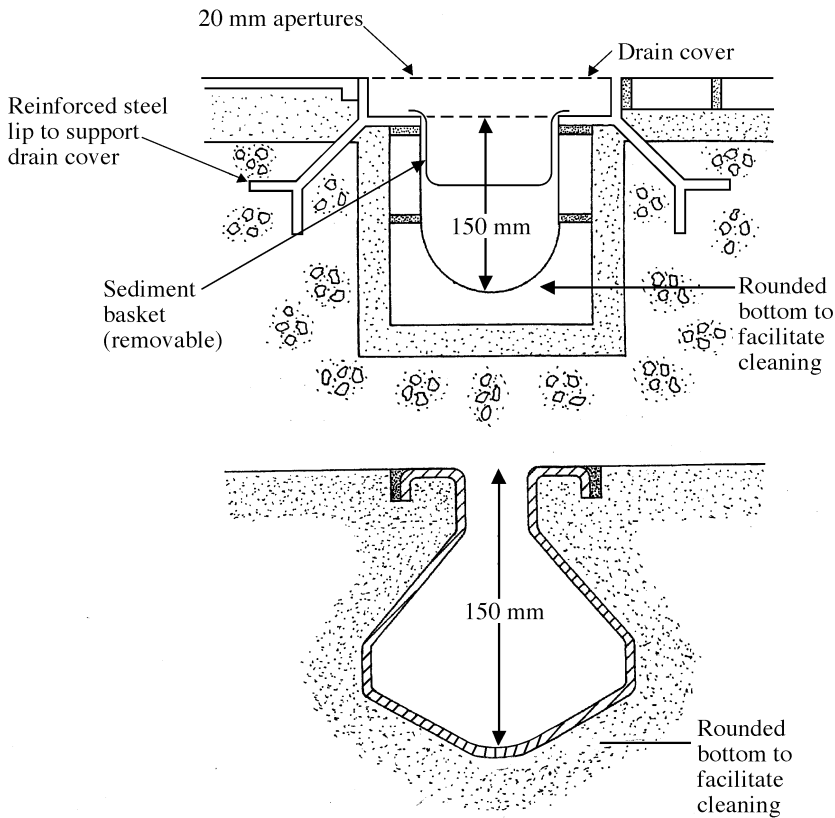


Fig. 6.7 Channel and aperture channel drain designs.

Stainless steel is also finding a wider use in other drain fittings, e.g. various designs of traps, and for the channels of shallower (low-volume) drainage systems. The profile of aperture channel drains is such that all internal surfaces can be easily cleaned.

The drainage system should flow in the reverse direction of production (i.e. from high to low risk) and, whenever possible, backflow from low-risk to high-risk areas should be impossible. This is best achieved by having separate low- and high-risk drains running to a master collection drain with an air-break between each collector and master drain. The drainage system should also be designed such that rodding points are outside high-risk areas. Solids must be separated from liquids as soon as possible, by screening (with, for example, removable sediment baskets), to avoid leaching and subsequent high effluent concentrations. Traps should be easily accessible, frequently emptied and preferably outside the processing area.

6.9 Services

Hygienic building design must take account of service equipment such as pipework for water, steam and compressed air; electrical conduits and trunking; artificial lighting units; ventilation ducts; compressors, refrigeration/heating units and pumps. Ashford (1986) suggests building a 'box within a box' by creating insulated clean rooms within the structural box of the factory, with the services and control equipment located in the roof void above the ceiling. Equipment and ductwork are suspended from the structural frames and access to all services is provided by catwalks, as shown in Fig. 6.8. This arrangement, if properly undertaken, eliminates a major source of contamination from the process area.

Service pipes should be routed outside the process area and pass through walls local to their point of usage. Where this is not possible, services should be grouped 50 mm apart on a stainless steel structure around the plant with minimum support rackets to walls or plant. Overhead pipes should not pass over open vessels or production lines. This is to prevent dripping of condensation droplets, which may form if the pipes are above a process area, and contamination from leakage, lagging, flaking paint or dust. Services should not be positioned too closely to walls and floors in production areas and should have a minimum 50 mm clearance to allow for cleaning, inspection, maintenance and repair. Pipework entering production areas should be grouped together and sheathed in an appropriate material.

The number of openings in walls around the process area should be kept to a minimum in order to prevent pest access, limit the ingress of airborne contamination, and facilitate environmental control. All pipes and cables passing through internal walls and floors should be built in to prevent pests from using

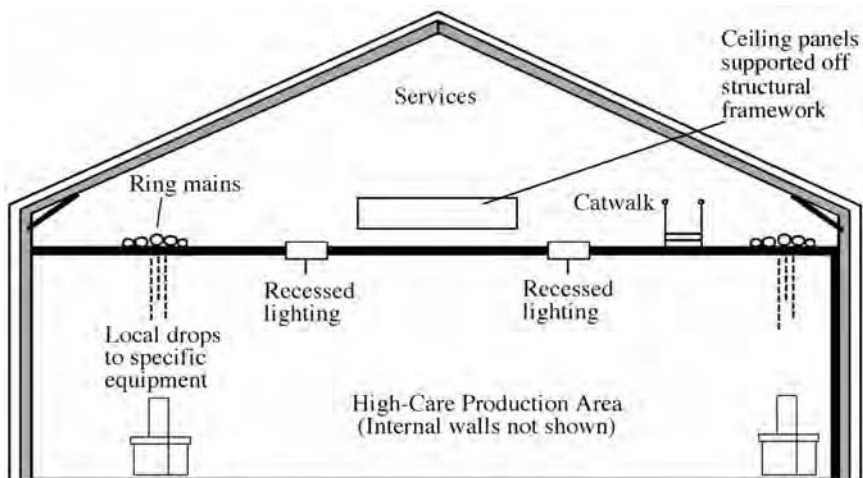


Fig. 6.8 'Box within a box' design of a factory interior to separate production from service operations.

them as runways. Underground ductwork used for heating, water and other services can allow pests to move around within and between buildings. Barriers should be built across the duct at the outside wall of each building. Where ductwork carries pipes or cables from one part of a building to another they should be proofed at each floor level and access provided for inspection cleaning and treatment. The most effective way of passing services through walls is by means of sleeves or prepared openings. Ducts may pass through walls as follows:

- Cast directly into concrete wall or built into brickwork/blockwork. This is a costly and impractical solution because it requires separate supports to hold the duct in place and in the case of concrete makes it difficult to strip shutters.
- With flanges exposed on each side of the wall for connections. This method is prone to distortion and is difficult to cast into concrete walls.
- Running through an opening fixed with angles bolted to angle inserts in the wall. A seal is then made between the duct and the wall using a two-part polysulphide sealer which provides a degree of flexure to accommodate thermal and other movement.
- Passing through the wall via a prepared opening using a concrete or steel lintel to bridge the gap. A seal is made between the duct and the wall using polysulphide.

Pipework services in processing areas may be stainless steel, galvanised steel or PVC. Steam should be transported in malleable iron pipes which should be clad with stainless steel. Supports and hangers should be stainless steel or hot dip galvanised steel. Painted steel should be avoided to obviate the risk of paint flaking. Pipe insulation material must be CFC free. Cladding must be crevice free with a durable surface.

Ideally, all cables should be situated behind walls or above the ceiling. If this is not possible cables in production areas should be placed in enclosed, rounded conduits or racks which will not accumulate dirt and are accessible for cleaning, pest control and maintenance. No cables should be routed above processing machinery. To avoid dirt accumulating, cable racks should preferably have vertical rounded supports. Light fittings should fit smooth against surfaces like the ceiling or construction parts. Good lighting is essential to ensure clean conditions, encourage good housekeeping and safety and facilitate maintenance. Lighting levels should be no less than 500 lux in most areas where operators are required. This level may be less in areas such as loading bays or conveyor halls or more in areas such as inspection, filling or packaging. All water systems must be designed to prevent water stagnation. To limit the risk of *Legionella* growth within water systems, water supply tanks and calorifiers must be well enclosed, insulated and accessible with short, direct pipe work where the cold water pipes are lagged to prevent the water from warming to the critical range of 20–45°C. Non-potable water, which may be used for steam production, refrigeration or fire control, must not pass through processing areas. It must be carried in a separate line, identified by colour, and have no cross-connection with the potable system.

Natural ventilation should be avoided in most instances because it varies and therefore cannot be controlled. Extraction systems are a relatively inexpensive way of drawing out hot or stale air and steam, but excessive use of this method results in the build-up of negative pressure unless there is a corresponding supply of fresh air to balance the atmosphere. The best and most efficient system is to combine supply and extract systems which will provide a balanced and controlled system using light overpressure. Air within the production areas should have a small positive pressure (25 pascals minimum) to prevent ingress of contaminants from outside. Air must be kept dry in compressed air lines to prevent the growth of microorganisms, and be microbiologically filtered (uv filtering) if used in contact with the food product. Ventilation systems should provide a number of air changes per hour, the number of which will vary in accordance with usage of the area. Air flow must pass from clean or high-risk areas to dirty or low-risk areas. Incoming air must be filtered into processing areas. Ventilation to provide a clean, contaminant-free environment must be accomplished by a combination of measures such as air filtration, humidity and temperature control and pressure variation. In general the production should have a humidity of 50–60%. Fans and condensers should be positioned outside production areas with ducting surface mounted onto walls or ceilings. Access to ducting must be provided to allow regular cleaning operations to be effected.

The steps and floors in a staircase should be closed. The steps should be provided with a kicking edge with a height of 100 mm minimum. On the steps and floors fluid must be able to drain completely. The staircase construction and the stair rails should not have any horizontal surfaces. Tube profiles should be closed completely.

6.10 Internal barriers separating manufacturing processes

The final set of barriers to contamination are those within the factory itself. Two levels of barriers are required:

1. The first level separates processing from non-processing areas.
2. The second levels separates 'high-risk' from 'low-risk' processing areas.

The design of any food processing area must allow for the accommodation of five basic requirements:

- Raw materials and ingredients
- Processing equipment
- Staff concerned with the operation of such equipment
- Packaging materials
- Finished products.

A single one-way flow of production operations from raw materials at the beginning to finished products at the end minimises the possibility of

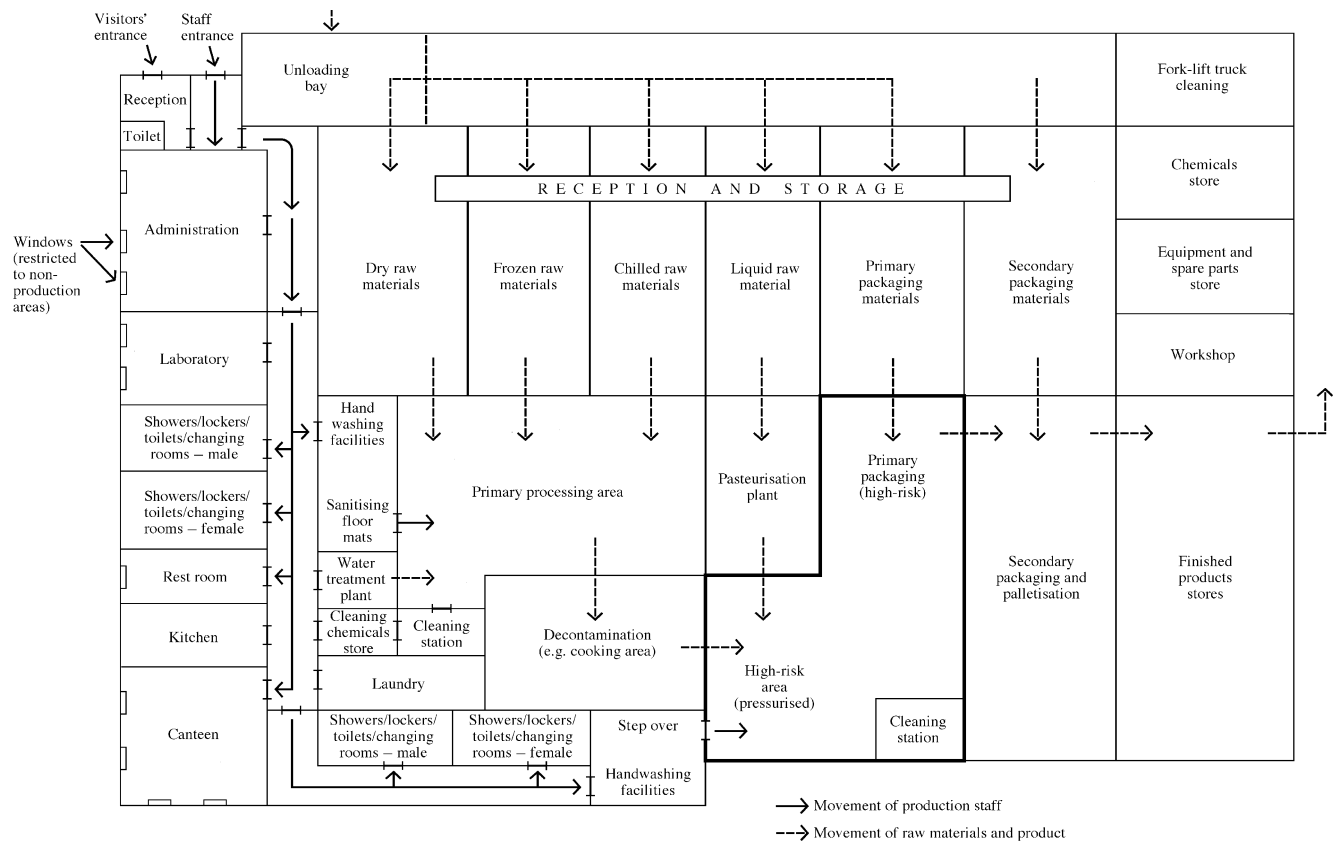


Fig. 6.9 Hygienic internal layout of a food processing factory.

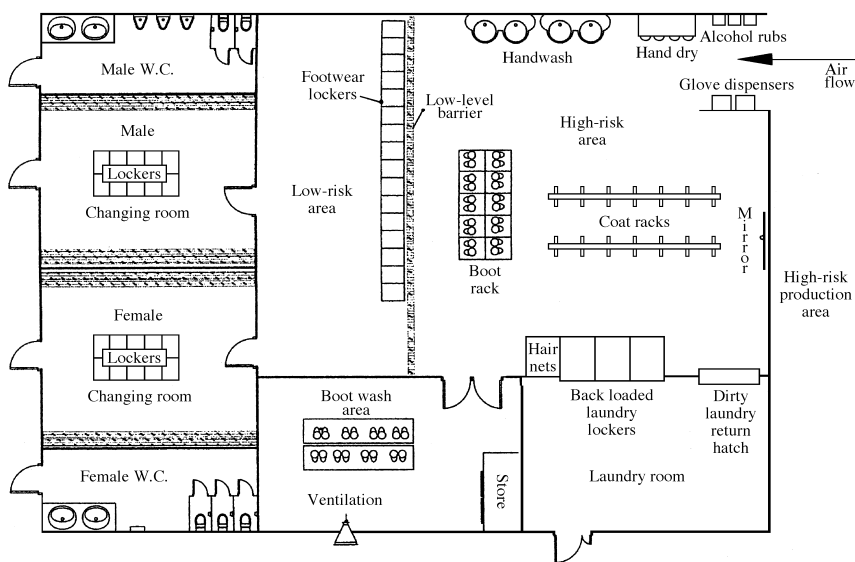


Fig. 6.10 Layout of low-risk and high-risk changing rooms.

contamination of processed or semi-processed product by unprocessed or raw materials and is more efficient in terms of handling. It is also easier to segregate clean and dirty process operations and restrict movement of personnel from dirty to clean areas. While ideally the process line should be straight, this is rarely possible, but there must be no backtracking and, where there are changes in the direction of process flow, there must be adequate physical barriers.

A possible layout is shown in Fig. 6.9. The layout shows the different levels of hygienic design and operation required in different parts of the factory:

- Non-production 'low-risk' and operations with a high risk of contamination such as waste disposal are situated as far as possible from production areas, particularly 'high-risk' areas.
- Entrance from non-production to production areas is only possible via changing rooms where personnel are required to wash and change into appropriate clothing.
- Entrance into 'high-risk' areas is only possible through a further changing room specifically designed for high-risk operations (though changing facilities can be combined – see Fig. 6.10).
- The 'high-risk' area is physically separated from 'low-risk' areas to prevent unauthorised entry of personnel or materials.
- Movement from lower-risk production areas such as raw material reception and finished goods dispatch to higher-risk areas is strictly controlled.
- Raw materials flow one way to minimise contamination or recontamination with barriers to prevent raw materials, semi-finished and finished products coming into contact.

The layout should also consider that provision is made for the space necessary to undertake the process and associated quality control functions, both immediately the factory is commissioned and in the foreseeable future. Space should also be allowed for the storage and movement of materials and personnel, and for easy access to process machinery. Imholte (1984) states that 915 mm (3.0 feet) should be considered as the bare minimum of space surrounding most processing units. He recommends 1830 mm (6.0 feet) as a more practical figure to allow production, cleaning and maintenance operations to be undertaken in an efficient manner.

6.11 High-risk areas

Within the overall manufacturing area, a further, final set of barriers is required between 'high-risk' and 'low-risk' processing areas. High-risk areas may be broadly defined as areas processing food components that have undergone a decontamination or preservation process and where there is a risk of product contamination. In contrast, low-risk areas refer to those processes dealing with food components that have not yet undergone a decontamination/preservation process. Some experts make a further distinction, for example, between 'high-risk areas' (HRAs) and 'high-care areas' (HCAs). The UK Chilled Food Association, for example, uses both terms (Anon., 1997a). In general the requirements in both types of areas dealing with decontaminated product are the same. It is important also to note that the distinction between high- and low-risk areas does not mean that lower overall standards are acceptable in 'low-risk' areas, for example raw material reception or final product storage or distribution. Unsatisfactory practices in 'low-risk' areas may put greater pressure on the barriers separating the two, either increasing the level of initial contamination or increasing the risk of recontamination, for example through poor storage or damage to the packaging of the final product.

The final barrier between high- and low-risk processing areas is composed of a number of sub-barriers designed to control contamination from a number of routes:

- The point at which the product leaves the preservation/decontamination process and enters the high-risk area
- The movement of other materials into and out of the high-risk area (e.g. waste, packaging)
- The air
- The movement of employees and equipment into and out of high-risk areas.

Some of these potential sources of contamination may be controlled by appropriate procedures, for example governing movement of personnel and materials. The principal areas where hygienic design is the critical factor discussed here are as follows:

- The interface between preservation/decontamination and the high-risk area
- Appropriate facilities to support the movement of personnel into and out of the high-risk area.

Decontamination/preservation equipment must be designed such that as far as possible a solid, physical barrier separates the low- and high-risk areas. Where it is not physically possible to form a solid barrier, air spaces around the equipment should be minimised and the floor junction between low- and high-risk areas should be fully sealed to the greatest possible height. The fitting of devices that provide heat treatment within the structure of a building presents two main difficulties. Firstly, the devices have to be designed to load product on the low-risk side and unload on the high-risk side. Secondly, the maintenance of good seals between the heating device surfaces, which cycle through expansion and contraction phases, and the barrier structure, which may have a different thermal expansion, is problematical. Of particular concern are ovens:

- Some ovens have been designed such that they drain into the high-risk area. This is unacceptable since it may be possible for any pathogens present on the surface of product to be cooked to fall to the floor through the melting of the product surface layer (or exudates on overwrapped product) at a temperature that is not lethal to the pathogen. The pathogen could then remain on the floor or in the drain of the oven in such a way that it could survive the cook cycle. On draining, the pathogen would then subsequently drain into the high-risk area. Pathogens have been found at the exit of ovens in a number of food factories.
- Problems have occurred with leakage from sumps under the ovens into the high-risk area. There can also be problems in sump cleaning where the use of high-pressure hoses can spread contamination into the high-risk area.
- Where the floor of the oven is cleaned, cleaning should be undertaken in such a way that cleaning solutions do not flow from low-risk areas to high-risk areas. Ideally, cleaning should be from the low-risk area with the high-risk area door closed and sealed. If cleaning solutions have to be drained into the high-risk area, or in the case of ovens that have a raining water cooling system, a drain should be installed immediately outside the door in the high-risk area.

Within the factory building, provision must be made for adequate and suitable staff facilities and amenities for changing, washing and eating. There should be lockers for storing outdoor clothing in areas that must be separate from those for storing work clothes. Toilets must be provided and must not open directly into food-processing areas, all entrances of which must be provided with handwashing facilities arranged in such a way that their ease of use is maximised.

In high-risk operations, personnel facilities and requirements must be provided in a way that minimises any potential contamination of high-risk operations. The primary sources of potential contamination arise from the operatives themselves and from low-risk operations. This necessitates further

attention to protective clothing and, in particular, special arrangements and facilities for changing into high-risk clothing and entering high-risk areas. Some laundries in food processing operations now operate according to low-/high-risk principles. Dirty laundry enters 'low risk', is loaded into a washing machine that bridges a physical divide, is cleaned and disinfected and exits into 'high risk' to be dried and packed.

The high-risk changing room should provide the only entry and exit point for personnel working in or visiting the area and is designed and built both to house the necessary activities for personnel hygiene practices and to minimise contamination from low-risk areas. In practice, there are some variations in the layout of facilities of high-risk changing rooms. This is influenced by, for example, space availability, product throughput and type of products, which will affect the number of personnel to be accommodated and whether the changing room is a barrier between the low- and high-risk operatives or between operatives arriving from outside the factory and high risk. Generally higher construction standards are required for low-/high-risk barriers than for outside/high-risk barriers because the level of potential contamination in low risk, both on the operatives' hands and in the environment, is likely to be higher (Taylor and Holah, 2000). In each case, the company must evaluate the effectiveness of the changing-room layout and procedure to ensure the high-risk area and products prepared in it are not being put at risk. This is best undertaken by a Hazard Analysis Critical Control Point (HACCP) approach, so that data are obtained to support or refute proposals regarding the layout or sequence.

A basic layout for a changing room is shown in Fig. 6.10 and has been designed to accommodate hand hygiene procedure and the following requirements:

- An area at the entrance to store outside or low-risk clothing. Lockers should have sloping tops.
- A barrier to divide low- and high-risk floors. This is a physical barrier such as a small wall (approximately 60 cm high), that allows floors to be cleaned on either side of the barrier without contamination by splashing, etc., between the two.
- Open lockers at the barrier to store low-risk footwear.
- A stand on which footwear is displayed/dried.
- An area designed with suitable drainage for bootwashing operations. Research has shown (Taylor *et al.*, 2000) that manual cleaning (preferably during the cleaning shift) and industrial washing machines are satisfactory bootwashing methods.
- Handwash basins to service a single handwash. Handwash basins must have automatic or knee-/foot-operated water supplied at a suitable temperature (that encourages handwashing) and a waste extraction system piped directly to drain. It has been shown that handwash basins positioned at the entrance to high-risk areas, which was the original high-risk design concept to allow visual monitoring of handwash compliance, gives rise to substantial aerosols

- of staphylococcal strains that can potentially contaminate the product.
- Suitable hand-drying equipment, e.g. paper towel dispensers or hot-air dryers, and, for paper towels, suitable towel disposal containers.
- Access for clean factory clothing and storage of soiled clothing. For larger operations this may be via an adjoining laundry room with interconnecting hatches.
- Interlocked doors are possible such that doors allow entrance to high-risk areas only if a key stage, e.g. handwashing, has been undertaken.
- Closed-circuit television (CCT) cameras as a potential monitor of handwash compliance.
- Alcohol hand rub dispensers immediately inside the high-risk production area.

There may be the requirement to site additional handwash basins inside the high-risk area if the production process is such that frequent handwashing is necessary. As an alternative to this, Taylor *et al.* (2000) demonstrated that cleaning hands with alcoholic wipes, which can be done locally at the operative's workstation, is an effective means of hand hygiene.

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Control of airborne contamination

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7.1 Introduction: why control of airborne contamination is important in food production

The air is an important, potential source of pathogens and the intake air into a high-risk area has to be controlled. Air can enter high-risk via a purpose-built air handling system or can enter from external uncontrolled sources (e.g. low-risk production and packing or from outside). Environmental air of a particular quality (temperature, humidity, dust content, microbial content and fresh air volume) may be required for the manufacture of specific products. For example, chilled food production areas are often run at a temperature of 10–12°C in order to maintain the chill temperature of product prior to packaging. Once product is sealed inside a container, it is more difficult to chill the product if it is above the required temperature. For high-risk areas, the aim of the air handling system is to supply suitably filtered fresh air, at the correct temperature and humidity, and at a slight overpressure to prevent the ingress of air from external sources. Control of airborne dust in cereal milling operations is important for worker health and to minimise the risk of explosions. Dry product areas may also require humidity control to prevent hygroscopic ingredients becoming spoilt.

A 'high-care area' is an area designed to a high standard of hygiene where practices relating to personnel, ingredients, equipment, packaging and environment aim to *minimise* product contamination by micro-organisms. A 'high-risk area' by comparison is a physically segregated area designed to a high standard of hygiene where practices relating to personnel, ingredients, equipment, packaging and environment aim to *prevent* product contamination by pathogenic micro-organisms (Chilled Food Association, 1997).

Types of airborne contamination include dust, water droplets, skin particles and airborne micro-organisms. Dust can be generated from a variety of dry product and ingredient handling operations. The significance of the presence of dust may range from simple nuisance (requiring regular cleaning) to inhalation hazard or risk of explosion. Particle diameters less than $10\text{ }\mu\text{m}$ are of concern for respiratory damage to humans. Occupational asthma caused by flour dust is a real problem in the baking industry (Tee, 1993). Information on the control of occupational exposure to dust is given in HSE Guidance Note EH 44, 'Dust in the workplace: general principles of protection' (HSE, 1984). Flour dust is a respiratory sensitiser and has been given a 'sen' notation in EH40/2001 (HSE, 2001). There is also a risk assessment document available for flour dust (EH72/11) (HSE, 1999). The Maximum Exposure Limit (MEL) is 10 mg/m^3 (8-hr TWA) with a short-term limit of 30 mg/m^3 (15 min). Grain dust (which includes all stages up to the first-break roller mill in flour production) is covered by EH66 and EH67 (HSE, 1993a, 1993b). Dust explosions have caused serious industrial accidents in the food industry. Explosible food dusts include flour, custard powder, instant coffee, sugar, dried milk, potato powder and soup powder. Further information is available in HSE Food Sheet 2 (HSE, 1992) and on the HSE website, <http://www.hse.gov.uk>. The explosibility properties of dispersed flour dust are described in *Chorleywood Digest*, issue 119 (Anon., 1992).

Micro-organisms can be dispersed in airborne water droplets that are generated by cleaning operations. Holah *et al.* (1990) demonstrated the potential for spread of *Listeria* in food production areas by use of hoses and spray lances. Droplets containing micro-organisms can also be dispersed from condensate on the cooling fins of evaporative chillers by the velocity of air going through the chiller. Large water droplets above $15\text{--}20\text{ }\mu\text{m}$ will not remain airborne for long, whereas smaller droplets will disperse readily. Some cleaning operations, e.g. boot washer brushes, may also impart a ballistic force to droplets that can disperse quite large (1 mm) droplets 1 or 2 metres from source.

Skin particles according to Noble (1961) have a mean equivalent diameter of $13.5\text{ }\mu\text{m}$ and fewer than 30% of the particles carrying staphylococci were less than $10\text{ }\mu\text{m}$ in equivalent diameter. Clark and Cox (1973) calculated that of the order of 7 000 000 skin scales per minute are liberated from the human body.

Airborne micro-organisms can be free-floating as in the case of bacterial or fungal spores, suspended in water droplets, or attached to dust or skin particles. The mistake is often made of assuming that the particle size of airborne micro-organisms is the same as that of the micro-organisms themselves. This is not often the case. Frequently the particle size will be much larger; for example, a $1\text{ }\mu\text{m}$ diameter bacterium may be inside a $15\text{--}25\text{ }\mu\text{m}$ diameter water droplet.

7.2 Sources of airborne contaminants

7.2.1 Air from outside the controlled zone

The air outside a factory will contain airborne micro-organisms but the concentration may in fact be lower than inside the factory. Levels of airborne micro-organisms outdoors depend very much on location, season, urbanisation and prevailing weather conditions. Levels may often be higher in rural locations, probably because of the much greater surface area of vegetation compared to city locations. In a study in Mexico City, Rosas *et al.* (1993) obtained airborne fungi counts ranging from 26 to 603/m³ at three different locations. The arithmetic mean counts ranged from 96 to 293/m³. By comparison, Holah *et al.* (1995) reported a TVC mean of 285/m³ and a fungal count of 37/m³ outside 34 and 38 food factories respectively. These counts are low compared to those quoted by Crook and Olenchok (1995) where counts of up to 100/m³ TVC and 1000/m³ fungi were found outdoors.

At a vegetable packing operation, Brown (2001) found a mean mould count outside the factory of 81/m³ but inside the greenhouse supplying the factory the count was 4923/m³ and in the packing hall it was 1168/m³. Clearly in this operation, the air in the greenhouse adjoining the packing hall was of more significance than the outside air quality. At a different factory that had a clean room, the TVC mean count was 630/m³ outside the factory but only 8/m³ inside the clean room.

7.2.2 Dust from milling and weighing operations

Milling operations, spray drying, weighing of powders and general handling of dried ingredients and products can create dust aerosols. Cleaning operations such as vacuuming can also generate airborne dust from the exhaust of the vacuum cleaner unless appropriate filters are fitted. In slow-moving air, large dust particles above 15–20 µm will quickly settle close to the source while smaller particles may remain airborne for some hours and travel long distances from the source. As air speed increases, even large particles will remain airborne and move considerable distances. An example of how far airborne dust can travel is demonstrated by the occasional deposition of sand from the Sahara desert in the UK.

7.2.3 Water droplets from jacuzzi-style salad washing

Salad washing is sometimes done in jacuzzi-style systems. The breaking of air bubbles on the surface of the wash water is likely to generate aerosols of water droplets containing micro-organisms (Sawyer *et al.*, 1993) and chlorine. The author once visited a salad washing factory where the wash water contained 70–100 ppm chlorine. The aerosols generated from the wash tanks had entered the air handling system and corroded the aluminium cooling fins in the main factory air handling system to such an extent that the fins had almost disappeared.

7.2.4 Aerosols from cleaning operations (hoses, air lances, brushing, boot washing, hand washing, tray washing)

It is vitally important that the potential for aerosols generated by cleaning operations to contaminate open product and food contact surfaces is understood. This is particularly important for high-risk operations where pathogens such as *Listeria* may be dispersed by lack of attention to cleaning operations (Holah *et al.*, 1990). *Listeria monocytogenes* has been shown to survive in aerosols for up to 210 min (Spurlock and Zottola, 1991). It is essential that cleaning equipment is itself cleaned regularly to prevent build-up of micro-organisms inside the equipment, and use of highly dispersive techniques such as high-pressure hoses is not allowed in high-risk areas.

7.2.5 People

Spendlove and Fannin (1983) reviewed the sources of airborne micro-organisms from people. Citing Buckland and Tyrell (1964), they reported that sneezing and blowing the nose were more than 1000 times more efficient than coughing in producing infectious aerosols from nasal secretions. Jennison (1942) showed with high-speed photography that up to 40 000 droplets were expelled during a violent sneeze whereas a cough released only a few hundred droplets. Other researchers showed that the size of these droplets was in the range 0.5–12 μm with the majority being in the range 1–2 μm . Spendlove and Fannin (1983), citing May and Pomeroy (1973), reported that men are more profuse disseminators of bacterial aerosols than women: fully clothed men released 1008 cfu/min on average, whereas women released 75 cfu/min on average.

Brown *et al.* (2002) investigated the factors affecting the release of airborne particles and bacteria from people. A clean environment, 3.42 m³ body box was constructed for the work. Typically, personnel released between 10⁵ and 10⁶ particles/m³ into the body box in 5 min. Bacterial release was lower, typically 10² to 10³ cfu/m³. High particle counts did not always mean a correspondingly high airborne bacterial count. Particle size analyses showed that most of the particles released were smaller than 5 μm but the larger particles (over 10 μm) were more likely to land onto settle plates. Airborne particles released from personnel could still be detected 2 hours after the person had left the body box, showing that, once airborne, particles released from personnel could pose a risk for a long time.

Various clothing styles were evaluated for ability to control particle and microbial release. Cleanroom styles were better at preventing particle and bacterial release than typical factory coats. Release of particles and bacteria from bare or covered arms with tight cuffs was similar and less than from covered arms with loose cuffs. Mobcaps were marginally better than hairnets and a close-fitting hood was better than all other designs. 'Bouffant' style hats appeared to act as bellows when patted. Contact plates applied to the forehead and head hair picked up higher counts from people with little or no hair than from people with long hair. In simulated factory trials, with four people in a

room (43 m^3) the mean numbers of bacteria landing on settle plates (90 mm diameter) in 5 min were 2.2–4.4 per plate, while presumptive *Staphylococcus* counts were between 0.7 and 1.4 per plate. Near to the people, the highest TVC and presumptive *Staphylococcus* counts were 7 and 3 per plate respectively in 5 min.

7.3 Dust control

Dust control should be viewed differently from general environmental air quality control. The filter systems used for dust control are quite different from those used for environmental air filtration. Dust control in the food industry serves five main purposes:

- To protect operators from inhaling fine particles, e.g. from milling operations
- To prevent the spread of dust in processing areas which may lead to cross-contamination
- To prevent accumulations of dust which could provide food for rodents and insects
- To prevent environmental pollution
- To prevent explosion.

It is important to choose the correct dust control system for each application. Examples of different types of filtration and wet scrubber types of dust control are given in Tables 7.1 and 7.2. This is a specialist area and specialist advice should be sought.

7.4 Environmental air quality control

A typical environmental air handling system (Brown, 1996) is shown in Fig. 7.1. This figure also shows the standardised terminology used by ventilation engineers. Not all systems will have all the components shown in Fig. 7.1 because installations tend to be tailor-made for individual sites. It is usual to recirculate a proportion of the air for energy-saving reasons. Fresh air make-up is required to provide fresh air for operatives to breathe and to replace air lost by transfer to other parts of the factory through doorways and conveyor hatches. Process air is shown as a separate supply and this is provided by a separate air compressor. Process air may be used simply to operate pneumatic equipment or as headspace air in tanks or air to convey product. It is important that this air is of good microbiological quality if the controlled space is also being supplied with air that is filtered to a high standard and especially if it is in product contact.

A typical air handling system is shown in Fig. 7.2. Again not all components will be present in all installations. The fresh air and recirculated air mix together in a mixing box and then pass through the first or pre-filter. This first filter will

Table 7.1 Filter dust control systems

Filter type	Application	Comments
Dry cyclones	Pre-collector of large quantities of dust from conveying air	Not usually suitable as final filters. Efficiency rarely exceeds 80–90% for particles of 10 μm
Dry fabric filters (bag filters)		
1. Static	Low dust load applications with intermittent use	
2. Mechanically shaken	Light to medium dust burden intermittent use applications	Alternative bag styles available; take care in selecting correct filter for purpose
3. Reverse jet	Heavy continuous dust burden at constant pressure drop	Select correct bag filter for purpose. Membrane-coated filter media achieve higher efficiency than conventional needle felt material. Discharge burden typically 7–15 mg/m^3
Rigid element filters		
1. Cartridge	Low cost high efficiency filter	Over life of cartridge, pressure drop will rise steadily and this governs element change frequency
2. Rigid plastic element	High efficiency, low failure	Not suitable for high temperatures or solvent atmospheres. Discharge burden typically <5 mg/m^3
Secondary filters	To prevent release of dust should failure occur in primary filter	
Electrostatic precipitators	Not used as product collectors. Main application for pollution control of fine particles in large exhaust systems (e.g. boilers)	

Table 7.2 Wet scrubber dust control systems

Filter type	Comments
Venturi	Most efficient wet collectors. Efficiency increases with pressure drop across throat
Wet cyclonic separators	Low pressure drop, low-efficiency collector used mainly as mist eliminator to follow a more efficient wet collector
Induced spray or S-curtain	Medium-efficiency collector that relies on induced spray caused by negative pressure exerted by exhaust fan. Efficiency typically 80–90% by mass of input dust burden

be of a coarse grade and will protect the secondary and final filters from large dust particles and also help to protect the fan motor from dust. The heating, cooling and humidification sections will be tailored to the customer’s requirements. Cooling coils will require condensate drains that are designed to withstand the pressure inside the air handling unit. For design of water traps readers are referred to Brown (1996).

7.4.1 Filtration

Environmental filters can be supplied in different grades as shown in Table 7.3. A high-efficiency filter system will have a full set of coarse, secondary and final

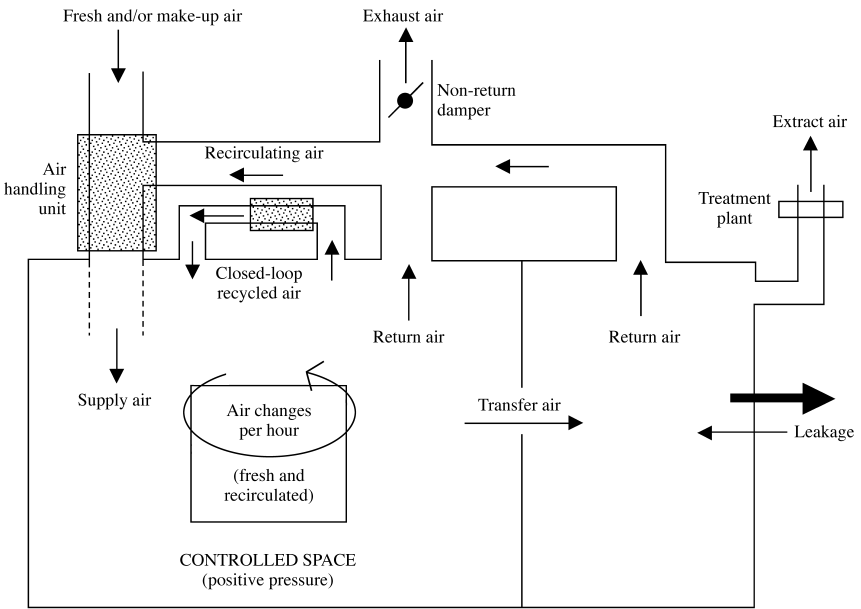


Fig. 7.1 Standardised terminology for air at different stages of air handling.

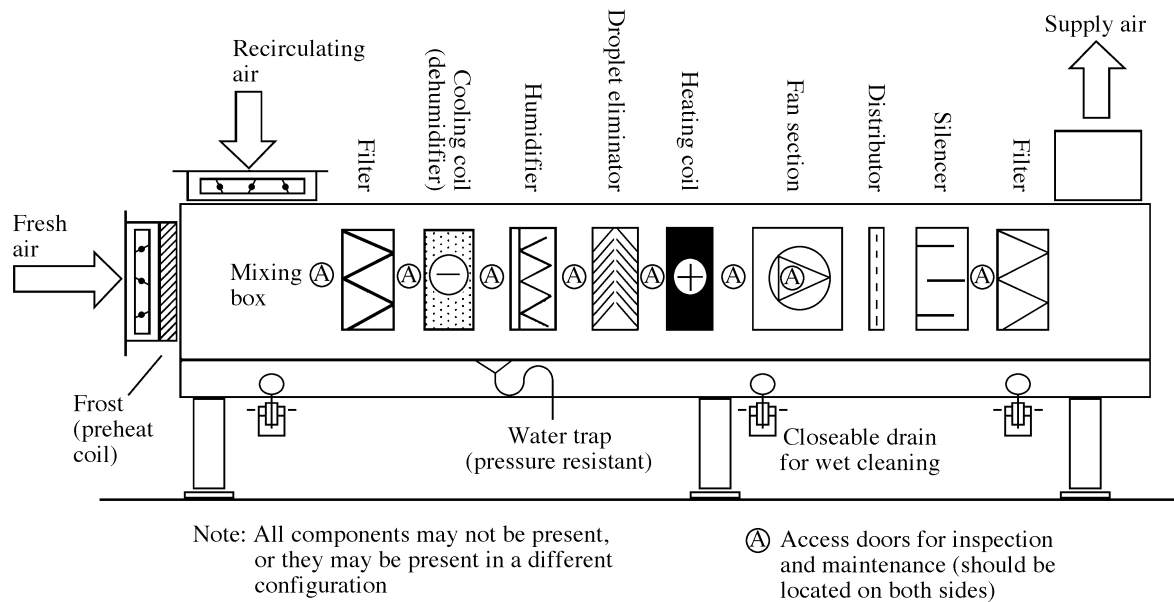


Fig. 7.2 Typical air handling unit configuration.

Table 7.3 Environmental air filter cross-reference chart

General filter type	Filter test reference and classification		Operating characteristics
Coarse dust or primary filter (arrestance of 5 micron particles)	Eurovent 4/5 average arrestance EU1 <65 EU2 65<80 EU3 80<90 EU4 >90	BS EN 779 average arrestance G1 <65 G2 65<80 G3 80<90 G4 >90	Low efficiency Low static pressure drop 1 m ² media area in typical filter unit
Fine dust or secondary filter (arrestance of 1 micron particles)	Eurovent 4/5 average efficiency % EU5 40<60 EU6 60<80 EU7 80<90 EU8 90<95 EU9 >95	BS EN 779 average efficiency % F5 40<60 F6 60<80 F7 80<90 F8 90<95 F9 >95	Medium and higher efficiencies Higher static pressure drop 6 m ² + media area in typical filter unit
Higher efficiency particulate air filter, semi HEPA and HEPA (arrestance of 0.3–0.5 micron particles)	Eurovent 4/4 minimum efficiency EU10 95<99.9 EU11 99.9<99.97 EU12 99.97<99.99 EU13 99.99<99.999	EN 1822 maximum penetration MPPS % H10 85 H11 95 H12 99.5 H13 99.95 H14 99.995	High efficiency range of filters High static pressure drop 300 mm filter unit up to 15 m ² media area
Ultra low penetration air filter, ULPA		U15 99.9995 U16 99.99995 U17 99.999995	Highest range of particulate filters High static pressure drop Various designs to suit specific applications

filters. Choice of filter requirements depends on the air quality required in the controlled space. It should be appreciated that the environmental filter will provide clean air into the controlled space but will not prevent generation of aerosols from cleaning and production operations within the area. Control of air quality needs to take into account practices within the controlled space and is not simply a question of installing a particular filter grade.

A common misconception is that a filter can be specified by simply stating the particle size that is required to be removed (e.g. 'A 2 μm filter is required'). Reference to Fig. 7.3 will show that all filter grades from G2 to EU10 will remove 2 μm particles but with different efficiencies. The same holds true for any other particle size. Filter efficiency also increases with use as the filter gradually becomes blocked. The choice of filter grade should therefore be made on the basis of the overall air quality required to be supplied to the controlled space. For a general GMP area, filter grades EU1–4/G1–G4 may be quite satisfactory; for medium care, EU5–7/F5–F7 should be adequate. 'High-care' areas, where the aim is to minimise air contamination, would require filtration to

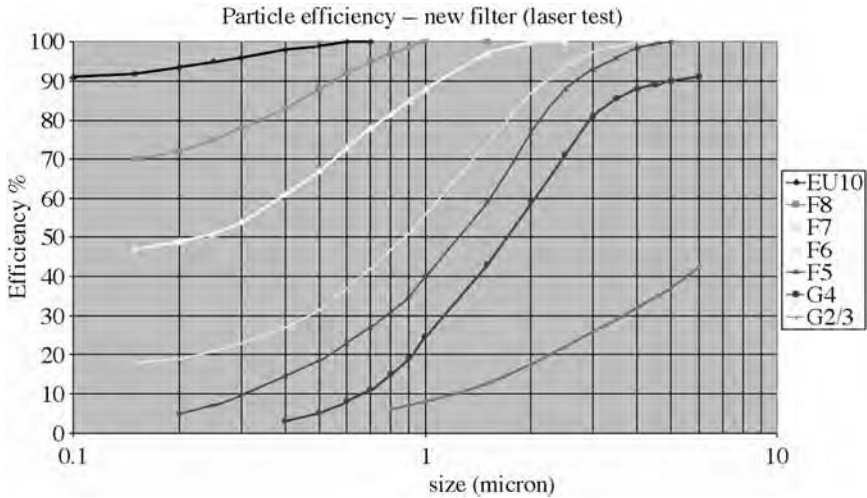


Fig. 7.3 Chart of particle efficiencies of different environmental filter grades when new (efficiency increases as filters become blocked with use).

EU7–9/F7–F9, whereas ‘high-risk’ areas that are designed to prevent recontamination would require EU10/H11. Again it is emphasised that cleaning and production practices should mirror the air quality required.

7.4.2 Control of air movement

Filtered air is supplied to the controlled space usually via grilles or textile air socks. Grille design, location and orientation have a significant effect on the direction and speed of air movement in the room. Textile sock systems provide a more diffuse and gentler air movement. Air displacement systems are also available where air is supplied at low level and is extracted at ceiling level. Older installations simply provide clean air into the controlled space, air movement within the space being uncontrolled. The problem with these installations is that airborne contamination can be picked up and spread randomly throughout the controlled space.

A better approach is to control the air movement and air quality close to the open product. This is more likely to be successful in providing clean air consistently to the zone of risk close to the open product. Various methods are available for achieving local control, including unidirectional air flow, open troughs, semi-closed and totally enclosed tunnel systems (Burfoot *et al.*, 2000). Open conveyors were fitted with chilled filtered air supplies along each side and challenged with aerosols of spores of *Bacillus subtilis* var *globigii* at a concentration of approximately 10^6 per m^3 . Settle plates were located alongside and on the conveyor and exposed for 55 min. The average colony count on the settle plates alongside the conveyor was around 500 whereas within the

protected zone along the conveyor it varied from 0 to 35. The airborne challenge level was much higher than would be expected in a typical food factory but was set at $10^6/\text{m}^3$ to give countable numbers of colonies within the protected zone. In a real factory airborne contamination of open product on conveyors could be reduced to insignificant levels.

7.4.3 Temperature and humidity control

Many high-care and high-risk production areas are chilled to maintain a low product temperature during the production process. This is necessary because it is not usually practical or economic to chill the food once it is wrapped and stacked on pallets. The Food Safety (Temperature Control) Regulations (HMSO, 1995) specify a maximum temperature of 8°C for foods that may support the growth of harmful bacteria or formation of toxins. However, the Health and Safety Executive also specify a reasonable working temperature of at least 16°C, or 13°C where work involves serious physical effort. There is therefore an apparent conflict of temperature requirements, one for food safety and the other for operator comfort. There are ways of addressing this issue as described in Brown (2000) where guidance is given on the legislation, product temperature control and risk assessment, design of air handling systems and clothing requirements for operatives.

Humidity problems in the food industry are usually caused by too much water in the air rather than too little. (Cheese maturation is an exception where humidity levels may need to be over 95%.) As air temperature rises, it can hold more moisture, but if the air is then exposed to a cold surface, condensation will occur. This could then allow microbial growth, corrosion or other moisture-related problems such as absorption of water by dry ingredients. The most common method of dehumidifying air is to pass it through a cooling coil; the water then condenses and is drained away (Brown, 1996). The cleaning and disinfection of cooling coils must be included as part of the overall plant hygiene programme.

Humidification, if required, can be done by the use of either atomising humidifiers (where a fine mist of water vapour is introduced into the air flow) or by steam injection humidifiers. Micro-organisms including *Legionella* may grow in the water used for humidifiers, so regular cleaning and maintenance are essential.

7.5 Process air control

Process air may be low, medium or high pressure depending on the application. Low-pressure process air may be used for laminar flow enclosures for fillers, air to tank headspace, fluidised beds or spray dryers. Environmental HEPA filters would normally be used for these systems. Medium-pressure air would be used where it is to come into contact with the product but not be added to it, such as in air conveying. Either cartridge or environmental filters may be used depending

on the working pressure. High-pressure process air is designed to be included in the product, for example in whipped products, or used to purge product from process systems. The 3-A Sanitary Standards divide air under pressure into low (<150 psig) and high (>150 psig) pressure systems (Anon., 1995).

Process air that is delivered directly to the food product and pneumatic equipment may be filtered using cartridge filters (Brown, 1996). The choice of filter should ensure that it is suitable for food use and is robust enough for the particular application. There is no British or European standard for comparison of filter cartridges from different manufacturers. Efficiency levels are very high in comparison to environmental air filters with removal efficiencies in excess of 99.999 999 99% when presented with a bacterial aerosol challenge.

7.6 Air disinfection systems

7.6.1 Disinfectant fogging

The purpose of fogging a production area is to reduce the numbers of airborne micro-organisms and also to apply disinfectant to surfaces that may be difficult to reach (such as overhead surfaces). Applications include freezers, chillers, ripening rooms, process lines and production areas. Manufacturers of salads, sandwiches, ready meals and dairy products frequently use some form of fogging.

There are various types of fogging systems available. They aim to disperse an aerosol of disinfectant into the air of the production area after cleardown. (Fogging must not be regarded as a replacement for traditional cleaning and disinfection routines.) Personnel are usually excluded during this procedure. Research carried out under the UK Advanced and Hygienic Manufacturing Link Programme (Burfoot *et al.*, 1999) demonstrated that fogging is effective in reducing the number of micro-organisms on upward-facing surfaces but, in general, is not effective on vertical or downward-facing surfaces. The fogging was most effective when the median diameter of the fog droplets was between 10 μm and 20 μm . Droplets in this size range dispersed well and settled within 45 minutes. The results of the study of the effectiveness of disinfectant fogging were also published by MAFF (1998) as a practical guide.

7.6.2 UV treatment

UV light can be used for air disinfection. The germicidal wavelength is approximately 254 nm. There are low-power systems with lamp ratings of 15–100 W and more powerful medium-pressure arc tubes with ratings of 0.5–5 kW. Burfoot (1999) reports the use of a UV system that could achieve kill rates over 99% in air flows up to 2 m³/s. It is important to avoid shadowing because micro-organisms in the shade will not be destroyed. The dose required for one decimal reduction varies widely between species, from 2 mW s/cm² for vulnerable bacteria like *Legionella pneumophila* to 132 mW s/cm² for *Aspergillus niger*

(Brown, 1996). High-intensity UV can cause skin cancer and cataracts of the eye. Proper screening from operatives and interlock devices are therefore an essential part of the design system.

7.6.3 Ozone

There is currently a lot of interest in the use of ozone for air disinfection. Kim and Yousef (2000) tested ozone against *Pseudomonas fluorescens*, *Escherichia coli* O157:H7, *Leuconostoc mesenteroides* and *Listeria monocytogenes*. Exposure to 2.5 ppm for 40 s produced 5–6 log decrease in numbers, with *E. coli* O157:H7 being the most resistant. Work by Taylor and Chana (2000) has indicated a 2 log reduction in both airborne and surface adhered *Pseudomonas aeruginosa* in 2 h when exposed to 2 ppm ozone. Ozone is toxic to humans and even at 0.5 ppm can cause nausea and headaches. At 50 ppm, 30 minutes exposure can be fatal. The Health and Safety Executive (HSE) Guidance Note EH 38 (HSE, 1983) recommends an exposure limit of 0.1 ppm as an 8 h weighted average and 0.3 ppm as a 15 min average for short exposure. Care should be taken to ensure that operatives are not exposed to levels of ozone above the recommended limits. Ozone disinfection is most effective at high (80–100%) relative humidity levels.

7.7 Future trends

The trend is today away from controlling whole production areas and towards local control of production lines. The reason for this has been the evidence from modelling studies of factory air movements that show that control of the whole area is complex and almost impossible (Burfoot, 2000b). There is now considerable interest in localised control techniques (Burfoot, 2000a).

Computational Fluid Dynamic (CFD) modelling has been found to be increasingly useful in solving existing problems with air movement and also in designing new factories. A Guidelines document is available from either the Silsoe Research Institute or the Campden and Chorleywood Food Research Association, entitled 'Best practice guidelines on air flows in high-care and high-risk areas' (Burfoot and Brown, 2001).

Following the work of Brown *et al.* (2002) there is likely to be more interest in the type of clothing that personnel wear in food production areas. Already clothing suppliers are providing high-care clothing following laundering. Localised air systems can be designed to minimise the risk of airborne bacteria from food production personnel landing on open product.

7.8 Sources of further information and advice

Much of the research work in the UK food industry on air movement and risk of airborne contamination has been done jointly by the Campden and Chorleywood

Food Research Association and the Silsoe Research Institute. This work has combined the microbiological expertise and modelling of air movement through a number of government LINK programmes. Other organisations that can provide information and advice include the Heating and Ventilating Contractors' Association (HVCA), the Chartered Institution of Building Services Engineers (CIBSE), the Building Research Establishment (BRE) and the Building Services Research and Information Association (BSRIA). Safety is covered by the Health and Safety Executive. In addition there are a number of heating and ventilation companies who have been associated with the LINK projects, including ABB Climate Systems and Filtration Engineering who have considerable experience of food factory requirements.

One of the key reference books on airborne micro-organisms is the *Bioaerosols Handbook* (Cox and Wathes, 1995). The key food industry guide is Guideline No. 12 of the Campden and Chorleywood Food Research Association, 'Guidelines on air quality standards for the food industry' (Brown, 1996).

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8

Hygienic equipment design

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8.1 Introduction: key criteria in hygienic design

The purpose of hygienic equipment design is to (Shapton and Shapton, 1991):

- give maximum protection to the product
- provide product contact surfaces necessary for processing which will not contaminate the product and are readily cleanable
- provide junctures which minimise 'dead' areas where chemical or microbial contamination may occur
- give access for cleaning, maintenance and inspection.

Food contact areas include all surfaces that are directly exposed to the product and all indirect surfaces from which splashed product, condensate, liquid or dust may drain, drop or be drawn into the product (Shapton and Shapton, 1991). This means that, in the hygienic design of equipment for open processing, the area above the product processing surface must also be taken into consideration.

8.1.1 Safety

Good hygienic design prevents the contamination of the product with substances that would adversely affect the health of the consumer (Holah, 2002). Such contamination might be microbiological (e.g. pathogens), chemical (e.g. lubricating fluids, cleaning chemicals) and physical (e.g. glass). There have been many examples of product recalls, lost production and even site closure due to contamination arising from poorly designed equipment. Physical foreign body contaminants, such as pieces of plastic, affect the wholesomeness of food but rarely receive media attention. Physical contaminants of a more serious

nature, e.g. glass fragments or caustic CIP fluids, however, are much more serious. Perhaps of most concern are pathogenic microorganisms such as *Listeria* or *Escherichia coli* O157:H7, which may be harboured in equipment and then subsequently grow during production and contaminate the product. Under favourable conditions such microorganisms grow very rapidly. Consequently gaps and crevices, where microorganisms can harbour and multiply, must be avoided (Lelieveld, 2000). Good hygienic design also maintains product in the main product flow. This ensures that product is not 'held-up' within the equipment where it could deteriorate, affect product quality on rejoining the main product flow, and encourage the growth of spoilage and pathogenic bacteria (Wirtanen, 1995).

8.1.2 Cleaning

Cleanliness is clearly essential in preventing contamination. If product residues accumulate, microorganisms can multiply rapidly. Equipment which is difficult to clean will also need more frequent cleaning, more aggressive chemicals and longer cleaning and decontamination cycles (Hauser *et al.*, 1989). The result will be higher cost, reduced availability for production, reduced lifetime of the equipment, and more effluent. To be cleaned effectively, surfaces must be smooth and free from crevices, sharp corners, protrusions, and 'shadow' zones, not only when new but during the lifetime of the equipment (Holah, 2000; Timperley *et al.*, 1993).

8.1.3 Inspection

Irrespective of the quality of hygienic design, experience has shown that inspection, testing and validation of the resulting design are very important in checking whether hygienic requirements have been met (Holah, 2002). In some cases it may be necessary to check cleanliness as part of maintenance procedures. The equipment designer has to make sure that relevant areas are accessible for inspection and/or validation (Venema-Keur *et al.*, 1997).

8.1.4 Compatibility with processing function

A design with excellent hygienic characteristics but unable to perform its functional duties is of no use, and a designer may have to compromise (Lelieveld, 2000). Any compromise between hygienic design and processing function will, however, have to be compensated by more intensive cleaning and decontamination procedures. It must therefore be documented so that users of the equipment are aware of the nature of the compromise. Where an acceptable compromise cannot be reached, hygienic requirements must prevail even if this reduces the potential processing efficiency of the equipment. However, good hygienic design reduces the time required for an item of equipment to be cleaned. This reduction of cleaning time is significant over the lifetime of the

equipment. Hygienically designed equipment which is initially more expensive (compared to similarly performing poorly designed equipment) will be more cost-effective in the long term. In addition, savings in cleaning time may lead to increased production. Upgrading existing designs to meet hygienic requirements can be prohibitively expensive and may be unsuccessful. Ideally hygienic requirements should be taken into account at the design stage. Complying with hygienic requirements may increase the life expectancy of equipment, reduce maintenance and consequently lead to lower manufacturing costs.

8.2 Risk assessment in equipment design

Food processing equipment is designed and built to be suitable for purpose. In practice, this means different levels of hygienic design for differing pieces of equipment (Holah, 2000). As an example, a mixer for raw meat need not be designed to the same hygienic level as a slicer of cooked meats (Timperley and Timperley, 1993). Similarly, aseptic fillers have usually been designed to a much higher hygiene standard than can filling machines. This difference in standards of hygienic design is related to the risk of a hazard being transferred from the equipment to the product produced and thus the consumer (Lelieveld, 1994).

The degree of risk from eating foodstuffs is dependent to a large extent on how that product has been processed, its degree of preservation and what further cooking steps (if any) the consumer has to perform prior to consumption. As an example, a stable preserved product e.g. canned or dried goods, or one which requires thorough cooking prior to consumption, is less likely to confer a microbiological risk than a ready-to-eat chilled food (Brown, 2002). All of the above food products may, however, convey similar risks in terms of non-microbiological hazards, i.e. physical hazards (e.g. glass, plastic) or chemical hazards (e.g. lubricating fluids, cleaning chemicals, pesticides). In deciding hygienic requirements, the designer and manufacturer of food processing equipment needs to:

- identify the process for which the machine is intended
- identify the relevant hazards associated with the products produced
- design methods/measures which can eliminate hazards or reduce their risk
- identify any other hazards introduced by the methods used to reduce the hazard under analysis
- verify the effectiveness of the hazard elimination or risk reduction
- describe any residual risks and any additional precautions necessary for the machine's safe use.

To help equipment manufacturers meet this challenge, and thus both control the risk of transfer of a hazard to a food product during manufacture and produce the equipment in a cost-effective manner, food manufacturers should enter a dialogue with equipment manufacturers to consider the following:

- **The intended use of the equipment.** Will the equipment be used for one specific purpose only, for which the hazards are readily identifiable, or could the machine be used for a wide range of products in many industries (e.g. a pump)?
- **The product type to be processed.** Will the product be already contaminated (e.g. a raw material) or will it be 'preserved' or 'aseptic'?
- **The degree of further product processing.** Will the product processed by the equipment subsequently undergo a further process which functions as a hazard elimination step (e.g. a heat treatment) or is the process for which the machine is intended the final process?
- **The degree of cleaning and/or inspection.** Is the equipment to be cleaned and/or inspected after every use, routinely during the day, every day or every week, for example?
- **The use of the machine.** Is the equipment likely to be well maintained or used infrequently? Is it designed for high or continuous use? Is it liable to abuse?

After a risk assessment has been made, it is possible to assign the suitability of an item of equipment to one of several categories for intended use (Holah, 2000). These can be described as follows:

1. Equipment that satisfies the minimum requirements to make it safe for its intended purpose. This may involve the control of single hazards, e.g. the equipment contains no glass.
2. Equipment that satisfies all the current best-practice hygienic design criteria and is thus fit for the production of most foods, though it needs to be dismantled prior to cleaning.
3. Equipment that satisfies all the current best-practice hygienic design criteria and can be cleaned without dismantling.
4. Equipment that satisfies all the current best-practice hygienic design criteria and is designed for a specific heat or chemical decontamination treatment.
5. Equipment that satisfies all the current best-practice hygienic design criteria, is also designed for a specific heat or chemical decontamination treatment and will prevent ingress of microorganisms. Such equipment would be suitable, for example, for the production of aseptic foods.

Whilst it is acceptable (though not necessarily cost-effective) to use equipment designed for a higher hygienic requirement for a lower risk product, it is unlikely to be acceptable to use equipment designed for a lower risk category or food products for higher risk or aseptic products.

8.3 Regulatory requirements for hygienic equipment design: the EU

In the EC, the Council Directive *on the approximation of the laws of Member States relating to machinery* (89/392/EEC) was published on 14 June 1989. The

Directive includes a short section dealing with hygiene and design requirements which states that machinery intended for the preparation and processing of foods must be designed and constructed so as to avoid health risks. It consists of seven hygiene rules that must be observed. These are concerned with the following:

- Materials in contact with food
- Surface smoothness
- Preference for welding or continuous bonding rather than fastenings
- Design for cleanability and disinfection
- Good surface drainage
- Prevention of dead spaces which cannot be cleaned
- Design to prevent product contamination by ancillary substances, e.g. lubricants.

The Directive requires that all machinery sold within the EC shall meet these basic standards and be marked accordingly to show compliance (the 'CE' mark).

Subsequent to this Directive, a European Standard EN 1672-2, *Food processing machinery – Safety and hygiene requirements – Basic concepts – Part 2: Hygiene requirements* (Anon., 1997), has been adopted to further clarify the hygiene rules established in 89/392/EEC (Holah, 1998). In addition to this, a number of specific standards on bakery, meat, catering, edible oils, vending and dispensing, pasta, bulk milk coolers, cereal processing and dairy equipment are in preparation (Holah, 2000). The basic hygienic design requirements as presented in EN 1672-2 can be summarised under 11 headings and are described below:

1. **Construction materials.** Materials used for product contact must have adequate strength over a wide temperature range, a reasonable life, be non-tainting, corrosion and abrasion resistant, easily cleaned and capable of being shaped. Stainless steel usually meets all these requirements. There are various grades of stainless steel which can be selected for their particular properties to meet differing operational requirements, e.g. Type 316 which contains molybdenum and is used where improved corrosion resistance is necessary.
2. **Surface finish.** Product contact surfaces must be finished to a degree of surface roughness that is smooth enough to enable them to be easily cleaned. Rougher surfaces will deteriorate more rapidly with age and wear (abrasion), making cleaning more difficult.
3. **Joints.** Permanent joints, such as those which are welded, should be smooth and continuous. Dismountable joints, such as screwed pipe couplings, must be crevice-free and provide a smooth continuous surface on the product side. Flanged joints must be sealed with a gasket because, although metal/metal joints can be made leaktight, they may still permit the ingress of microorganisms.
4. **Fasteners.** Exposed screw threads, nuts, bolts, screws and rivets must be avoided wherever possible in product contact areas. Alternative methods of

fastening can be used where the washer used has a rubber compressible insert to form a bacteria-tight seal.

5. **Drainage.** All pipelines and equipment surfaces should be self-draining because residual liquids can lead to microbial growth or, in the case of cleaning fluids, result in contamination of product.
6. **Internal angles and corners.** These should be well radiused, wherever possible, to facilitate cleaning.
7. **Dead spaces.** As well as ensuring that there are no dead spaces in the design of equipment, care must be taken that they are not introduced during installation.
8. **Bearings and shaft seals.** Bearings should, wherever possible, be mounted outside the product area to avoid possible contamination of product by lubricants (unless they are edible), or to avoid possible failure of the bearings due to the ingress of the product. Shaft seals must be designed to be easily cleaned. If they are not lubricated by the product itself, then the lubricant used must be edible. Where a bearing is within the product area, such as a foot bearing for an agitator shaft in a vessel, it is important that there is a groove completely through the bore of the bush, from top to bottom to permit the passage of cleaning fluid.
9. **Instrumentation.** Instruments must be constructed from appropriate materials. If they contain a transmitting fluid, such as in a bourdon tube pressure gauge, the fluid must be approved for food contact. Many instruments themselves are hygienic but often they are installed unhygienically.
10. **Doors, covers and panels.** Doors, covers and panels should be designed so that they prevent the entry of and/or prevent the accumulation of soil. Where appropriate they should be sloped to an outside edge and should be easily removed to facilitate cleaning.
11. **Controls.** These should be designed to prevent the ingress of contamination and should be easily cleanable, particularly those that are repeatedly touched by food handlers to allow process operation.

8.4 Drainability

All pipelines and equipment surfaces should be self-draining, because residual liquids can lead to microbial growth or, in the case of cleaning fluids, result in contamination of product (Anon., 1983). Care should be undertaken with the installation of equipment so that its drainability is not impaired. Sharp corners must be avoided to ensure good drainability and cleanability. Corners must also be properly radiused. Surfaces and pipes should not be completely horizontal but slope towards drain points and there should be no ridges which may hamper draining (Anon., 1980). Horizontal surfaces must have a slope of more than 3 towards the outlet. In the case of external surfaces, sloping should result in any liquid flowing away from the main product area (Curiel *et al.*, 1995).

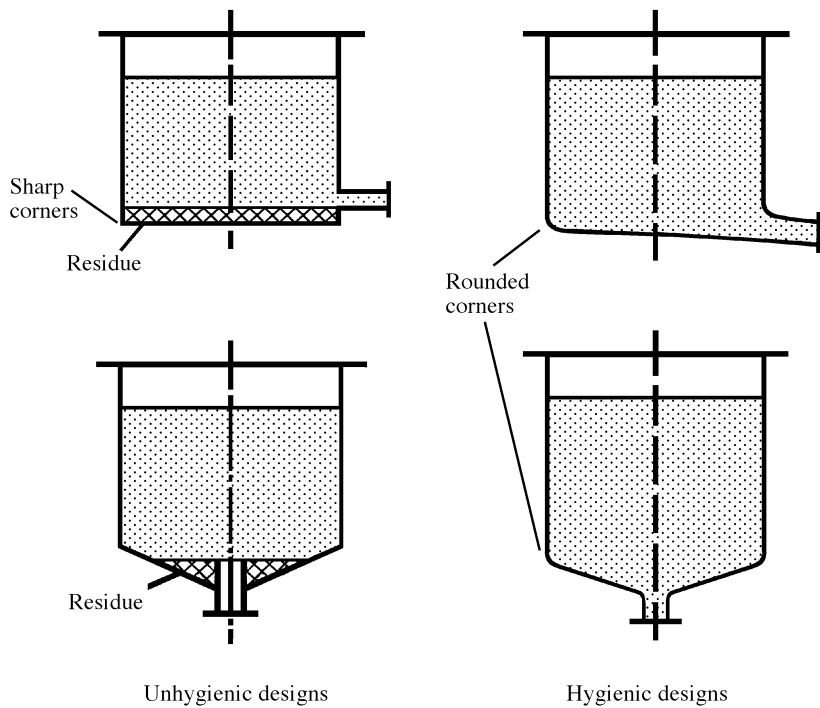


Fig. 8.1 Self-draining container designs.

Food-containing equipment (tanks, containers, vessels, troughs, reservoirs, hoppers, bins, chutes) with discharge openings must also be fully self-drainable. Figure 8.1 illustrates self-drainable designs with discharge openings at the lowest level, sloped bottoms ($\geq 3^\circ$) and well-rounded corners. Equipment which can be tipped for discharging must also have well-rounded corners and be fully drainable and easily cleanable (Fig. 8.2).

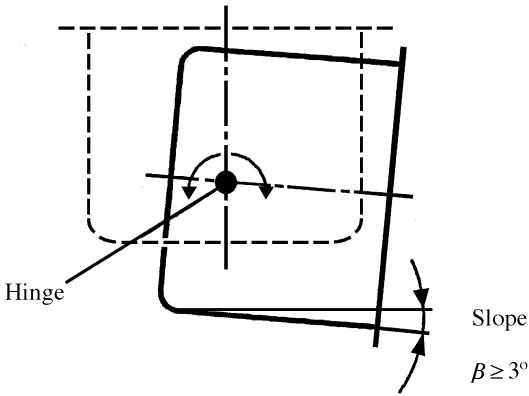


Fig. 8.2 Hygienic design of tipping containers.

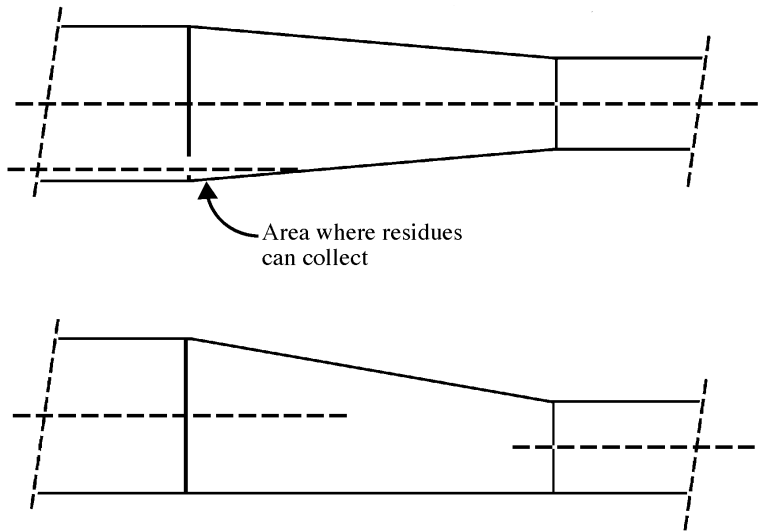


Fig 8.3 Hygienic connection of pipes of different diameters: the upper design hampers draining; the lower design facilitates draining.

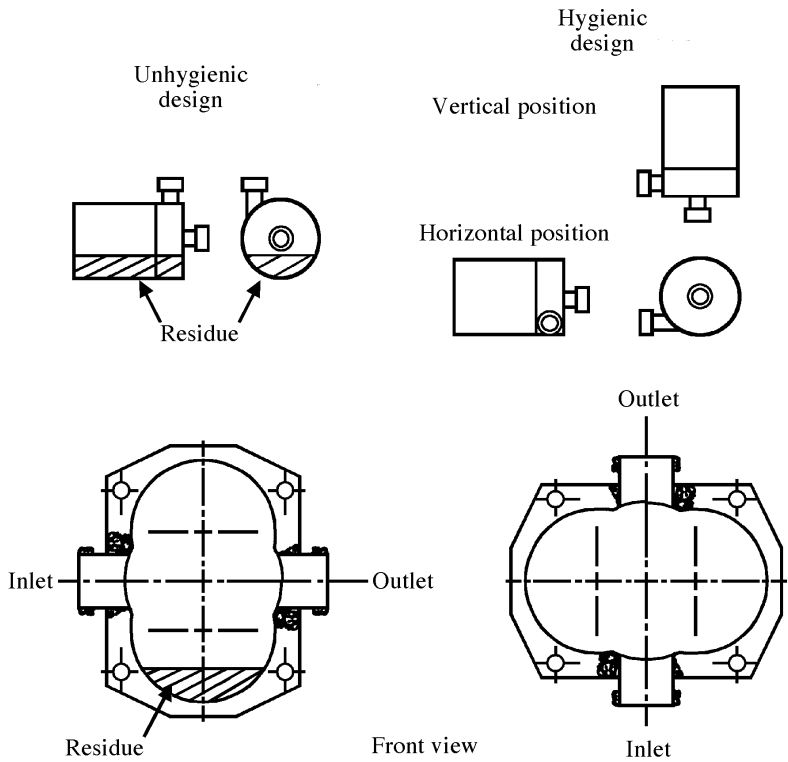


Fig. 8.4 Hygienic and unhygienic design of centrifugal (top) and lobe (bottom) pumps.

Care must be taken that any closed process line can be fully drained. Piping should slope 3° towards draining points. Even smooth constructions may hamper draining. This is illustrated in Fig. 8.3, which shows the connection between pipes of different diameters (Curiel *et al.*, 1993b). Although for vertical piping a concentric reducer is fully acceptable, this is not so for horizontal piping, where it would affect drainability. For horizontal piping an eccentric reducer must be used. Self-evidently, reducers should be long enough to avoid shadow zones. Some types of pumps are traditionally positioned in such a way that draining is impossible without dismantling. The same type of pumps can also be designed for positioning in a drainable position (Fig. 8.4).

Where it is not possible to build equipment in such a way that proper draining is possible, procedures must be designed to ensure that residues of cleaning and disinfection liquids can be removed in another way. The method used should be well documented with clear instructions.

8.5 Materials of construction

Materials used for product contact must:

- have adequate strength over a wide temperature range
- be durable and have a reasonable life
- be non-toxic, non-tainting and non-absorbent
- be resistant to cracking, chipping, flaking corrosion and abrasion
- prevent penetration of unwanted matter under intended use
- be easily cleaned and capable of being shaped (Curiel *et al.*, 1993a).

Stainless steel usually meets all these requirements. There are various grades of stainless steel which can be selected for their particular properties to meet operation requirements, for example Type 316 which contains molybdenum and can be used where improved corrosion resistance is necessary. It is important to avoid direct metal-to-metal joints other than by welding since metal-to-metal contact may harbour soil and microorganisms. In the case of equipment intended for aseptic processing, metal-to-metal seals will not prevent the ingress of bacteria. Elastomers and other polymers should retain their surface and conformational characteristics when exposed to the conditions encountered in production, cleaning and decontamination.

Materials for non-food-contact surfaces must be easily cleanable and resistant to the product and to cleaning and disinfecting agents. As with product contact surfaces, stainless steel is to be preferred. If components are coated (e.g. motors, drives, casings) the coating must be non-toxic and resistant to cracking, chipping or flaking. Coated components should not be positioned directly above open product areas. Insulation must be vapour tight to avoid growth of microorganisms. Materials of construction are dealt with in detail in Chapter 11.

8.6 Surface finish

All surfaces in contact with foodstuffs must be easily cleanable (Holah and Thorpe, 1990). Surfaces must therefore be smooth, continuous and free from cracks, crevices, scratches and pits which can harbour and retain soil and/or microorganisms after cleaning. Although good cleanability is the key requirement for surfaces rather than smoothness, a maximum roughness is specified for food contact surfaces since cleaning time required increases with surface roughness. Both the American 3-A organisation and the European Hygienic Equipment Design Group (EHEDG) specify a maximum roughness for food contact surfaces (3-A Sanitary Standards Committee, 1995; Curiel *et al.*, 1993a). Product contact surfaces should have a finish of an acceptable R_a value and be free of imperfections such as pits, folds and crevices (for definition of R_a , see ISO, 1982). For large surface areas product contact surfaces should have a surface finish of $0.8 \mu\text{m } R_a$ or better (Curiel *et al.*, 1993a). A roughness of $>0.8 \mu\text{m}$ may be acceptable if test results have shown that the required cleanability is achieved because of other design features. For closed equipment (that used for liquid handling and usually cleaned-in-place (CIP)) a surface finish of $0.8 \mu\text{m } R_a$ is recommended, with higher R_a values being acceptable if they can be shown to be cleanable. It should be noted that cold rolled steel has a roughness of $R_a = 0.2$ to $0.5 \mu\text{m}$ and therefore usually does not need to be polished to meet surface roughness requirements, provided the product contact surfaces are free from pits, folds and crevices when in the final fabricated form. However, grinding is required for hot-rolled steel unless there are special requirements regarding the process involved. As the surface roughness of cast materials and carbon steels does not meet the recommended figure, the cleanability of the components made with these materials will require further investigation. Non-product contact surfaces must also be smooth enough to ensure that cleaning is easy. Porous surfaces are usually unacceptable.

Table 8.1 shows the surface roughness achieved by differing surface treatments of stainless steel. It is important to measure whether the intended surface roughness has been achieved. Measuring instruments are readily available and, for surfaces that cannot be reached by such an instrument, surface replicas can be made for indirect measurement.

8.7 Corners, crevices and dead spaces

Corners should be well rounded or radiused, wherever possible, to facilitate cleaning (Anon., 1983). Corners should preferably have a radius equal to or larger than 6 mm with a minimum radius of 3 mm. Sharp corners ($<90^\circ$) must be avoided. Possible exceptions are equipment where the sharp corner is continually swept, such as lobe pumps. If sharp corners cannot be avoided or, for technical reasons, the radius of a corner must be smaller than 3 mm, the design must be such that the loss of cleanability is compensated. If used as a

Table 8.1 Examples of surface treatments of stainless steel and resulting surface roughnesses

Treatment	R_a in μm
Cold-rolled stainless steel	0.2–0.5
Hot-rolled stainless steel	>4
Glass bead blasting (depending on bead size)	1.0–1.2
Descaling	0.6–1.3
Bright-annealing	0.4–1.2
Pickling	0.5–1.0
Electropolishing	Electropolishing does little to improve R_a value, but does round off peaks, improving cleanability
Mechanical polishing with aluminium oxide or silicon carbide, abrasive grit number:	
500	0.1–0.25
320	0.15–0.4
240	0.2–0.5
180	≤ 0.6
120	≤ 1.1
60	≤ 3.5

sealing point, corners (larger than 180°) must be sharp to form a tight seal at the point closest to the product/gasket interface. Edges must be deburred. Figure 8.5 shows how to weld without sharp corners.

Crevices should be avoided since they cannot be cleaned. They retain product residues, which may effectively protect microorganisms against inactivation. In most cases, crevices are the result of poor equipment design. When parts of equipment must be mounted together, metal-to-metal contacts (other than welds) must be avoided as they leave very narrow and deep crevices. Elastomers should be used between metal components. The elastomeric material must be mounted in such a way that the seal is at the product side and that, to prevent destruction of the elastomer, excessive compression is prevented. This can be achieved by including design features which align the surfaces of the various parts and

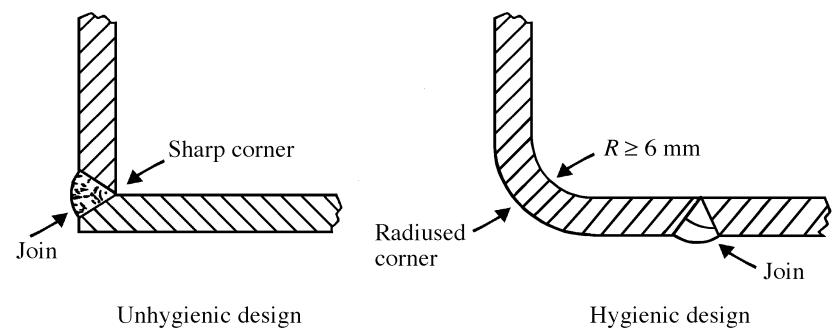


Fig. 8.5 Hygienic and unhygienic welding: corners.

provide a metal stop (Curiel *et al.*, 1993b; 1995). Care must be taken in the use of o-rings since these can also create crevices (Baumbach *et al.*, 1997). Seals are discussed in more detail later in this chapter.

In some cases crevices are unavoidable. This may be the case if slide bearings are needed in contact with product (e.g. as bottom bearings or top-driven stirrers and as bearings in scraped surface heat exchangers). Their presence should be taken into account when writing procedures for cleaning and disinfection. These procedures may need instruction for partial or total dismantling of equipment for cleaning and specific procedures for cleaning and reassembling component parts.

Dead spaces and shadow zones are areas outside the main product flow (Curiel *et al.*, 1993b). Typical examples are T-sections in pipes used, for example, to mount sensors such as pressure gauges. An example is shown in Fig. 8.6. The decrease in product flow velocity relative to the depth of the T-section is also shown in Fig. 8.6. In this example, where the length of the T-section is equivalent to the diameter of the main pipe, a flow velocity of 2 m/s in the main pipe results in a velocity of 0.3 m/s in the T-section. This decrease in flow velocity provides a relatively stable pocket or 'dead leg' in which product residues can accumulate and microorganisms begin to multiply. During cleaning there is much less transfer of energy to the food residues (soil) in zones which are outside the main flow of cleaning liquids than to the soil in the main flow. Such areas are difficult to clean and therefore should be avoided. Effective cleaning requires a velocity of cleaning liquid of 1.5 m/s (Timperley, 1981).

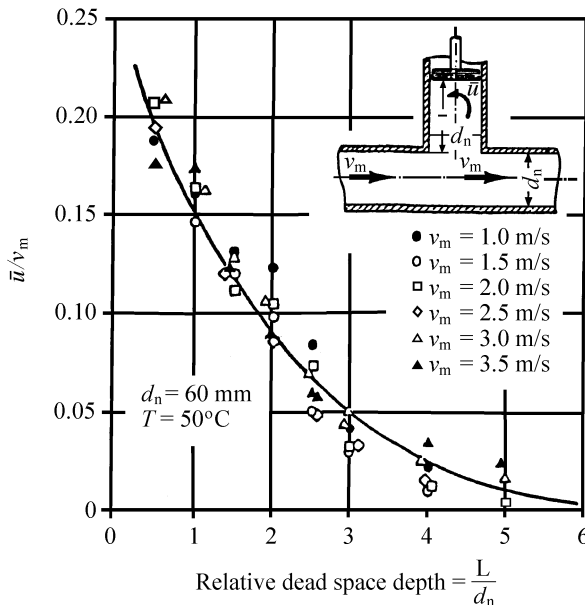


Fig. 8.6 Fluid motion in a dead space: decrease in product flow velocity relative to the depth of a T-section.

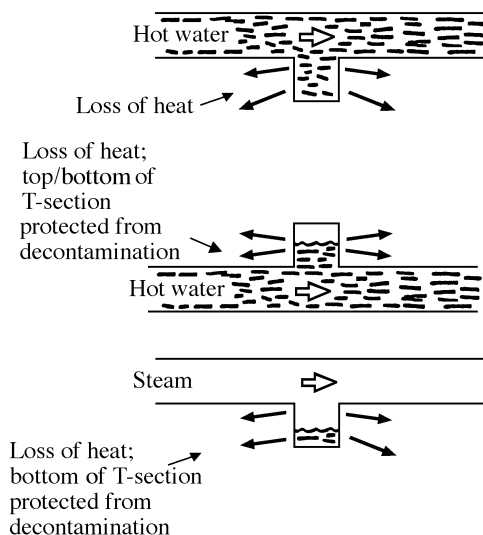


Fig. 8.7 Impact of T-sections on decontamination by hot water or steam.

Lower velocities may dramatically increase the time required for cleaning. If hot water is used to pasteurise a process line, an upward pointing leg of a T-section will trap air, thereby reducing the rate of heat transfer and causing the decontamination of the dead leg – and what is connected to it – to fail. If a process line is sterilised with steam, an upward pointing dead leg, if clean and not too long, will probably be decontaminated properly, as steam will condense on the surfaces of the leg and fall down to let more steam to condense and give off its energy. With steam sterilisation, downward pointing legs give problems. Here condensation will be collected in the leg and hamper heat transfer. The temperature will be too low for complete sterilisation (unless the presence of the leg has been taken into account in defining sterilisation procedures). A downward pointing T-section may also compromise sterilisation by hot water since the temperatures of the surfaces in the dead area, which will be outside the main flow of hot water, may be too low. The impact of T-sections on decontamination is shown in Fig. 8.7. A properly designed food processing line therefore should not have unnecessary dead legs. Those which are unavoidable should be in the correct position for the selected decontamination treatment. If unavoidable, their presence should be taken into account when devising cleaning procedures. Duration and temperature of treatment must be clearly described in operation procedures (Curiel *et al.*, 1993b).

If a T-section is unavoidable, it must be as short as possible (Anon., 1973). For pipe diameters of 25 mm or longer it should have a depth of preferably under 28 mm (see Fig. 8.8). For smaller pipe diameters the length should be smaller than the diameter. For most liquids, the dead leg should be positioned as shown in Fig. 8.9(a). This configuration may not be suitable, however, if products contain any particulate matter, which may accumulate in the dead leg.

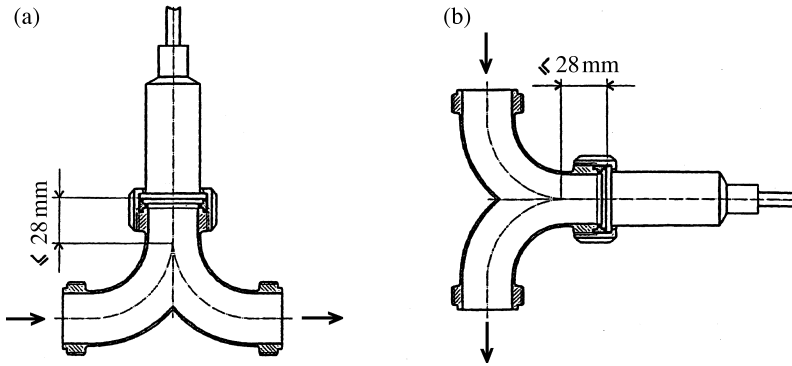


Fig. 8.8 Optimal depth of T-sections relative to pipe diameter.

Configurations (b) and (c) may be acceptable if the dead leg is very short. In all cases, the cleaning procedure must take the presence of the dead leg into account. The direction of the flow of product has a significant influence on the residence time in the dead leg and therefore should be as indicated. If T-sections are necessary, short right-angle tees or so-called swept tees (Fig. 8.8) may be used. Swept tees must be used with caution, however, as in horizontal pipelines (Fig. 8.8(a)) a swept tee could hamper draining. They are best mounted in a vertical pipeline as in Fig. 8.8(b).

Flow diversion should not be done in a way that would cause part of the product to stand still in a dead leg (Fig. 8.10). The two-valve system for flow diversion (Fig. 8.10(a)) creates a dead leg towards the closed valve. The correct type of valve is shown in Fig. 8.10(b). Dead areas are also created where product pumps are equipped with a pressure relief valve or with a bypass in case the pumps have insufficient capacity for circulating the cleaning liquid at the required velocity (Fig. 8.11). During production in configuration (a) product is

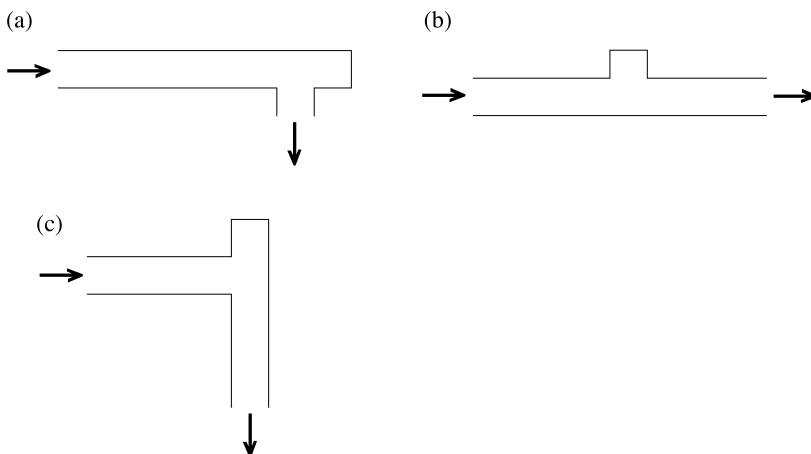


Fig. 8.9 Optimal positioning of dead legs.

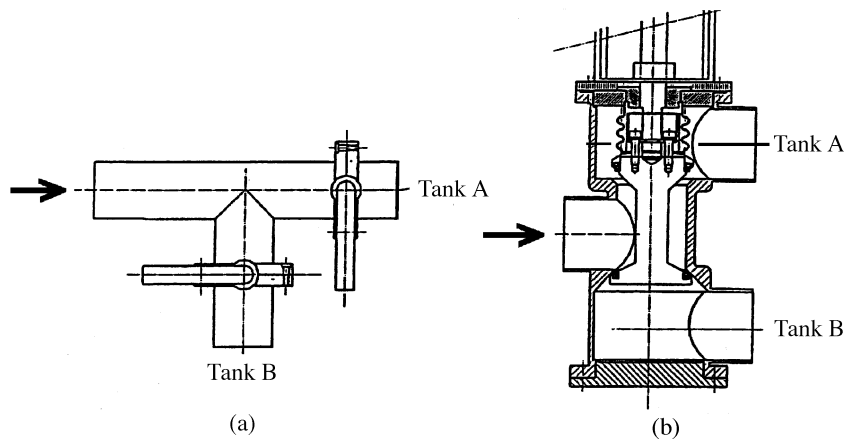


Fig. 8.10 Hygienic product flow diversion.

entrapped in two large-volume dead legs when the valve is closed. Such product may spoil and infect the passing product. In open position, the valve provides a bypass to relieve pressure or to allow a higher flow rate of cleaning fluid through the process line than the pump would allow. Note that in such cases the pump and the piping between pump and valve may need a longer time for cleaning. The pump on the left is also shown in a position that does not allow draining. With the same valve it is also possible to construct a dead leg free bypass as in Fig. 8.11(b).

8.8 Welds and joints

Joints should be avoided where possible. Bending of pipes is preferable to the use of prefabricated bends with couplings. If pipe bending is not possible, welding is preferred, provided that the welding is done correctly to ensure a smooth and continuous weld (Eastwood *et al.*, 1993). It is better to use permanent joints rather than dismantable joints to reduce the hygienic risks caused by projections, protrusions, edges, recesses, metal-to-metal contact

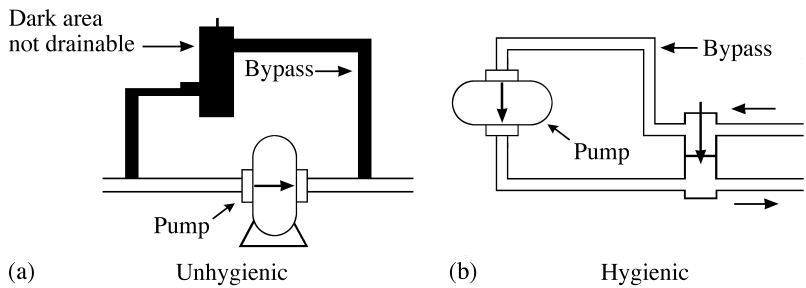


Fig. 8.11 Hygienic positioning of pumps.

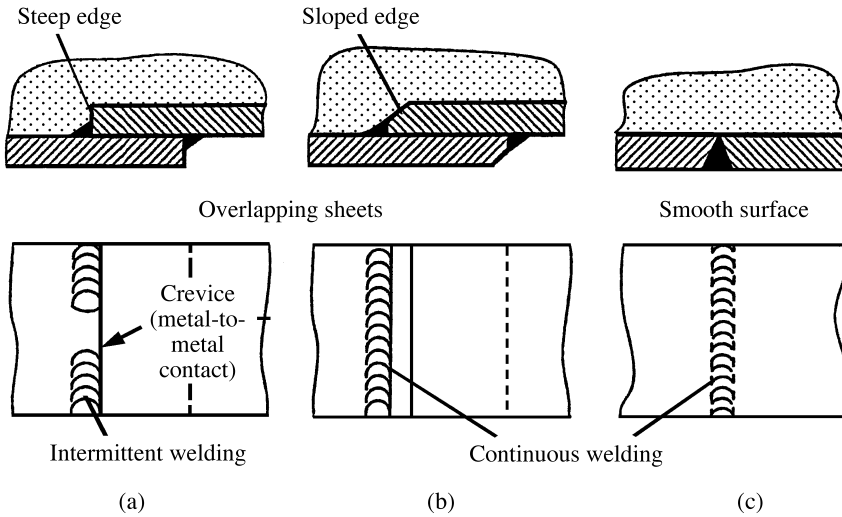


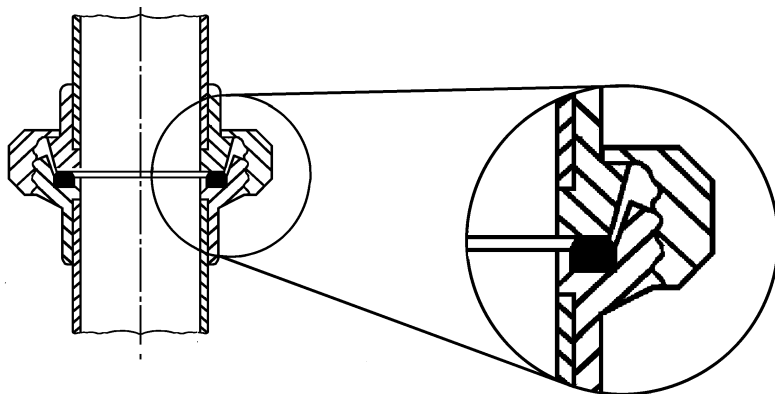
Fig. 8.12 Hygienic welding: joining plates.

and crevices in sealing gaskets (Curiel *et al.*, 1995). Permanent joints, such as those that are welded or bonded, should be smooth and continuous and free from recesses, gaps or crevices. They should preferably be welded. There are several types of common defects arising in welded joints (e.g. misalignment, cracking, porosity, inclusions) which can act as a source of microbiological problems. To avoid these problems, the product contact surface of welds must be smooth (ground flush with the surrounding surface). To avoid crevices through metal-to-metal contact, the welded seams must not be intermittent but continuous (Fig. 8.12). Overlapped welded joints should not be used since they retain soil and form 'dead' or 'shadow' areas at the overlap edge which are difficult to clean. If overlapping is unavoidable, it will be necessary to develop well-documented and adequate procedures for draining and cleaning these shadow areas. The welded seams should be ground flush and smooth. In the case of thick sheets the edge of the upper plate must be sloped. If necessary, edges must be ground. Figure 8.12(a) illustrates the problem with overlapping sheets, particularly if they are combined with an intermittent rather than continuous weld seam. Figure 8.12(b) shows an improved design with a sloped edge which is less likely to harbour residues and is easier to clean. Figure 8.12(c) shows an ideal design with smooth, continuously welded sheets. Welding in sharp corners of equipment must be avoided. Radiused corners (sloped sides) and welding seams away from corners are recommended (Fig. 8.5).

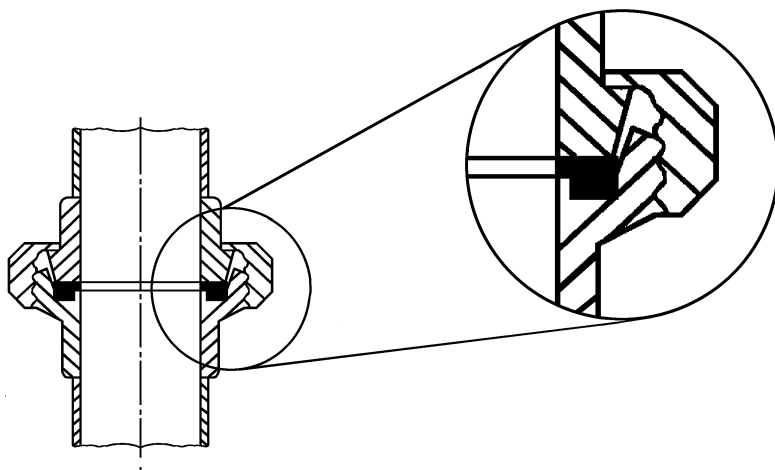
If adhesives are used for permanent joints they must be compatible with materials, products and cleaning/disinfecting agents with which they are in contact. All bonds should be continuous and mechanically sound so that the adhesives do not separate from the base materials to which they are bonded.

Metal-to-metal joints (other than welds) seal as a result of the deformation of the contacting metal surfaces. This causes permanent damage to these surfaces, making it more difficult to obtain a tight seal after every disconnection. Even when these joints are not visibly leaking, the ingress of microorganisms is possible. The seal obtained is also very unlikely to be at the product side and is more likely to follow an irregular line between the inside and outside. The resulting annular crevice will trap product and create a hygiene risk. Metal-to-metal joints should therefore be avoided.

Dismountable joints (e.g. of plates or appendages) fixed by fasteners (e.g. screws or bolts) must only be used if dismantling is unavoidable. Where detachable joints are necessary, they should be sealed by elastomers (Baumbach



Unhygienic design

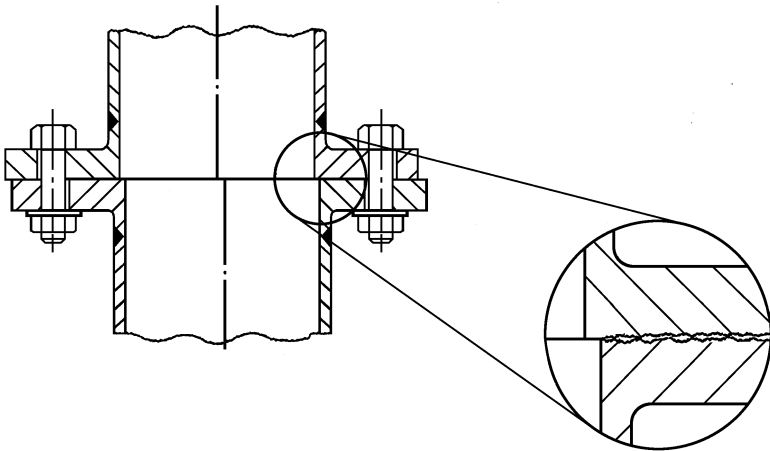


Hygienic design

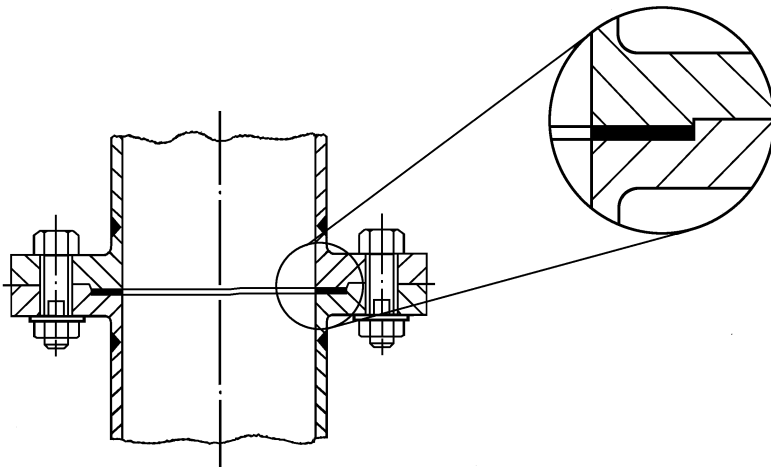
Fig. 8.13 Hygienic and unhygienic screwed pipe couplings (DIN 11851).

et al., 1997). Dismountable joints, such as screwed pipe couplings, must be crevice-free and provide a smooth continuous surface on the product side (Fig. 8.13). Flanged joints must be located with each other and be sealed with a gasket because, although metal-to-metal joints can be made leaktight, they may still permit the ingress of microorganisms (Fig. 8.14).

The sealing of metal-to-metal contact surfaces requires particular care. Figure 8.15 illustrates the problem of using overlapped screw joints. Screws or nuts are



Unhygienic design



Hygienic design

Fig. 8.14 Hygienic and unhygienic flanged joints in pipe couplings.

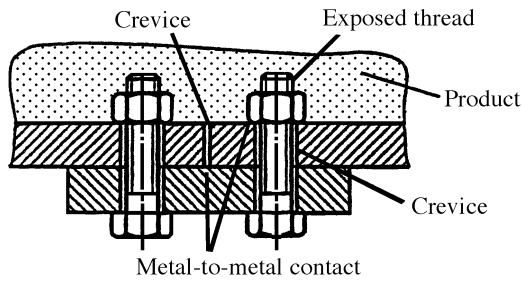


Fig. 8.15 Poor design of joints.

unable to provide sufficient compression to prevent crevices between sheet edges. Moreover, exposed screw heads and unsealed threads create additional hygiene hazards. An improved design is shown in Fig. 8.16 where the combined use of crews and pins provides improved compression and the two edges are properly sealed. In addition, screw and pin joints on the reverse side to the product remove the extra hazards shown in Fig. 8.15. However, the design of grooves for seals needs to allow space for the expansion of the seal into the product area during heating. A further improved design is shown in Fig. 8.17 using flanged sheets for controlled compression and allowing space for heat expansion. Seals are discussed in more detail later in the chapter.

The welding of permanent joints should be done by trained and experienced welders following the appropriate guidelines (Eastwood *et al.*, 1993). Not all

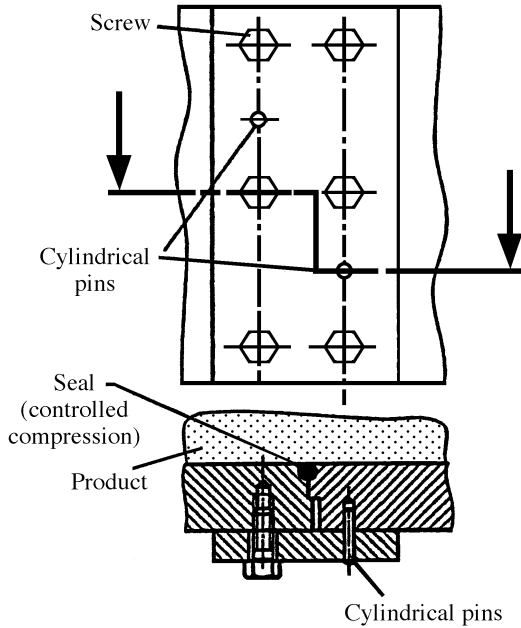


Fig. 8.16 Improved design of joints.

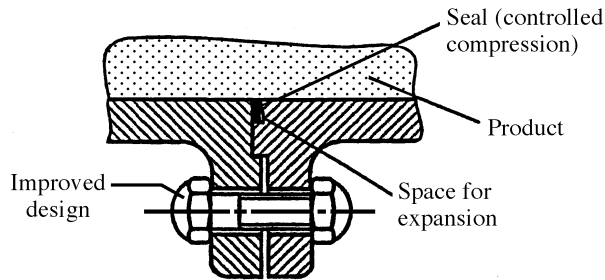


Fig. 8.17 Further improved design of joints.

welding techniques can produce welds of a sufficient standard. Tungsten-inert-gas (TIG) welding should be used. To obtain a good weld, materials must match (in composition *and* in dimensions). During welding the materials must be fully protected by inert gas and the welding temperature must be correct. Otherwise, welds which may seem correct when fresh and polished will corrode rapidly in use. The preferred method for pipework is automatic orbital welding. If properly programmed, an orbital welding machine is capable of producing consistently high quality welds.

8.9 Fasteners

One of the most usual failures of sanitary design is the use of unsuitable fastenings such as nuts, bolts and screws (Curiel *et al.*, 1995). Where possible on the product side welding must be used following the guidelines for hygienic welds. An acceptable alternative might be the use of adhesives. If adhesives are used, care must be taken to ensure that the seal obtained is reliable and can withstand process and cleaning conditions. Self-evidently the adhesive must be approved for food contact applications.

Fasteners present two problems. The first is the danger that they might work loose and fall into the product flow. If fasteners are unavoidable, they should ideally have magnetic properties so that downstream magnets as well as metal detectors have a chance to remove them. However, some types of stainless steel are less magnetic than others, and it may not always be possible to take this precaution. The second problem is the presence of metal-to-metal contact which, with increased wear, creates growing crevices which will trap product residue. Fasteners also create dead spaces and other soil trap points. These are illustrated in Fig. 8.18.

If nuts or screws are unavoidable, they should be hygienically designed and installed (Anon., 1974). Ideally they should be inserted on the reverse side to the product (Fig. 8.19). If not, they should be designed with a domed head which minimises the risk of product adhering to the head and facilitates cleaning. Collars should also be circular and sloped. A metal-backed elastomer gasket should be used to seal the thread (Fig. 8.20). Rivets should not be used for joining surfaces. As equipment dismantling for cleaning, inspection and

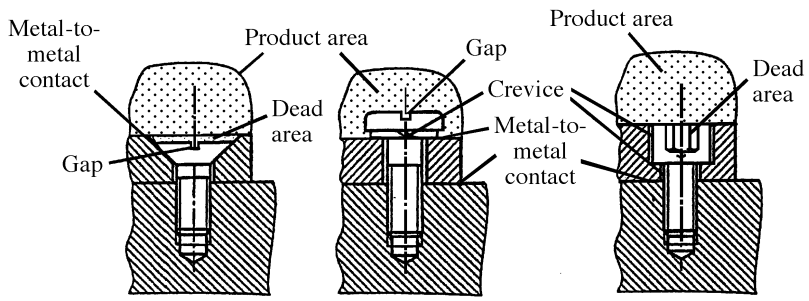


Fig. 8.18 Hazards created by unhygienic use of screws.

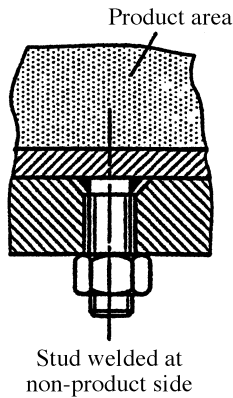


Fig. 8.19 Hygienic use of screws: non-product side.

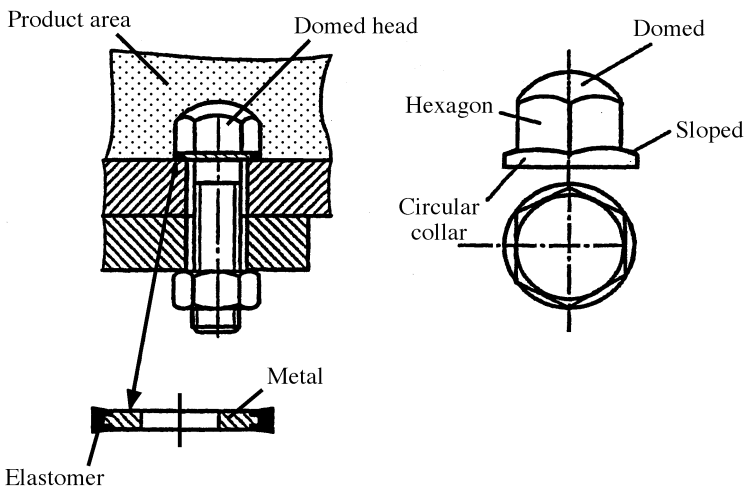


Fig. 8.20 Hygienic design of screws: product side.

maintenance involves loosening of nuts and bolts, ease of removal is essential. Any potential thread seizure through over-tightening must be prevented and therefore selection of the nut and bolt material is important. If threads are damaged during dismantling, they should be immediately re-threaded or the damaged fastener replaced. Lubricants should be avoided as they may be a source of contamination.

8.10 Seals

Seals have traditionally been made from rubber and particularly from synthetic rubbers or elastomers. Seals must be able to withstand a variety of conditions such as sub-zero temperatures during processing and temperatures above 100°C during sterilisation (Curiel *et al.*, 1993b). Materials must also be easily cleaned during sanitation. They must also withstand a variety of products, such as acid and alkaline solutions as well as oils. To ensure a smooth durable surface with sufficient temperature and corrosion resistance, equipment manufacturers tend to use polytetrafluoroethylene (PTFE) as gasket material in food processing equipment. PTFE, however, lacks resilience. It has an expansion coefficient of approximately $100 \times 10^{-6}/\text{K}$, compared to approximately $16 \times 10^{-6}/\text{K}$ for stainless steel. Due to this large difference in thermal expansion coefficient between PTFE and stainless steel, a heat treatment changes the shape of the PTFE gasket and after cooling down a crevice occurs (as shown in Fig. 8.21). For a gasket of 5 mm thickness and a temperature change from 20°C to 120°C and back, the crevice may be 36 μm wide if there is no resilience at all (in practice the gap will be slightly smaller). It is important not to use seals made from non-resilient materials (Lelieveld, 1994).

As well as selecting appropriate materials, it is also important to control compression of elastomers. Overcompression may lead to destruction of the elastomer, particularly if the overcompressed elastomer is heated (for example, in pasteurisation and sterilisation processes). The elastomer may become brittle and fail to provide the required seal, while parts of the elastomer may contaminate the product. Secondly, overcompression may lead to protrusion of the elastomer into the equipment, thereby hampering cleaning and draining. Undercompression is also a potential problem as it may lead to crevices and fail to provide a reliable seal. Even when it is not visibly leaking, the seal may permit the ingress of microorganisms (Fig. 8.22). Pipe coupling needs therefore

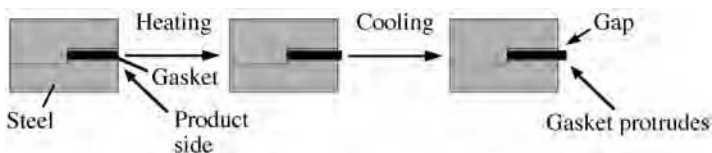


Fig. 8.21 Deformation of non-resilient gasket material.

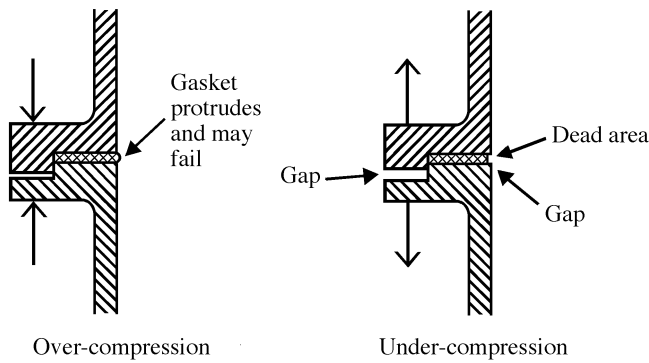


Fig. 8.22 Over- and under-compression of gasket material.

to take account of gasket compression as well as other factors such as control of alignment (Baumbach *et al.*, 1997). Figure 8.23 shows a number of designs which ensure control of the compression of elastomers. Figure 8.23(c) shows an ISO 2853 coupling which uses a T-gasket design to control compression (Anon., 1976; Curiel *et al.*, 1993b).

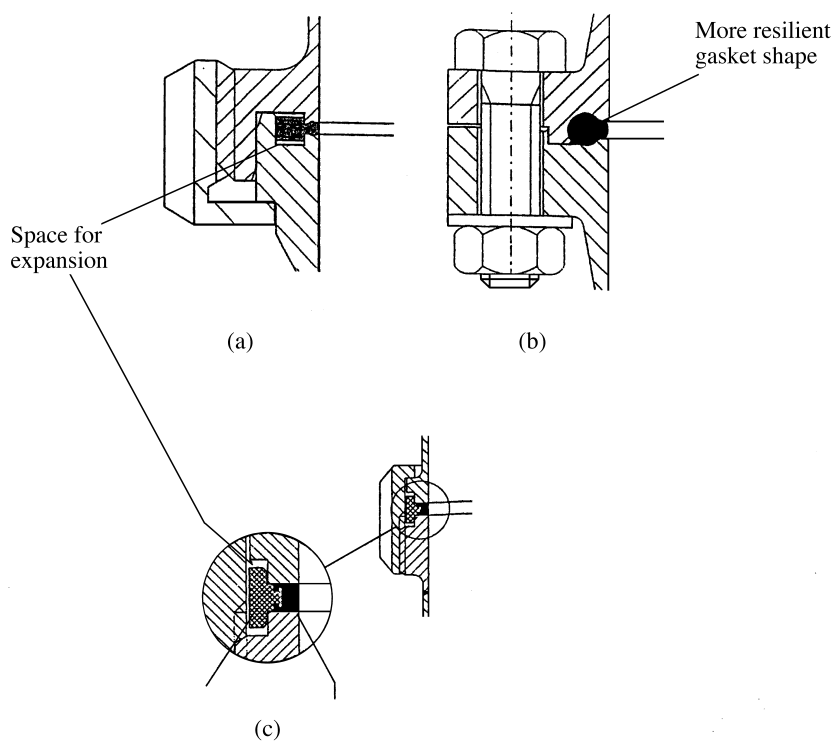


Fig. 8.23 Hygienic design of pipe couplings controlling both alignment and compression.

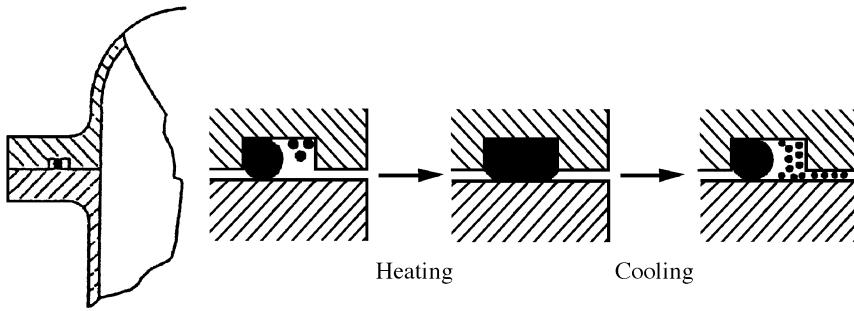


Fig. 8.24 Unhygienic o-ring seal.

Installations containing conventionally designed o-ring seals invariably create crevices that are impossible to clean in place and provide dead spaces in which microorganisms can multiply. This problem is a consequence of the different thermal expansion coefficients of elastomers and steel. Heat causes the o-ring to expand, protecting microorganisms trapped between the o-ring and the steel surface against contact with hot water, chemical solution or steam. After cooling down and shrinkage of the o-ring, the survivors will be freed and will infect the product that will fill the gap at the start of the production (Fig. 8.24).

O-rings can only be used if mounted in a way that ensures that the area of steel covered by the rubber at the product side is not influenced by thermal expansion. Often this leads to large forces inside the o-ring and as a result the lifetime of the o-ring may be reduced significantly. Figure 8.25 illustrates hygienic design using o-rings. Figure 8.25(a) shows a pipe coupling and Fig. 8.25(b) shows a pH-electrode fitting. In both cases the o-ring is almost completely enclosed with the surrounding metal partially protected from the product contact surface. However, because of the volume of the elastomer, its virtually complete enclosure and the differences in expansion between

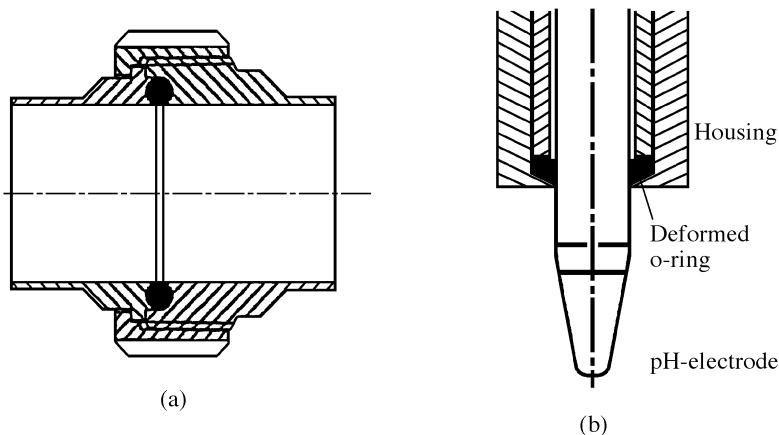


Fig. 8.25 Hygienic use of o-rings in a pipe coupling (left) and a sensor (right).

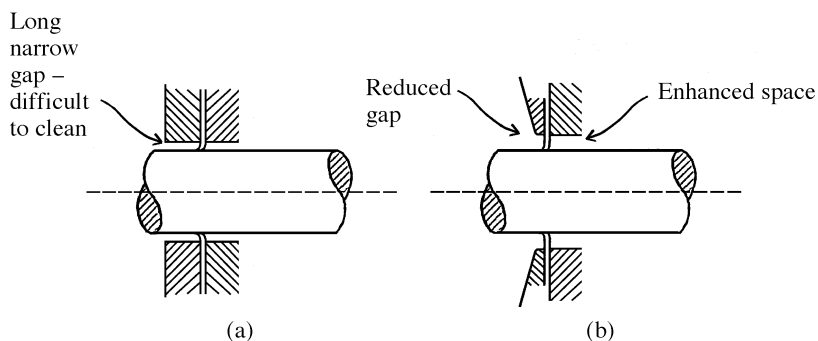


Fig. 8.26 Hygienic and unhygienic design of dynamic seals.

elastomer and steel, forces inside the elastomer may result in accelerated ageing, so that periodic replacement may be required. The use of metallic stops would ensure bacteria-tightness but avoid destruction of the elastomer during heating.

Dynamic seals also require careful hygienic design so that they can be easily cleaned. The space around the seal should be as wide as possible. The narrow annular space which is usually found at the product side of the seal must be avoided. Figure 8.26(a) illustrates the problem, whilst Fig. 8.26(b) illustrates a design which both reduces the volume of annular gap around the shaft and ensures sufficient space around the seal. Since they will still allow the passage of some microorganisms, dynamic seals should be avoided in aseptic equipment. This may be achieved by using bellows or diaphragms that separate the seal from the product side. Where that is not possible (e.g. in the case of rotary seals), double seals must be used (Fig. 8.27). The space between the seals must be flushed either with an antimicrobial fluid (such as hot water, steam or a solution

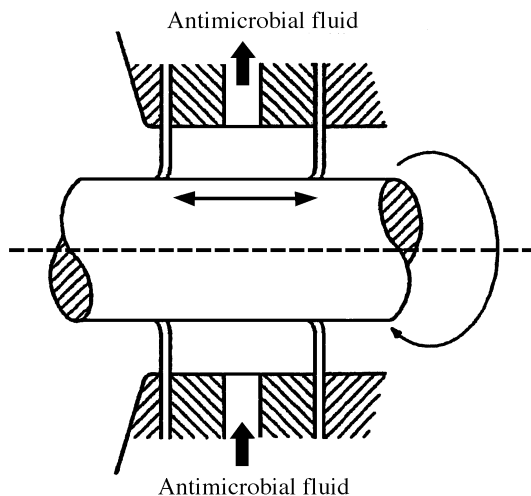


Fig. 8.27 Hygienic design using a double seal.

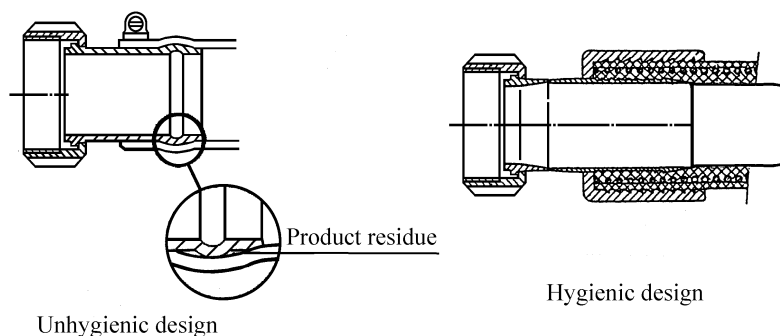


Fig. 8.28 Hygienic and unhygienic joints for flexible hoses.

of an antimicrobial chemical) or with sterile water. The choice of flushing fluid will depend on product requirements. To avoid the transfer of microorganisms from the outside of the equipment to the inside, without a sufficiently long exposure to the antimicrobial fluid, the distance between the two seals must always be larger than the stroke of the reciprocating shaft. It should be realised that rotating shafts often exhibit some axial mobility and hence assist penetration of microorganisms. Flexible hoses are frequently used to connect moving and static parts of process lines (e.g. moveable dosing heads on filling machines). Figure 8.28 shows the non-cleanable crevice created by the traditional way of mounting hoses to pipes and how this can be done correctly without crevices.

8.11 Shaft ends

Equipment such as stirrers, homogenisers, mixers or cutters can pose a significant risk (Timperley and Timperley, 1993). Crevices caused by metal-to-metal contact or dead spaces in grooves must be avoided. If adhesives are used for metal-to-metal joints, they and the bonds created by their use must follow the recommendations given for permanent joints (Section 8.8). Hubs, nuts and coupling shafts must be carefully sealed under controlled compression. Corners (e.g. hubs and nuts) must be radiused and horizontal areas sloped. To avoid any screwed joints, appendages (such as blades) should be welded to the hub. Figure 8.29 illustrates good and bad hygienic design of a blade attachment. Design (a) employs metal-to-metal contact, creating crevices, and uses exposed screw heads, which both harbour microorganisms. Design (b) shows a hygienically designed detachable blade attachment with a sealed, sloping cap and joints. Design (c) illustrates a welded blade attachment with a sloping cap which facilitates cleaning.

Bearings should, wherever possible, be mounted outside the product area to avoid possible contamination of product by lubricants (unless they are edible) or

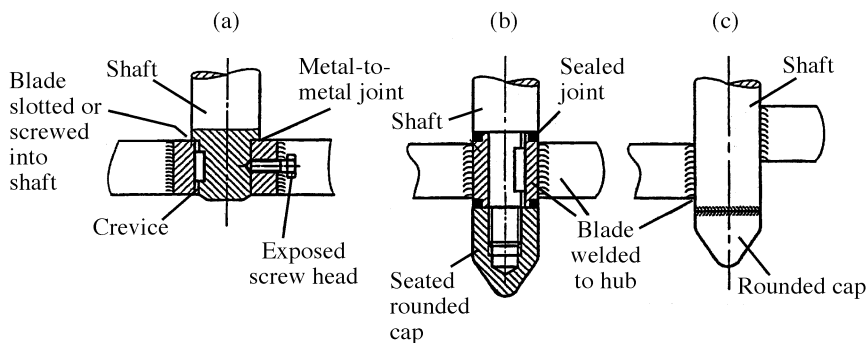


Fig. 8.29 Hygienic and unhygienic design of blade attachments.

possible failure of the bearings due to the ingress of the product. Shaft seals must be of such design so as to be easily cleaned and, if not product lubricated, then the lubricant must be edible. Where a bearing is within the product area, such as a foot bearing for an agitator shaft in a vessel, it must be mounted clear of the base to allow free cleaning of the feet. It is also important that there is a groove completely through the bore of the bush, from top to bottom, to permit the passage of cleaning fluid. Figure 8.30 illustrates a hygienic design for a foot bearing with grooves in the bearing area to facilitate lubrication by fluid products and cleaning operations, and mounted clear of the base.

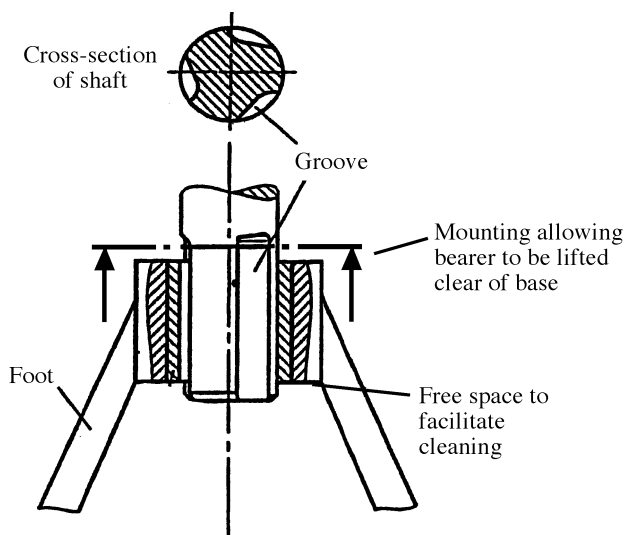


Fig. 8.30 Hygienic design of a foot bearing.

8.12 Doors, covers and panels

Doors, covers and panels should be designed so that they prevent the entry and/or accumulation of soil. Where appropriate they should be sloped to an outside edge and should be easily removed to facilitate cleaning. Figure 8.31 shows how a lid of a vessel, intended to protect a product, may accumulate dirt that will contaminate the product in the vessel when the lid is opened. Figure 8.32 illustrates more hygienic designs. Covers can be completely detachable for cleaning, as in Fig. 8.32(a) and (b). Non-removable covers must be sloped for drainage (Fig. 8.32(c)). If hinged covers are used, the hinge must be designed in such a way that it can be dismantled or cleaned easily and that accumulation of product, dust and foreign bodies (including insects, etc.) is avoided. Pipes or instruments attached to or passing through covers must be welded or carefully sealed. Figure 8.33 illustrates an incorrect (a) and correct (b) way of mounting a lid. Design (b) has a sloped top which avoids the sharp corner created by design (a) in the closed position which would be difficult to clean. Tanks should not be opened at all during production unless absolutely necessary.

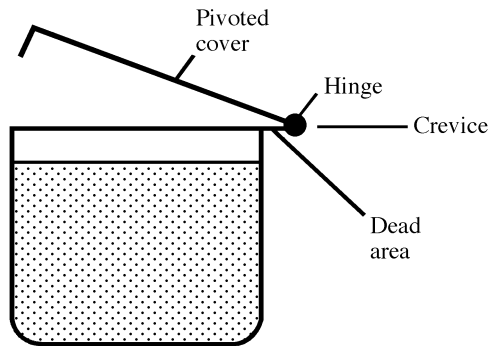


Fig. 8.31 Hygiene risks from equipment covers.

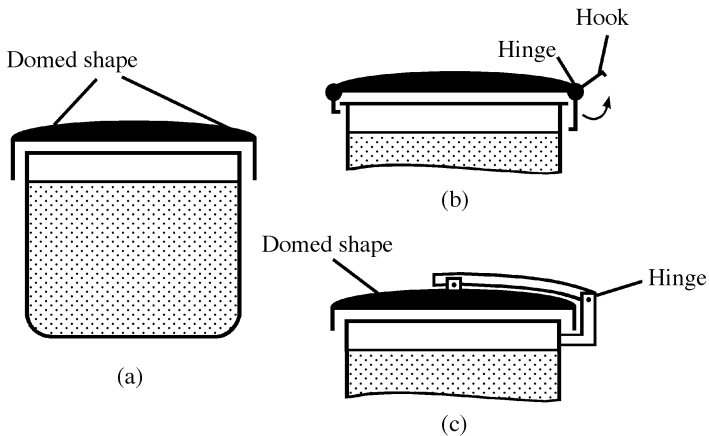


Fig. 8.32 Hygienic designs for equipment covers.

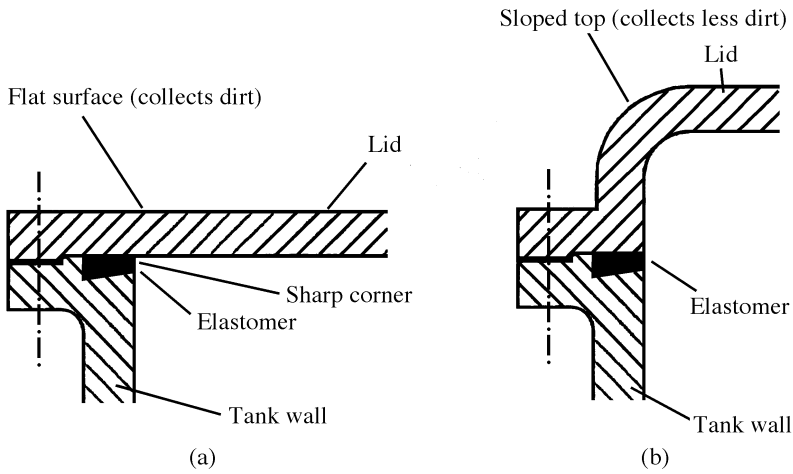


Fig. 8.33 Hygienic and unhygienic mounting of lids.

8.13 Rims

The design of top rims of product-containing equipment (e.g. containers, chutes, boxes) must avoid ledges where product can lodge and which are difficult to clean (Fig. 8.34). Open top rim designs must be rounded and sloped for drainage (Fig. 8.35). If the top rim is welded to the wall, the weld must be flush and polished to provide a smooth surface. In this case, the rim must be totally closed. Any holes, therefore, must be sealed by welding or by fitting sealed caps (Fig. 8.36) (Curiel *et al.*, 1995).

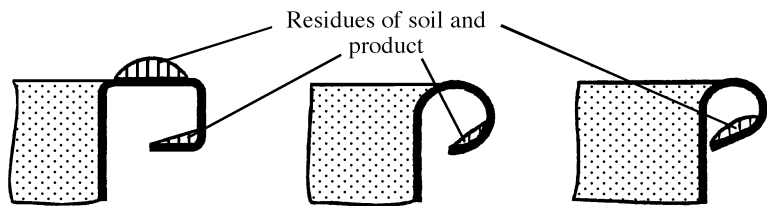


Fig. 8.34 Unhygienic rim designs.

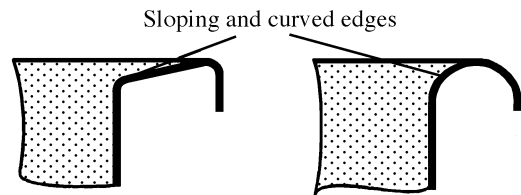


Fig. 8.35 Hygienic design of rims.

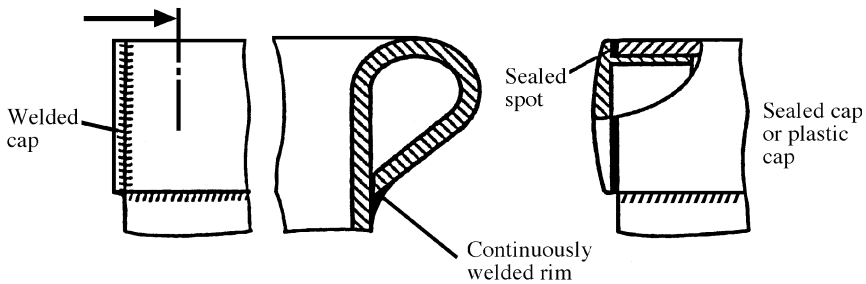


Fig. 8.36 Sealed rims and caps.

8.14 Conveyor belts

Conveyor belts present particular problems in hygienic design. It is very important to ensure that a conveyor belt does not absorb moisture as this will lead to microbial growth and contamination. Once microorganisms have colonised the inner fabric of the belt, it will be impossible to remove or inactivate them without destruction of the belt. Accumulation of soil around the edges of the belt must also be avoided, which requires a special construction. Even with proper design, thorough cleaning and inspection after cleaning is essential as spillage around the edges is very difficult to prevent completely (Curiel *et al.*, 1995).

Figures 8.37–8.41 illustrate a number of design issues. Open edges of reinforced belts cause hazards by crevices or absorption of liquids (Fig. 8.37(a)). Reinforced materials should therefore be encased within the main belt with the use of rounded edges for easier cleaning (Fig. 8.37(b)). Non-removable bearing surfaces for belts and non-removable covers allow dirt to accumulate and prevent cleaning. Pivoted covers with hinges also create crevices and are difficult to clean (Fig. 8.38(a)). A design with a detachable cover which can be removed for cleaning is preferable (Fig. 8.38(b)). The use of swivel-mounted rollers also facilitates cleaning. When the conveyor belt is not in use, the rollers can be raised to create a space between the belt and the bearing table which will allow cleaning to take place (Fig. 8.39). To avoid any hygiene risk, drives of belts and any appendages such as sensors must be covered, and the belt should be clear of framework to give open access to the belt and rollers for cleaning (Fig. 8.40). Sides of rollers which are not aligned and smooth cause dead areas

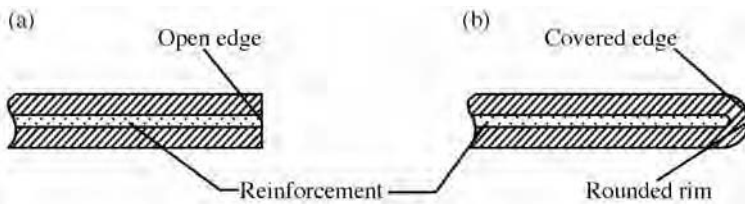


Fig. 8.37 Hygienic and unhygienic design of conveyor belt material.

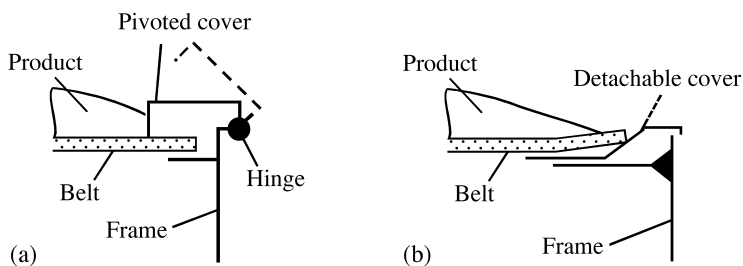


Fig. 8.38 Hygienic and unhygienic cover design for conveyor belts.

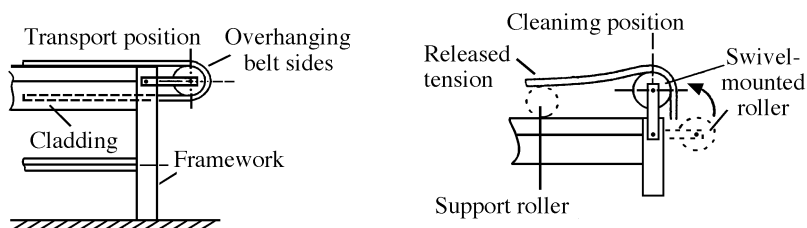


Fig. 8.39 Swivel-mounted rollers for conveyor belts to allow cleaning.

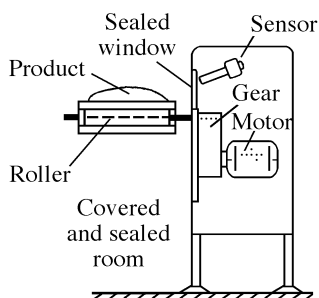


Fig. 8.40 Sealed casing for conveyor belt drives and monitoring equipment.

and crevices (Fig. 8.41(a)); aligned front sides which are properly welded to the roller and to the shaft avoid any hazard and can be cleaned easily (Fig. 8.41(b)).

8.15 Equipment controls and instrumentation

Controls, particularly those that are repeatedly touched by food handlers to allow process operation, should be designed to prevent the ingress of contamination and should be easily cleanable. Pathogenic microorganisms have been known to harbour in switches and be transferred to product every time they are opened (Holah, 2002). The importance of good hygienic design can be illustrated with reference to a sliced-meat factory which had slicers whose action

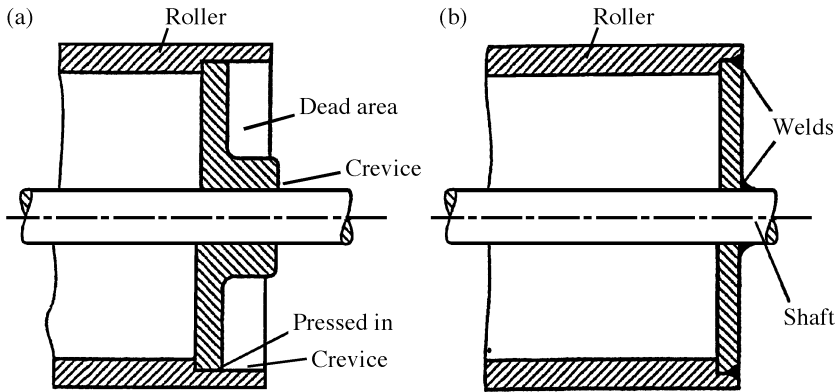


Fig. 8.41 Hygienic and unhygienic design of rollers for conveyor belts.

was initiated by pressing a control switch identical to that shown in Fig. 8.42. The factory concerned was having problems due to product contamination with *Listeria monocytogenes*, and was eventually forced to stop production for a few days with a subsequent financial loss in excess of £1 million. The problem was finally traced to a source of *L. monocytogenes* that was being harboured within the body of the slicer switches. At the beginning of production the slicing operative picked up a log of meat, placed it on the slicer and pressed the control switch to start slicing. From this point on, and every time he subsequently repeated this procedure, *L. monocytogenes* was transferred from his hand to the slicer and, by the middle of the shift, sufficient *L. monocytogenes* was present on the slicer to be detected in the product. The conclusion to the incident was the purchase of a number of rubber switch covers as shown in Fig. 8.43 for the cost of a few pounds.

Instruments must be constructed from appropriate materials. If they contain a transmitting fluid, such as in a bourdon tube pressure gauge, then the fluid must be approved for food contact. Many instruments themselves are hygienic but often they are installed unhygienically (Berrie, 2001). When choosing

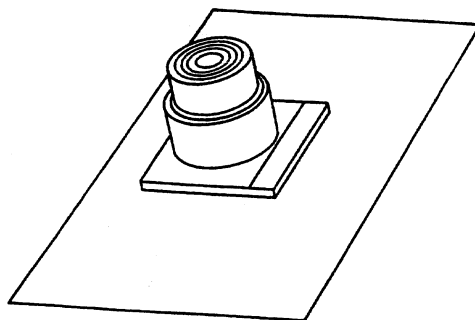


Fig. 8.42 Poor design of a control switch.

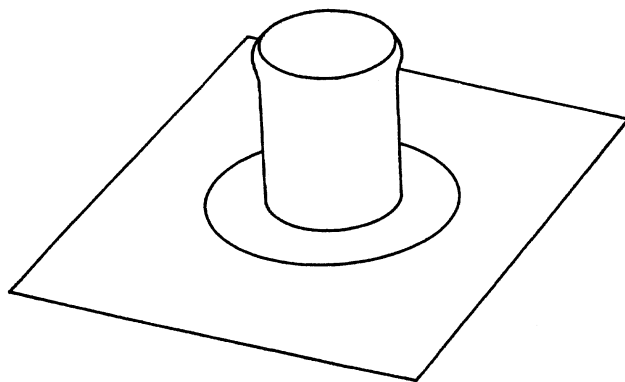


Fig. 8.43 Hygienic design of a control switch.

instrumentation for food production, it is always wise to bear in mind that it is not the normal operation of a device that gives problems, but rather the unexpected event. Thus, the risk of chemical contamination can be eliminated by using a suitable material for the wetted parts of the device. The risk of bacterial contamination can be reduced by regular cleaning and the use of suitably designed process connections. The introduction of foreign bodies, however, is only partially covered by the adoption of a high degree of protection. The case where equipment in direct contact with the product fails, producing debris or releasing contaminants, must also be considered. Here it is essential that the user is warned and/or that the released products are not dangerous to health.

The wetted parts of a device are those parts which are in contact with the medium being measured. For temperature measurement this might be the thermowell, for pressure measurement the isolating diaphragm and for a contacting level measurement the sensing element itself. Even so-called non-contact devices must be considered to have wetted parts when they intrude into the pipeline or tank. Here it is not so much the contact with the medium, but crevices and their exposure to high temperatures and vapours which have to be considered. The positioning of the measurement device must also be examined. Flowing gases, liquids or solids may cause abrasion or generate high mechanical forces, which combined with high temperature or vibration enhance electrochemical attack or mechanical fatigue. Moreover, the wetted parts must be able to withstand the forces and temperatures generated during cleaning or sterilisation-in-place procedures.

In addition to the normal mechanical design factors, the toxicological and bacteriological compatibility of the materials used for wetted parts must also be taken into consideration. As far as the toxicological properties are concerned, a material approved by the US Federal Drug Administration (FDA approval) or equivalent regulating body must be used. The bacteriological factor is a different matter. Although regular cleaning and gap-free design reduce the broad risk of infection, the proper design and finishing of the wetted parts is just as important. This basically means flowing contours and clean welding, no nooks and

Table 8.2 Stainless steels suitable for the food industry

Material	AISI*	Properties
1.4301	304	Good resistance against organic acids at moderate temperatures Good resistance against salt and alkalis at moderate temperatures
1.4404	316L	Increased resistance against non-oxidising acids such as acetic acid, tartaric acid, phosphoric acid Increased resistance against pitting and intercrystalline corrosion
1.4435	316l	Better corrosion resistance than Type 1.4404
1.4571	316 Ti	Increased corrosion resistance against particular acids and salt water Resistance against pitting corrosion

* The AISI steels are equivalents but do not have identical compositions.

crannies, and no obstructions that might cause the product to gather and rot. Usually all components in the tank are of highly polished stainless steel to prevent the product from sticking.

The corrosion resistance of the wetted parts is also important. This is not simply a matter of their resistance to the products and cleaning agents. Under high temperatures, strong vibration and mechanical stress, electrochemical corrosion or intergranular corrosion may be enhanced. The one results in surface pitting, providing an ideal breeding place for bacteria, the other in the depletion of the nickel and chromium at the grain interfaces, which means the component will rust. Table 8.2 lists some stainless steels suitable for the food industry.

The majority of process instruments are installed in pipes or tanks by means of threaded connections or flanges. Neither of these methods is suitable for food manufacture since both offer crevices and gaps where the product can accumulate and rot. In addition, the mounting and dismounting takes considerable effort, so cleaning becomes difficult. Ideally, a process connection should offer no gaps where the product can become trapped. One solution is to weld the instrument in place and then grind and polish the inside of the connection. Unfortunately this means that the instrument cannot be exchanged should it fail. For thermowells, where the sensor insert is easily replaced, and for flowmeters, however, it is quite feasible and is often encountered. Process instruments are generally installed by means of so-called sanitary couplings. These combine the need for a gap-free mounting with that of easy mounting and dismounting, allowing them to be quickly removed for cleaning. Over the years a number of different designs have come onto the market, a selection of which are summarised in Table 8.3.

Just as important as the wetted parts and process connection is the design of the housing of a process instrument. Depending upon the instrument type, this

Table 8.3 Sanitary couplings for the food industry

Type	Use	Description
Dairy coupling (to DIN 11851)	Pipes and tanks	Reasonably priced coupling that is frequently found in the food industry. Its weakness lies in the hygienic adaptation to the process which does not allow flush mounting. The coupling is made by a threaded boss and slotted sleeve. A conical seating and tapered nozzle with sealing ring comprise the process seal
Aseptic coupling (to DIN 11864)	Pipes (tanks in preparation)	Introduced in 1998 as a replacement for the dairy coupling. Designed to EHEDG recommendations, thanks to a flush sealing construction. The mechanical coupling is via bolts or a threaded sleeve, the seal being flush with the pipe wall
Varivent [®] coupling	Pipes	In-line housing that allows the flush mounting of the sensor, which is attached to the housing by means of a screw clamp. Three housing types cover a wide range of pipe diameters. For the majority of process sensors Type 3, for pipes of DN 40 upwards, is required. This facilitates the exchange of instruments
APV coupling	Pipes	In-line housing of similar construction to the Varivent coupling. The sensor, however, is bolted in position
SMS coupling	Pipes and tanks	Reasonably priced, Scandinavian standardised screw coupling which is also used in France. Its weakness lies in the hygienic adaptation to the process which does not allow flush mounting
IDF coupling	Pipes and tanks	International Dairy Federation screw coupling standardised in ISO
Tri-clamp [®] coupling	Pipes and tanks	Sanitary coupling with bevel seating produced by the Tri-Clover Company in America. Instruments are quickly mounted and fixed with snap-on clamps. The couplings find widespread use in America

may contain only the connecting terminals or the entire evaluating electronics. In both cases it must provide protection:

- from the ingress of dust or moisture from the outside
- when the sensor is used in an explosion hazardous area, from the egress or a spark or flame from the inside to the outside.

The former can be ensured by a suitable degree of protection, the latter by a suitable type of protection.

Table 8.4 Ingress protection categories to IEC 60 529

Code	Ingress protection against solids	Code	Ingress protection against water
0	Not protected	0	Not protected
1	≥50 mm diameter, e.g. hand	1	Vertical dripping
2	≥12.5 mm diameter, e.g. finger	2	Dripping (15° inclination)
3	≥2.5 mm diameter, e.g. tool	3	Water spray
4	≥1 mm diameter, e.g. wire	4	Splash water
5	Protected from dust	5	Jet of water
6	Dust-proof	6	Strong jet of water
		7	Temporary submersion
		8	Total submersion

As far as the ingress of dust and moisture is concerned, the world is divided into two camps. One half uses the IP standard (IEC 60 529) and the other the American NEMA Standard No. 250. Nowadays, however, many manufacturers quote both in their technical specifications. The IP standard is a description of the measures designed for the protection of the housing and the equipment within the housing. The degree of protection is indicated by a two-part code, e.g. IP 65. The first number is concerned with the protection from the ingress of solid matter, the second with water. As can be seen from Table 8.4, in order to withstand the frequent cleaning in a food production facility, housings with ratings of IP 65 or better are required. The NEMA standard comprises 14 type codes which deal with practical requirements on housings suitable for indoor and outdoor use. It also makes a statement about the protection from external influences and conditions such as mechanical impact, corrosion, humidity, mould, pests, dust, etc. As can be seen from Table 8.5, which lists only a

Table 8.5 Degree of protection of enclosures as per NEMA Standard 250 (selection)

Type	Indoor	Outdoor	Degree of protection
1	yes		Protection against contact with equipment within the housing
2	yes		Protection against a specified quantity of water droplets and dirt
3		yes	Protection against blown dust, rain, sleet and snow, and external ice formation
4	yes	yes	Protection against blown dust, splashes and jets of water
4X	yes	yes	Protection against corrosion, blown dust, splashes and jets of water
5	yes		Protection against dust falling, dirt and lubricating non-corrosive fluids
6	yes	yes	Protection against water penetration during occasional temporary submerging in limited depth

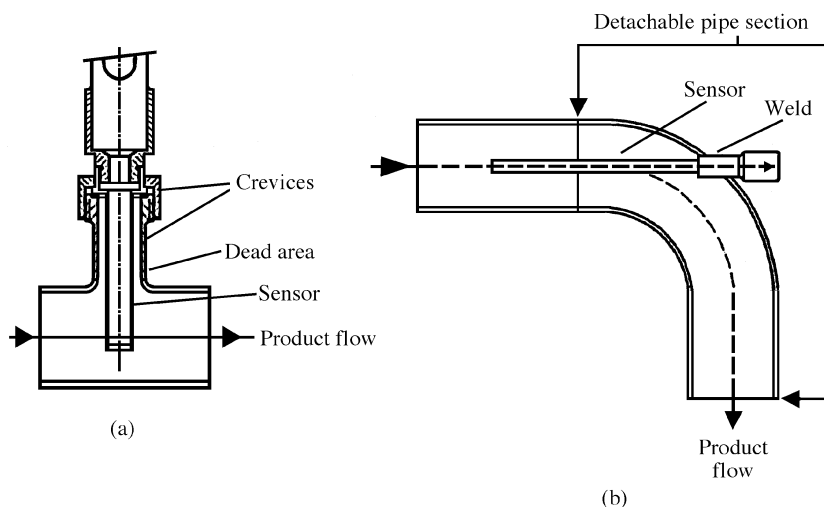


Fig. 8.44 Hygienic and unhygienic mounting of instruments.

selection of codes, a NEMA 4X enclosure is best suited to the requirements of the food industry.

In comparison to the chemical industry, there is less need for explosion protection in the production of food. If flammable liquids or easily ignitable gases are present, however, then the instrumentation must be approved for use in explosion hazardous areas. Powders can also be a problem, since clouds of dust are easily combustible under certain conditions. For milling, storage, conveyance and bagging operations, therefore, the Dust-Ex equipment should be used. The types of explosion protection are standardised in EN 50 014.

It is important to mount instruments hygienically so that they do not create crevices and dead spaces. Figure 8.44 shows an incorrect and correct mounting of a temperature probe. The mounting in Fig. 8.44(a) creates a dead area and potential crevices in the seal, while that in Fig. 8.44(b) is welded into the pipeline and avoids any dead area.

8.16 Equipment installation

The potential for well-designed and constructed equipment to be operated in a hygienic manner may be easily vitiated by inadequate attention to its location and installation (Thorpe and Barker, 1987). Timperley (1997), when considering the accessibility of equipment, recommended that it is more effective to consider complete lines instead of individual items of equipment and recommended the following:

- There should be sufficient height to allow adequate access for inspection, cleaning and maintenance of the equipment and for the cleaning of floors. A minimum of 300 mm is recommended.

- All parts of the equipment should be installed at a sufficient distance from walls, ceilings and adjacent equipment to allow easy access for inspection, cleaning and maintenance, especially if lifting is involved. A minimum distance of 1 m is recommended, though 2 m is often seen as a more practical minimum.
- Ancillary equipment, control systems and services connected to the process equipment should be located so as to allow access for maintenance and cleaning.
- Supporting framework, wall mountings and legs should be kept to a minimum. They should be constructed from tubular or box-section material which should be sealed to prevent ingress of water or soil. Rounded pedestals are also acceptable. In both cases, the base for such supports should be sloped to facilitate drainage and cleaning. Angle- or channel-section material should not be used.
- Base plates used to support and fix equipment should have smooth, continuous and sloping surfaces to aid drainage and cleaning. They should be coved at the floor junction. Alternatively, ball feet should be fitted.
- Pipework and valves should be supported independently of other equipment to reduce the chance of strain and damage to equipment, pipework and joints.
- Once installed, a series of maintenance measures should be put in place to ensure the required level of equipment hygiene is maintained for the equipment during its specified life.

Figure 8.45 illustrates examples of poor (a) and good (b) hygienic design using these principles. The risk of condensation on equipment, pipework, and the fabric of the building should be avoided. If unavoidable, the design should be such that condensate is diverted away from the product. Supports for piping or equipment must be fabricated and installed such that no water or soil can remain on the surface or within the supports. The possible adverse galvanic reactions between dissimilar materials should be taken into consideration. It is also

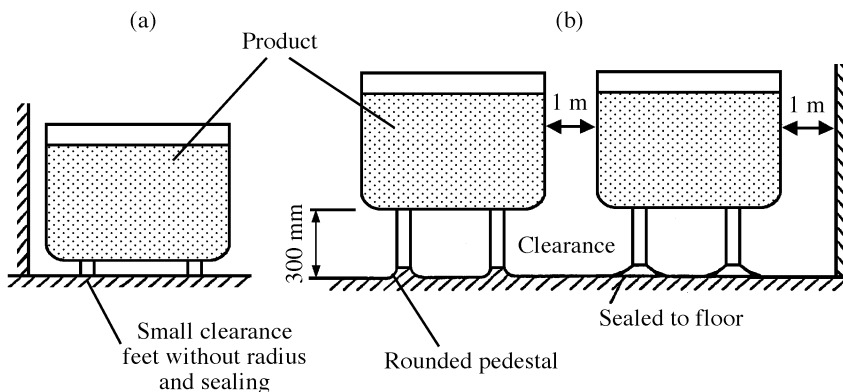


Fig. 8.45 Hygienic and unhygienic mounting of equipment.

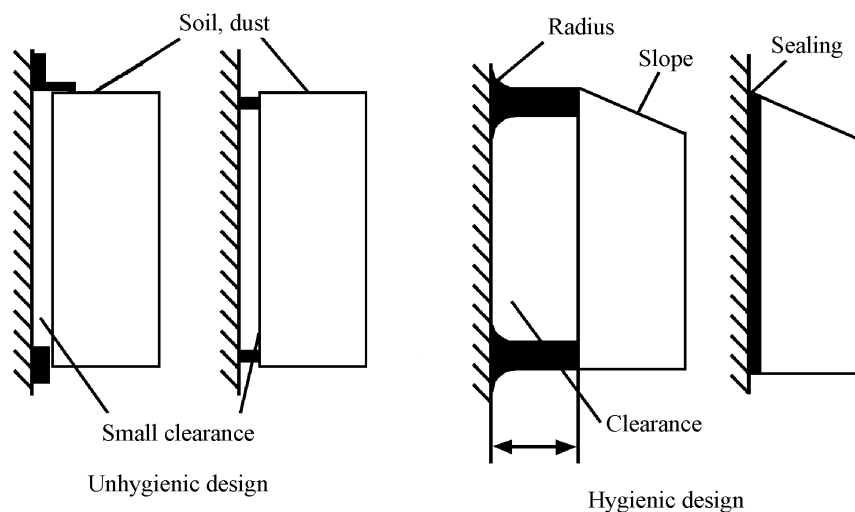


Fig. 8.46 Hygienic and unhygienic mounting of equipment on walls.

important to avoid steps due to misalignment in equipment and pipe connections which might harbour water or soil.

With equipment that is fixed to walls, any horizontal surfaces or the ledges of fasteners can retain soil, and a small clearance hampers cleaning between the wall and the equipment from the wall. Horizontal supports should be radiused and properly fixed to the wall, ensuring sufficient clearance. Alternatively, equipment can be fixed to the wall using sealing materials (Fig. 8.46). Equipment must not be mounted beneath tanks or vessels so that maintenance and cleaning are not possible. Accessible equipment can be more easily maintained and gives open space for handling and cleaning beneath tanks and sufficient clearance (Fig. 8.47).

Apparatus such as stirrers, homogenisers or mixers should preferably be arranged in such a way that sealing of shaft passages in the product area is avoided by mounting them above the product area (Fig. 8.48). In the case of

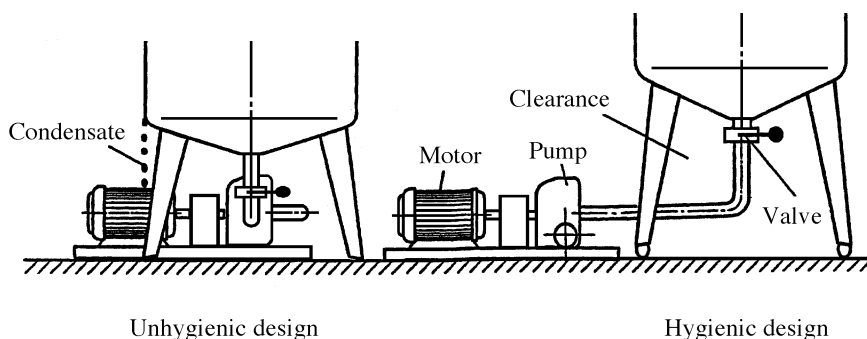


Fig. 8.47 Hygienic and unhygienic positioning of equipment beneath tanks.

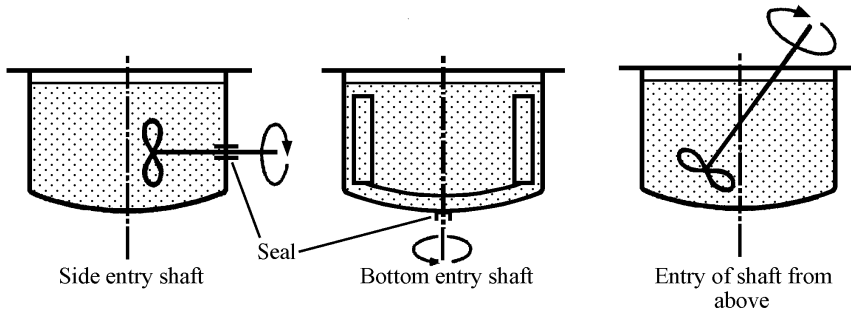


Fig. 8.48 Hygienic design of shafts.

arranging the motor drive above the product it should preferably be placed beside the equipment (Curiel *et al.*, 1995). The possibility of contamination by lubricants and soil from the motor or gearbox entering the product area must be avoided by using drip trays in combination with thrower rings on the shaft (Fig. 8.49). The motor should be covered by a hygienically designed cowl. If shaft passages are unavoidable, dynamic seals must be used.

Mesh, screens, grids or perforated sheets should be avoided in the product area. Application for guarding or for processes such as sieving and drying requires particular attention to ensure cleanability. Special, fully (vacuum) welded gridirons are available, avoiding any dead areas. A potential risk of cabling is contamination caused by the collection of dirt and dust as well as microbial growth. The following hygienic design criteria are required:

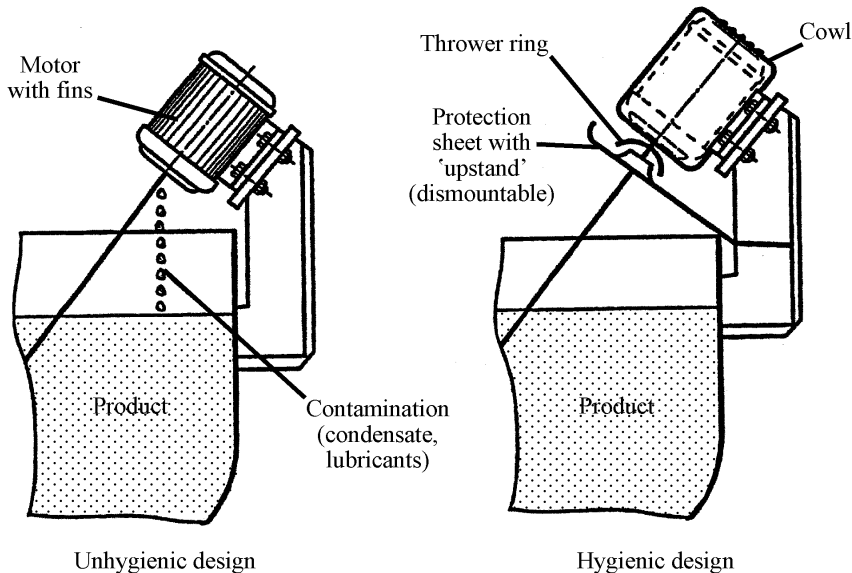


Fig. 8.49 Hygienic and unhygienic mounting of equipment above product.

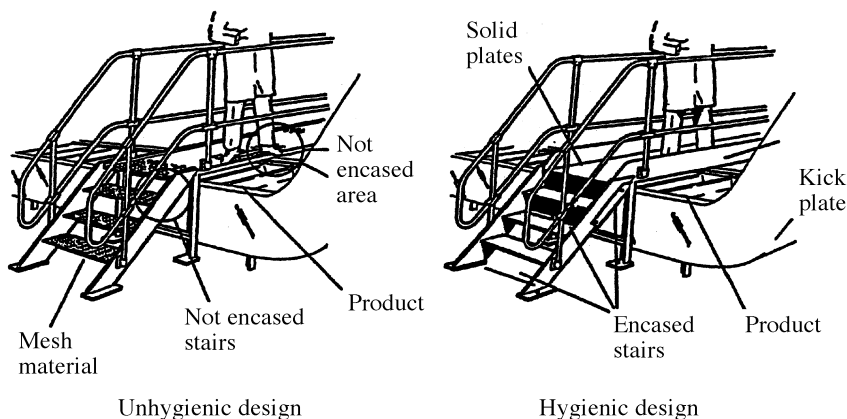


Fig. 8.50 Hygienic and unhygienic design of walkways.

- Cables should be located wherever possible in designated utility/servicing areas.
- The wiring and cabling should be located in plastic or stainless steel pipes and prepared so that dust and moisture cannot enter the pipes, thus preventing the possible risk of creating contamination conditions.
- If used, cable trays should be of grid design and be accessible and easy to clean. Only one layer of cables is recommended and there must be space between the cables. Vertical cable trays are preferred.

Raised walkways or stairs over any exposed product should be avoided because dirt may be transferred from clothing or footwear onto product lines beneath. If personnel movement is required in these areas, the equipment should be constructed to be fully enclosed. Kick-plates should be designed as a one-piece construction. The decking should be constructed from solid plates containing a raised anti-slip surface. Risers of staircases must be enclosed. Steps should be constructed of the same anti-slip material as the deck. The use of expanded metal or mesh must be avoided to prevent soil being transferred into the product (Fig. 8.50).

Framework supporting equipment should preferably be constructed from hollow square- or round-section members. Open ends of such framework must be closed by welded ends or plastic caps. For the design of framework that will be exposed to continuous vibrations (e.g. drying towers) the use of open profile construction should be considered. Small cracks can arise from vibration, allowing penetration of moisture, soil and microorganisms in closed profiles. For vertical parts of frames most cross-sections can be used. The horizontal placing of framework is more problematic. Figure 8.51 shows how various kinds of open and closed design can attract soil. To avoid soil trapped on the horizontal surfaces of frames, open and closed cross-sections must be self-draining and easily cleanable. Horizontally mounted cross-sections and framework should be designed as shown in Fig. 8.52.

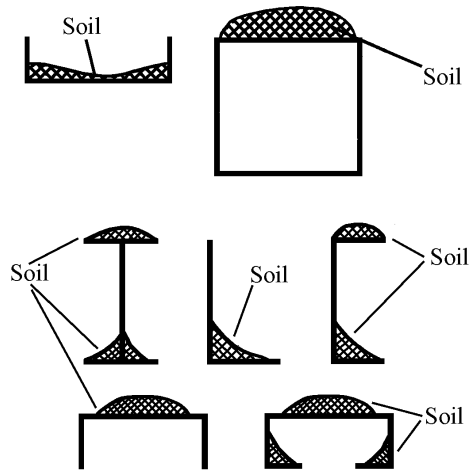


Fig. 8.51 Unhygienic design of supporting framework for equipment.

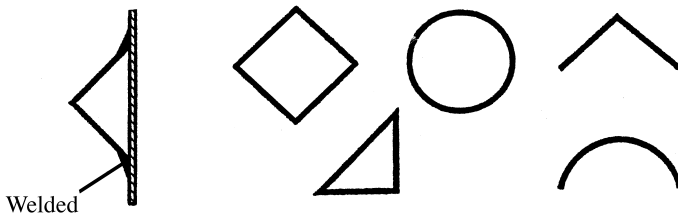


Fig. 8.52 Hygienic design of supporting framework for equipment.

8.17 Insulation and cladding

It is recommended to avoid use of insulation material wherever possible in order to prevent the possibility of microbial growth or dust build-up within the material (Curiel *et al.*, 1995). If insulation is needed for process, safety and/or environmental reasons, air insulation is the first recommended option. Pipework can be insulated by evacuation of air in the shell of a double-walled pipe. This is a very effective way of meeting hygienic design criteria. If vacuum insulation is not possible, non-chloride releasing insulation material should be used (such as appropriate grades of rockwool). The insulation material should be covered by a stainless steel outer tube, fully welded to prevent ingress of air, moisture or insects. Such ingress would promote corrosion between the walls, assisted by possible microbial growth. Ultimately, this will result in leaks, allowing microorganisms to contaminate the product. The same problem applies to the insulation of process vessels which should be insulated in the same way, as shown in Fig. 8.53. Depending on the use of the tank, it may be necessary to provide a vent hole to prevent unacceptable pressures between inner and outer wall, e.g. during sterilisation.

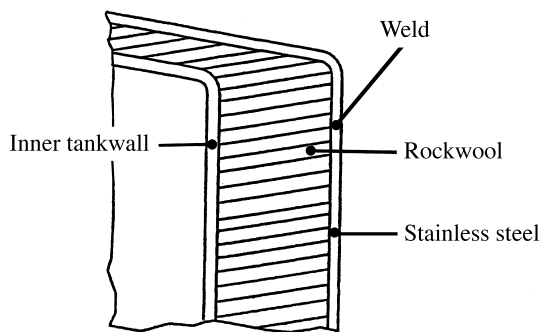


Fig. 8.53 Hygienic design of insulation.

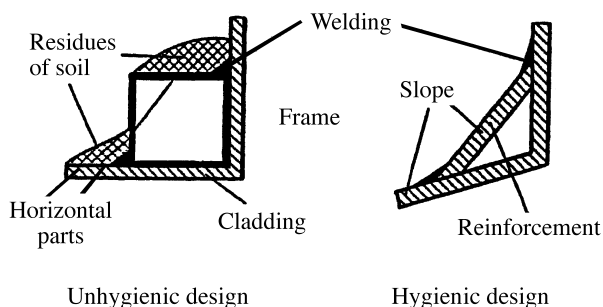


Fig. 8.54 Hygienic and unhygienic design of framework ledges.

Cladding of equipment must be smooth, continuous and without crevices to ensure that it is easily cleanable. Ledges, projections and pockets must be avoided because they retain soil. If unavoidable, horizontal ledges and projections should be sloped (Fig. 8.54). A minimum slope of 30° is required to avoid accumulation of dust and to facilitate inspection. Cladding must be installed such that a minimum clearance of 30cm is maintained between adjacent surfaces.

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9

Equipment construction materials and lubricants

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9.1 Introduction

The European Union Regulations (Directive 89/109/EEC of 21 December 1988, Article 2) require that ‘food contact articles under normal or foreseeable conditions of use must not transfer their constituents to foods which they are or are likely to be in contact with, in quantities which could endanger human health or bring about a deterioration in the organoleptic characteristics of food, or an unacceptable change in its nature, substance or quality’. There is currently a proposal under consideration by the EU to require food contact materials to carry batch numbers and also to have total traceability. For this section a range of materials and their suitability in the food industry is briefly discussed. Where appropriate an applications and corresponding testing scheme is shown in the form of a flow diagram.

Product contact materials must meet a number of requirements. They must be inert to the product under operating conditions, including variations in temperature and pressure, as well as to detergents and disinfectants under conditions of use. They must be corrosion resistant, non-toxic, mechanically stable, smooth and cleanable, and such that the surface finish is not adversely affected under conditions of use. Non-product contact materials must also be mechanically stable, smoothly finished and easily cleanable.

No toxic construction materials should be used. Stainless steel materials such as types AISI-304, AISI-316 and AISI-316L are fully acceptable for most applications. Care must be taken when polymer and elastomer materials are used as they may contain leachable toxic components. The same applies to the use of adhesives, lubricants and signal transfer liquids. In all cases the supplier must present evidence that the material is safe for use in contact with food.

Product contact surfaces should be smooth enough to be easily cleanable. A surface finish of $R_a = 0.8 \mu\text{m}$ is recommended. To achieve this quality of surface, polishing or other surface treatment may be required. Cold-rolled stainless steel sheet material, used for vessels and for piping, usually has an R_a value between 0.2 and $0.5 \mu\text{m}$ and thus treatment is not needed. The surfaces should also be free from imperfections such as pits, folds and crevices.

To retain the desired smoothness of the surface, materials must be resistant to the product under process conditions and withstand cleaning procedures during the intended lifetime of the material. Corrosion can be minimised by sticking to the concentrations, times and temperatures specified for process and cleaning operations, and by complete removal of residues (or neutralisation if any is left at non-product contact surfaces of equipment). Many food products contain chloride and have a pH between 3 and 5, a very corrosive combination. The corrosion resistance of stainless steel is provided for a large part by a thin but effective film of chromium oxide on the surface. If the film is damaged, mechanically or chemically, corrosion of the iron under the film starts. The lifetime of stainless steel can be extended substantially by ensuring that any damage to the chromium oxide film is repaired, which is possible by treatment with oxidising acids, such as nitric acid. This treatment is called 'passivation' and is discussed in Section 9.3.

Manufacturers need to be aware of other potential problems associated with particular processes. As an example, non-metallic surfaces used in dry materials handling can create electrostatic charges, which can cause surface adhesion by small particles of contaminating material. Electrostatic effects during dry materials handling in pneumatic conveying and other systems can be problematic. Such systems require particular care in the selection and use of materials.

9.2 Metals

From a practical point of view, the availability of alternative metals in use for food process equipment is very limited. While in certain parts of the industry metals other than stainless steel are used, it is the austenitic stainless steels that are the automatic choice as materials of construction for processing plants and equipment. Their popularity stems from their general resistance to corrosion by food products and to the recommended cleaning regimes, as well as from the ease with which they can be cleaned and sterilised.

In the majority of environments likely to be encountered in a food processing plant, the commonly used grades of stainless steel are the austenitic 18%Cr/10%Ni AISI-304 (1.4301) types and the four 17%Cr/12%Ni/2.5%Mo AISI-316 types. When choosing free-cutting stainless steels, it is important to ensure that the grade does not include lead or selenium. In fact, from the international suppliers of food processing equipment, type 316 stainless steel is now often the standard choice. But this is not always the case for specific plant items such as plate heat exchangers, which are available in a wide range of materials.

In most applications, the austenitic stainless steels give good service lives but, like any other material of construction, they have certain weaknesses. The major problem is their susceptibility to various forms of localised corrosion, to which they are susceptible for the very same reason that their overall corrosion resistance is so good. The tenacious, air-formed, oxide film which forms on their surface provides good corrosion resistance to most environments. However, where the oxide film is locally damaged, for instance by abrasion or fretting, and self-repairing action cannot take place, for whatever reason, intense local attack may ensue, often causing component failure for a relatively slight metal wastage. The four most common forms of localised corrosion are pitting, crevice corrosion, deposit attack and stress corrosion cracking, although given the appropriate conditions, corrosion fatigue is another possible failure mode. Localised corrosion in stainless steel is usually associated with environments containing the halide ions, which for the food process industry are almost always chlorides.

The flow diagram (Fig. 9.1) considers a number of factors that need to be taken into account when deciding which metal would be most suitable for the required application, and then gives a list of tests that would have to be carried out. The actual tests that are associated with the code numbers are shown below.

- A262 Practice for detecting susceptibility to intergranular attack in austenitic stainless steels
- A763 Practice for detecting susceptibility to intergranular attack in ferritic stainless steels
- B117 Test method for salt spray (fog) testing
- B571 Adhesion of metallic coatings
- G28 Test method for detecting susceptibility to intergranular attack in wrought, nickel rich, chromium bearing alloys
- G31 Practice for laboratory immersion corrosion testing of metals
- G32 Test method for cavitation erosion using vibratory apparatus
- G36 Practice for evaluating stress corrosion cracking test in a boiling magnesium chloride solution
- G44 Practice for evaluating stress corrosion cracking resistance of metals and alloys by alternate immersion in 3.5% sodium chloride solution
- G65 Measuring abrasion using the dry sand/rubber wheel apparatus
- G73 Practice for liquid impingement erosion testing
- G82 Guide for development and use of a galvanic series for predicting galvanic corrosion performance
- G99 Test method for wear testing with a Pin-on disk apparatus
- G102 Practice for calculation of corrosion rates related information from electrochemical measurements
- G110 Practice for evaluating intergranular corrosion resistance of heat treatable aluminium alloys by immersion in sodium chloride and hydrogen peroxide solution
- E8 Test methods for tension testing of metallic materials

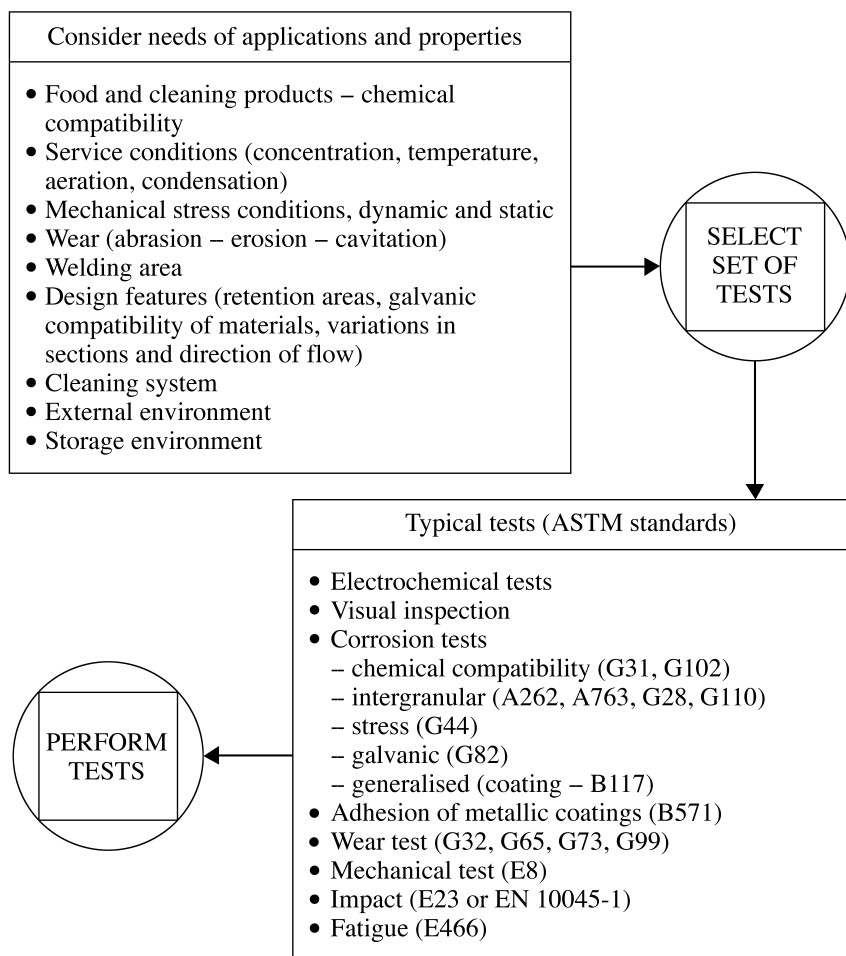


Fig. 9.1 Metallics flow chart of potential applications and their associated tests.

The correct selection and application of specific types of stainless steels depends on the corrosive properties of products, disinfecting and cleaning agents (especially chloride-containing fluids can lead to pitting corrosion or stress corrosion cracking) as well as on welding requirements. AISI-304 (or DIN Werkstoff No. 1.4301) is most commonly used in environments where product fluids do not contain any chlorides. Chloride-containing fluids can cause corrosion such as pitting. If chlorides are present, the molybdenum-containing AISI-316 types or sometimes titanium may be the better choice. AISI-316 (or Werkstoff No. 1.4401) and AISI-316L (or Werkstoff No. 1.4404) are recommended for equipment and pipework where chlorides are present and operating temperatures are moderate ($< 60^{\circ}\text{C}$). Stress corrosion cracking of AISI-316 type steel due to chloride attack does not occur at temperatures below

60°C, but will occur in the temperature range of 60–150°C. AISI-316 is recommended for components of equipment such as valves, pump castings, rotors and shafts, while AISI-316L is recommended for pipework and vessels due to its enhanced weldability. AISI-410 (or DIN Werkstoff No. 1.4006), AISI-409 (or DIN 1.4512), Duplex steel AISI-329 (or DIN 1.4460), and Incoloy 825 do not suffer from stress corrosion cracking, and may be required for specific applications.

Aluminium is not sufficiently corrosion resistant and should generally be avoided for most food contact applications. If nickel- or chromium-plated equipment is used, the plating must be manufactured reliably and its integrity checked. It must be ascertained that under conditions of use the plating cannot flake or otherwise contaminate the product and that it is resistant to corrosion from food products, cleaning and disinfecting agents. Chemically plated materials should be preferred over electroplating because of higher durability and more compact and dense surface layers.

Hygienic dry materials handling is best conducted with product contact surfaces of stainless steel. Suitable grades are SS 304, 304L (EN 1.4301/1.4306) and SS 316, 316L (EN 1.4401/1.4404). The 316 grades are more resistant to chloride-containing solutions, especially under wet and hot conditions. Metals that are at least as corrosion-resistant as stainless steel are also acceptable, for example Hastelloy. Aluminium and aluminium alloys (coated and non-coated) may also be used as dry material contact surfaces where only dry cleaning is applied. If aluminium is specified from an operational or weight aspect and wet cleaning is required, there is a potential corrosion problem which has to be addressed. Carbon steel can be considered as a contact surface in components involving dry processing and dry cleaning operations.

9.3 Passivation of stainless steel

Passivation is an important surface treatment that helps assure the successful corrosion-resistant performance of stainless steel used for product contact surfaces. Stainless steel derives its corrosion resistance from a thin, durable layer of chromium oxide that forms at the metal's surface and gives stainless steel its characteristic 'stainless' quality. The passive film on a stainless steel surface consists of a mix of iron, chromium and sometimes molybdenum oxides. The chromium oxide film forms in air instantaneously, if the stainless steel is clean and dry. This film will not form properly if product contact surfaces are not clean or contain surface defects. The passivation process enhances the chromium fraction in the passive film.

Passivation treatments are not designed to remove contaminants or defects such as heat tint, embedded iron particles, heat-treating scale, and other surface defects produced during fabrication. Elimination of these defects requires removal of the normal, protective oxide layers and between 25 μm and 40 μm of the substrate metal via pickling of the surface in a nitric-hydrofluoric acid bath.

Electrocleaning and electropolishing techniques are also useful alternatives to pickling.

The passivation process consists of:

- Mechanical cleaning
- Degreasing
- Inspection
- Passivation (immersion or spraying)
- Rinsing.

Cleaning and degreasing remove surface contaminants whilst the inspection stage checks that these stages have been successfully completed prior to passivation. The part to be passivated is then immersed or sprayed (depending on the size of the piece) in a nitric acid (HNO_3) solution. There are a number of solution variations (containing a combination of other oxidising acids) appropriate for all grades of stainless steel, in various heat treatment conditions and surface finishes. The use of an oxidising acid (such as nitric acid) for passivation has two purposes: firstly, the acid dissolves and high carbon steel; secondly, it assures a uniform, clean surface that results in the consistent formation of the passive chromium oxide film. Detailed information on passivation can be found in EHEDG Passivation guideline (Maller, 1998).

9.4 Plastics and composites

9.4.1 Plastics

Plastics are used in many areas, such as storage holders, hoses, pistons, conveyor systems, chains, moulds and polymethyl methacrylate sight glass. Plastic materials are often used to protect tools and implements from metal-to-metal contact (e.g. for shear edges of cutters), as guides and covers, or for hoses because of their plasticity and corrosion resistance. It must be noted that some plastics are porous and can absorb product constituents and harbour microorganisms. Poor initial selection has resulted in many failures of plastic components. Hence, the type of polymer must be approved for the application it is to be used for. There is such a wide range of different types of plastics with various properties that specific guidance, as given for stainless steel, is not possible. There is no standardisation available and it is dangerous to standardise. Thus only key points have been listed in Fig. 9.2.

Only certain materials are food approved and the supplier should be asked for details of the approved certification, and to demonstrate that the correct protocol has been followed to get approval in appropriate circumstances. The transfer of 'tainted' plastic results in the quality of the food being diminished. This occurs when food diffuses into the plastic and then subsequently there is leakage out of the plastic and back into 'later' food. Thus, diffusion rates and mechanical property changes must be determined. It should be noted that some cleaning detergents attack plastics, so it is essential that the correct agent is chosen for this purpose.

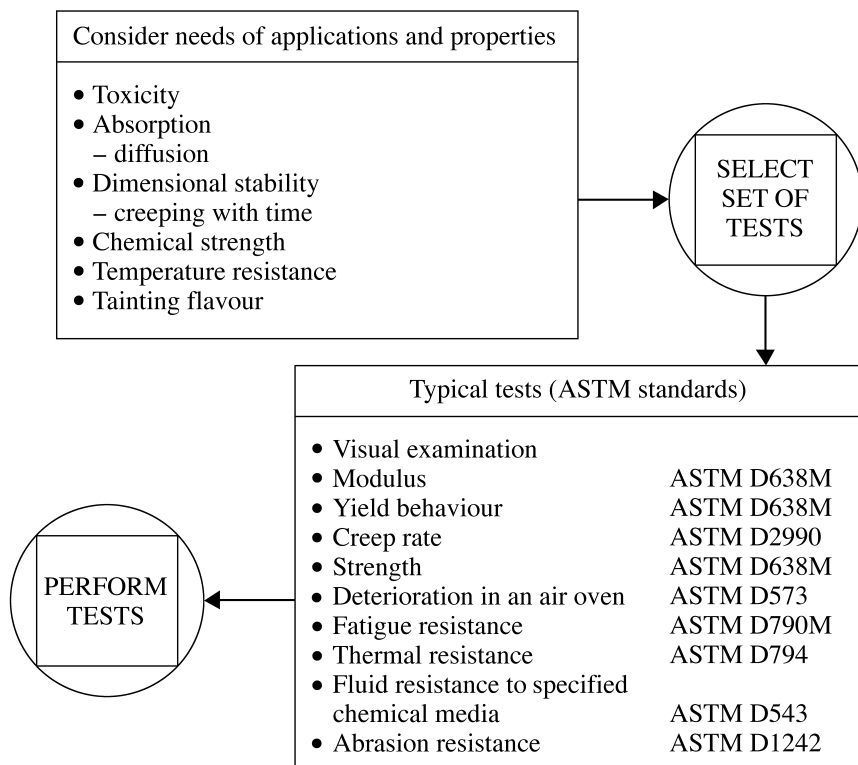


Fig. 9.2 Plastics flow chart of potential applications and their associated tests.

Plastics will degrade with time in certain chemical environments and the application of mechanical stress can accelerate this process and lead to environmental stress cracking (ESC). Combinations of effects, e.g. strain and temperature, occur in practice, so must also be considered. Accelerated tests can be performed that will enable plastics selection to be made in a more informed way. The problem with accelerated tests is that the method needs to be verified, i.e. extrapolation of the predictions and validity for the application. Injudicious choice of ageing temperatures also needs to be avoided. Specific plastics should be qualified for specific service conditions and expected lifetime. Currently fibre-reinforced plastics (FRP) and glass-reinforced plastics (GRP) are used for special cases, mainly at the front end of the process, i.e. storage of raw materials, etc.

The following plastics are easy to clean and are used in hygienic design:

- Polypropylene (PP)
- Polyvinyl chloride unplasticised (PVC)
- Acetal copolymer
- Polycarbonate (PC)
- High density polyethylene (PE).

Care should be taken if using polytetrafluoroethylene (PTFE) because it can be porous and then be difficult to clean. PTFE is not resilient enough to provide a permanently tight seal and is unsuitable for equipment intended for aseptic processing. Any exposed reinforcements (such as glass or carbon fibres and glass beads) in plastics should not come into contact with the product, unless the bond between reinforcement and plastic is such that penetration of product is not possible.

9.4.2 Composites

The main problem with woven composites is that they are susceptible to delamination, and for GRPs this can lead to the break-up of the glass fibre. However, special cases do exist, e.g. lined composite pipes. The use of carbon fibre could also help solve the problem. Typical tests that might need to be considered when choosing the most appropriate composite and the corresponding ASTM standards are shown below:

- Longitudinal tensile/compression modulus and strength (ASTM D3039, D3410)
- Transverse tensile/compression modulus and strength (ASTM D3039, D3410)
- In-plane/Interlaminar shear modulus and strength (ASTM D3518, ASTM D2344)
- Interlaminar fracture (ASTM D5528).

9.5 Elastomers

Rubber is one of the most widely used components for materials and equipment in the food industry. Rubber represents a family of materials whose main characteristic is high elasticity (resilience), i.e. the ability to return to the original shape once removed from the source of the stress. For this reason, rubber is considered the best material for objects such as gaskets, caps and hoses. A rubber compound is composed of a number of ingredients, e.g. elastomers, mineral fillers, plasticisers, activators, antioxidants, accelerants and vulcanising agents. The intrinsic properties of the rubber compound mainly originate from the elastomer, which is composed of long repetitive molecular chains of various origins, e.g. NR (Natural Rubber), EPDM (Ethylene-Propylene-Terpolymers), CIIR (Chlorobutyl-Isoprene-Isobutylene-Rubber), NBR (acryloNitrile-Butadiene-Rubber) and SBR (Styrene Butadiene Rubber).

Currently, compiling a list of suitable materials for a job is difficult for the following reasons:

- There are no standards for compounding between suppliers – thus precise compound formulations, mixing cycles and curing are required.

- All the conditions the material encounters, not just one specific condition, must be taken into account. These include not only such items as temperature range, ozone, UV, fat compatibility, etc., but also what the material is attached to, e.g. end fittings, and how it is treated, e.g. bent once and left in that position, subjected to continuous bending, etc.

To complicate the issue, there is a very wide range of elastomer types and for each one a large number of elastomer compounds that may be mixed by the supplier. Each of these may have different mechanical and chemical properties.

Accelerated tests can be performed that will enable elastomer selection to be made in a more informed way. However, there are limits to the knowledge available to interpret accelerated life tests. Thus, specific elastomer compounds should be assessed for specific service conditions and expected lifetime.

When considering fluid compatibility both mass uptake and leaching of ingredients by diffusion should be considered. Mass uptake curves should be obtained towards equilibrium and single-point fluid exposure tests should not be relied upon. For seals, the stress relaxation rate will reduce the sealing force and this may be enhanced by temperature cycles or by fluid contact during service even if there is no chemical effect.

Most suppliers' literature gives information on individual conditions, e.g. effect of stress, effect of temperature, etc. However, in reality the material will be affected by a combination of stresses and temperatures and this is not usually taken into account. It is important to know that high temperature combined with high stress can lead to premature failure. The scheme shown in Fig. 9.3 describes the general method for choosing the correct rubber for food products. Test results will decide whether a certain kind of rubber is or is not in accordance with the required standards, which themselves can change from time to time.

Many different types of elastomers are used in the food industry for seals, gaskets and joint rings. The recommended choices are:

- Ethylene Propylene Diene Monomer (EPDM) – though EPDM is *not* oil and fat resistant
- Nitrile rubber
- Nitrile/butyl rubber (NBR)
- Silicon rubber
- Fluoroelastomer (Viton).

The last two are appropriate for high-temperature applications (up to 180°C).

As with plastics, any reinforcement should not be allowed to contact product, unless the bond between the elastomer and the reinforcement is such that penetration of product is not possible. Excessive compression will cause damage to rubber components and may cause the elastomer to extrude into the product zone, adversely affecting cleanability. Therefore, where an elastomer is used as a seal between solid surfaces, the compression of the elastomer must be controlled (also taking into account thermal expansion during pasteurisation or sterilisation of product or equipment).

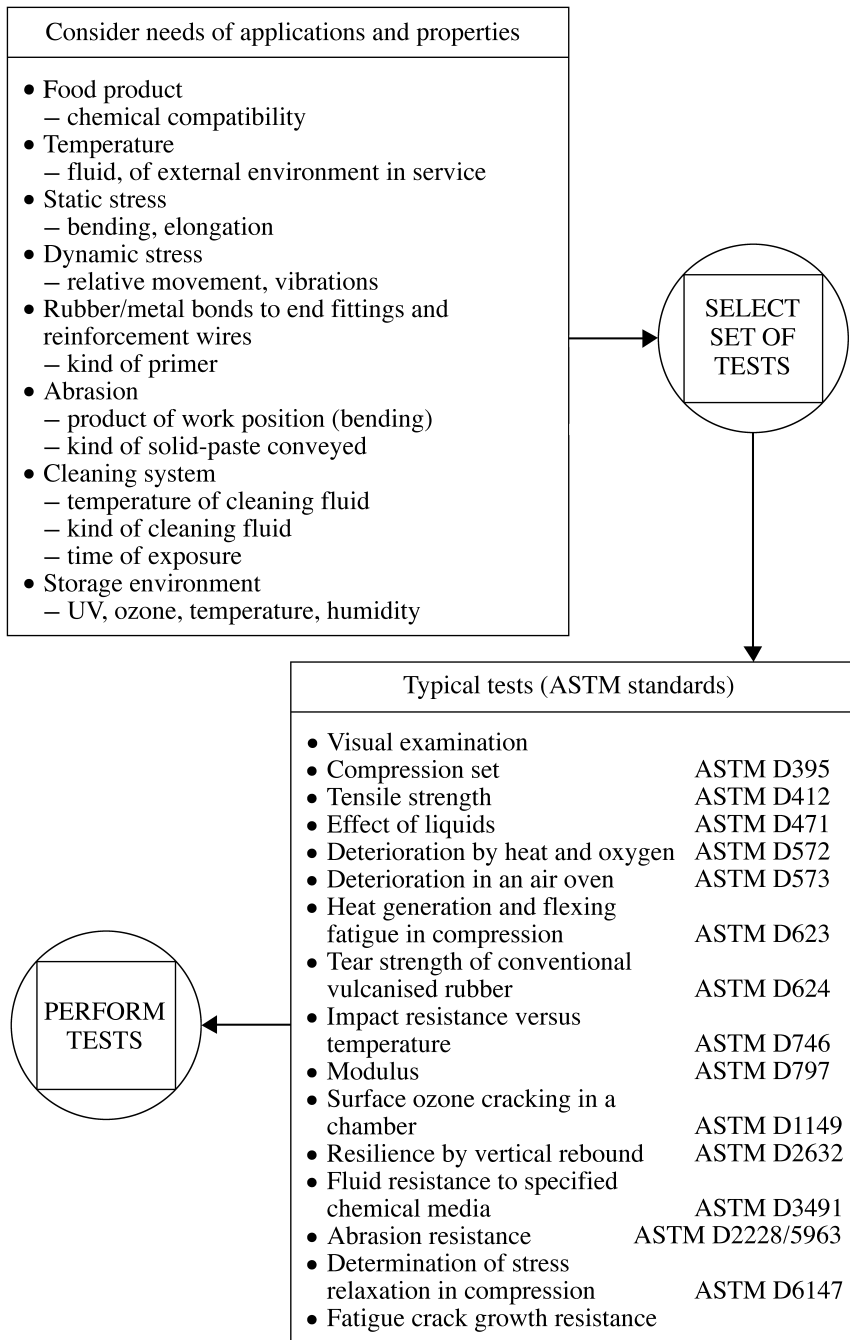


Fig. 9.3 Elastomers flow chart of potential applications and their associated tests.

9.6 Lubricants

Where machinery is intended to process foodstuffs, it must be designed and constructed so that no ancillary substances come into contact with the foodstuff products. Lubricants, grease and oil, however, are necessary components for the lubrication, heat transfer, pressure transmission and corrosion protection of machinery, machine parts, equipment and instruments. Even with the best design incidental contact with food cannot be fully excluded. In all these cases, lubricants need to be suitable for these sensitive areas under defined requirements. This requirement has been addressed by testing and authorising food-grade lubricants which are not toxic and will not cause taints or other quality problems.

The registration and authorisation of food-grade lubricants is based on procedures pioneered by the United States Department of Agriculture (USDA). It developed a series of procedures to authorise the inclusion of a lubricant in a positive list of 'Lubricants with Incidental Food Contact' set out in the US Code of Federal Regulations (21 § 178.3570). This registration process covered lubricants which could be used in machinery used for processing, packaging, holding or transporting food. It specified the chemical components allowed in oils and greases used for lubricating purposes, as protective anti-rust film, as release agent on gaskets and seals of tank closures, and for the lubrication of machine parts and equipment in locations where there is exposure of the lubricated parts to food or food ingredients. The registration of food-grade lubricants by USDA was accepted world-wide, including in Europe. USDA ceased its registration activities grading food-grade lubricants as H1 (authorised for food contact) or H2 (authorised for non-food contact uses only) in 1998. This decision left both lubricant manufacturers and the food industry with no independent, internationally recognised registration scheme, particularly for new lubricants not already registered under the USDA scheme.

The European Lubrication Institute (ELGI), the National Lubrication Institute (NLGI) and the European Hygienic Equipment Design Group (EHEDG) set up a working party in 1999 to develop a European equivalent to the USDA scheme. They developed a new Procedural Requirement for the Registration of Food Grade Lubricants (FGL 1/2000/issue 1) together with an audit checklist to verify that registration organisations are competent to review lubricants for registration (FGL 2/2001/issue 1). This formed the basis of a German standard DIN V10517 issued in 2001. The International Standards Organisation (ISO) are using this standard as a basis for a new ISO standard due to be finalised in 2003. In the United States the National Standards Foundation (NSF) has also developed a new standard, NSF 116-2000, based on the recommendations of the working party and DIN V10517. These standards are supported by guidelines, including those developed by the EHEDG.

9.7 Other materials

Ceramics are often used only for highly specialised applications such as active mechanical seal elements on rotating equipment. The use of glass is discouraged due to problems of detection in the plant should a breakage occur, but if glass has to be used, it has to be protected with a plastic coating. (Glass is commonly used as jars and containers, but not in product manufacture.)

Adhesives used for keeping gaskets in place must be non-toxic. They should always comply with the recommendations of the supplier of the equipment for which those gaskets are used. Adhesives can cause localised corrosion of stainless steel if not used according to the supplier's specification. All bonds must be continuous and mechanically sound so that the adhesive does not separate from the base materials to which it is bonded. Adhesives must be resistant to products and process conditions such as temperature.

Insulation equipment must be installed in such a way that the insulation cannot be wetted by ingress of water from the outside environment (e.g. hosing down, or condensation on cold surfaces). Ingress of water may lead to a build-up of chloride on stainless steel surfaces, resulting in stress corrosion cracking or pitting corrosion. Chloride attack can also take place from chloride release by improperly chosen insulating materials. Ingress of water will also encourage microbial growth and increase the risk of microbial contamination. Liquids used for signal transfer may come into contact with the process fluids if a membrane leaks. Food-grade qualities of silicone oil or glycerine should be used for this purpose.

Wood is appropriate only in a limited number of cases, for example when it plays a favourable role for relative humidity regulation and/or microbiology ecology (e.g. cheese ripening, the production of wine, vinegar, etc.) or when its mechanical properties cannot be obtained with other available materials (e.g. butchers' blocks). Wooden surfaces must be cleaned effectively and disinfected because they can retain microorganisms which can subsequently grow in the presence of product nutrients. Splinters can result in foreign body contamination.

9.8 References

MALLER, R. R. (1998) *Passivation of Stainless Steel*, EHEDG Guideline Doc. 18.

10

Piping systems, seals and valves

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10.1 Introduction

In a food processing plant piping systems are necessary for the transport of fluids between individual processing units such as raw material reception and storage to mixing tanks, fermentation, heat treatment and filling machinery. Typical elements of piping systems are pipelines (tube, bends, T-pieces), pipe couplings, valves and pumps. Hygienic design of such piping systems for the food industry differs from conventional industrial design in that hygiene aspects have to be integrated with normal design considerations to ensure the safe processing of food. Basic aspects of hygienic design and manufacture include:

- Hygienic materials and surfaces
- Drainability
- Cleanability
- Avoidance of dead spaces.

Piping should be designed to drain, with a pitch of 1 in 100. Pipework must be adequately supported to prevent sagging. Supports every 3–4 m are recommended. It is also important to provide for visual and microbiological inspection at key points, particularly those identified as difficult to clean. This can be achieved by having a short section which can be easily uncoupled to allow inspection of the rest of the pipe. The advantages and disadvantages of different configurations of piping are outlined in Table 10.1.

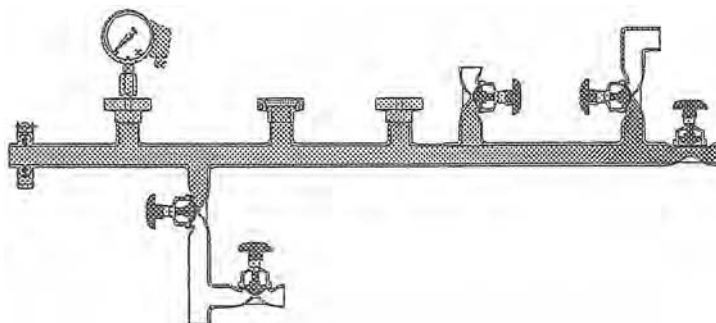
Hygienic pipe design must ensure in particular that all product contact areas are capable of being flushed during cleaning. It is still common practice to use T-sections for the installation of valves and instruments in process lines (Fig. 10.1). Hygienic design involves pocket-free installation to avoid harbouring

Table 10.1 Piping configurations for tank systems

Piping configuration	Characteristics	Advantages/disadvantages
Individual piping	<ul style="list-style-type: none"> Each tank has own connection for pipe No limitations to flexible use of tanks 	<ul style="list-style-type: none"> High flexibility Requires less planning re sequence of various functions Large amount of pipes and valves required
Group piping	<ul style="list-style-type: none"> Tanks grouped together Each group can be assigned to fulfil one function at one time 	<ul style="list-style-type: none"> Limited flexibility Requires pre-planning function sequence Limitation can be avoided by alternating functions between groups Reduced amount of pipes and valves required
Cross-piping	<ul style="list-style-type: none"> Tanks connected in cross-valve matrix Each group can be assigned to fulfil several functions at one time 	<ul style="list-style-type: none"> High flexibility Less planning of function sequence Fewer intersections and valves required

micro-organisms (Fig. 10.2). In addition, pockets, domes, sumps, pits, crevices, gaps, sharp edges or threads will influence cleaning efficiency.

To ensure cleanability, the minimum radius of internal corners under 135° should be 3.0 mm. A smaller radius must be carefully assessed to ensure it can be adequately cleaned under normal cleaning-in-place (CIP) procedures. All edges must be deburred. Exposed threads should be avoided wherever possible. Where these are necessary they must be suitably protected to prevent ingress of product,

**Fig. 10.1** Unhygienic use of T-sections creating dead spaces in piping.

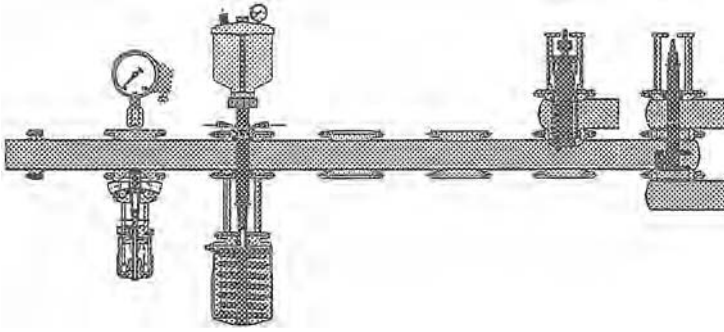


Fig. 10.2 Hygienic design of piping avoiding dead spaces.

or be of a proven open design that can be adequately cleaned under normal CIP processes. Similarly, where springs are employed in contact with the product, they must be of the open coil type, which when mounted in the equipment, allows easy access of cleaning fluid under normal CIP processes. Where spring ends are ground flat they should abut a flat surface with minimum surface contact.

Cleanability depends on ensuring, through good hygienic design, that cleaning fluid can reach all parts of the piping mechanism with sufficient force to remove product residue. Appendix A at the end of this chapter charts the impact of variables such as pipe diameter and surface frictional resistance on water flow velocity and pressure. Appendix B illustrates recorded drops in pressure resulting from different kinds of pipe fitting in pipes of differing diameters. Differing combinations of pipe diameter, surface roughness and fitting will give different pressures which, in turn, will determine the type of CIP process required and its effectiveness. Higher pressure drops or product velocity in some equipment, such as centrifugal pumps or packed glands of piston pumps, may make them easier to clean despite their not conforming to some of the hygienic requirements listed earlier.

10.2 Materials

All materials used for product contact surfaces should be inert, non-toxic, non-porous, non-absorbent and insoluble. In design and manufacture it is important to connect materials with the same level of corrosion resistance. In the majority of cases the AISI 300 series exhibit excellent corrosion resistance, but under certain circumstances corrosion problems can arise. The major weakness of stainless steels is their susceptibility to localised corrosion (such as pitting, crevice attack, deposit attack and stress corrosion), because the passive oxide film which normally forms a barrier to corrosion can be ruptured locally. This localised corrosion is invariably associated with environments that contain chlorides. The two most commonly used grades of stainless steel are the AISI 304 (18/10 Cr/Ni) and the AISI 316 (18/12/3 Cr/Ni/Mo) types. In the majority of

corrosive environments molybdenum-containing steel (316) is more corrosion resistant. Grade 316 is usually used for chloride-containing products especially when the products are hot. Previous experience of plant and equipment is a good indication of the grade of stainless steel that is required. Where increased material strength is needed, duplex steels, with similar or better properties than AISI 300, can be used.

Elastomeric or plastic materials may be used for gaskets, seals and O-rings. Such materials must conform to the requirements of an appropriate body, and must be able to withstand operational conditions. Lubricants that are sometimes used to facilitate the removal of the seals should be food-grade. Any bonding agents or adhesives should be non-toxic. There are some circumstances, particularly when highly acidic products containing chlorides are handled, when plastics are superior to stainless steel. The most widely used plastics materials for rigid pipes are polyvinylchloride (PVC), acrylonitrile butadiene systems (ABS), and polypropylene (PP). Plastic pipes are lighter and cheaper than stainless steel, but the maximum temperature at which they can be used is much lower (below 100°C). They also need a greater degree of support to prevent sagging. Plastic materials also have a much higher thermal expansion than stainless steel. Flexible pipes and hoses can be made of PVC, ethylene vinyl acetate, low density polyethylene, nylon, polytetrafluoroethylene (PTFE) or reinforced natural or synthetic rubber. The last two are mainly used in the brewing and dairy industries for emptying or filling road tankers.

10.3 Surfaces

Cleanability depends on the velocity of the cleaning liquid. Velocity depends in turn on a number of factors, including pump type and operation. If pumps of sufficient calibre are used, their effectiveness will still depend on surface resistance in the pipe. High cleaning liquid velocity will be achievable with surfaces with a roughness above $R_a = 0.8 \mu\text{m}$. Product contact surfaces above $R_a = 0.8 \mu\text{m}$ should be specified, and if higher levels of surface finish (a smoother surface with lower R_a value) are required, they should be clearly specified.

Surface treatments and coatings may be applied to product surfaces provided they meet a number of criteria. The thickness of engineering plating should not be less than 0.005 mm for all product contact surfaces when used on stainless steel. Cast or sprayed metallic coatings used on product contact surfaces should be at least 0.3 mm thick. Surface impregnation applied to product contact surfaces to enhance their corrosion resistance or wear resistance should be at least 0.1 mm deep. Ceramic materials used as coatings should be at least 0.8 mm thick. Non-product contact surfaces should be of corrosion-resistant material or material that is rendered corrosion-resistant.

10.4 Welding

The usual method of connecting component parts is by welding. Welds need to be sufficiently strong to meet operational requirements, including levels of pressure, as well as hygienic requirements (Eastwood *et al.*, 1993). To obtain a smooth weld the following should be prevented:

- Flaws in preparation due to: misalignment caused either by not aligning piping of the same size, or by the use of different sized pipes (slight differences in internal diameter can be eliminated by the use of an expansion device); too wide a gap between the parts which could lead to cracks in the centre of the weld; poor pipe cutting leading to variation in gap width
- Flaws in welding due to: porosity or imperfections in materials; using too much weld metal which then penetrates into the pipe and causes an obstacle for cleaning; using too little weld material, leaving a crevice left between the two parts; lack of fusion with the material from both parts, allowing crevices to form
- Lack of gas shielding: when welds are completed from one side only, for example pipework welds, the reverse surface must be shielded with an inert gas to avoid a roughened weld and heat affected zone.

Orbital welding is an automated version of manual TIG (Tungsten Inert Gas) welding. A typical orbital welding set consists of a motorised welding lead which rotates 360 degrees around a pipe, and a power source providing the current to strike the arc between the tungsten electrode and the weld area. A good manual welder can produce welds to the same quality as orbital welding, but an orbital welding machine will be consistent over time. Orbital welding should therefore be used whenever possible. Welds which are difficult to access should be completed in the workshop prior to installation (often this can also be done by the supplier of the piping). An alternative to welding bends into a pipe is to bend the pipe. This, however, requires skilled labour and specialised equipment. However, as many as 5 to 10 connections (welds or couplings) may be replaced by a single pre-bent pipe section.

10.5 Pipe couplings

Pipe couplings are an extremely important design feature, facilitating maintenance and replacement, and allowing greater flexibility in design. The basic requirement for hygienic pipe couplings are that they should be:

- reliably bacteria tight
- cleanable in place
- mechanically robust
- easy to handle and maintain.

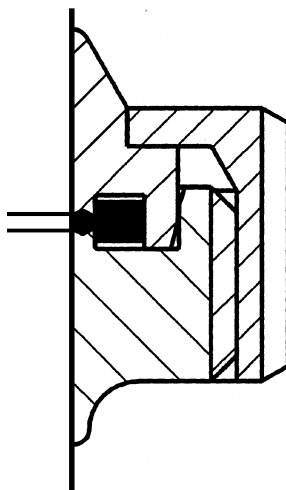


Fig. 10.3 Hygienic pipe coupling design (DIN 11846).

Table 10.2 Critical design parameters for pipe couplings

Critical design parameter	Recommendation
Resilient gasket material	Use elastomer gasket 70° Shore A
Surface roughness	Metal faces $\leq 0.8 \mu\text{m}$ R_a value Gasket surface as smooth as possible
Contact pressure	Minimum 1.5 N/mm^2 Maximum 2.5 N/mm^2
Pores at product contact surface	Metal parts: no pores Gasket: no pores $> 1 \mu\text{m}$
Friction	Avoid sliding during compression
Thermal expansion rate of elastomers = $15\times$ expansion rate of stainless steel	Minimise elastomer volume Provide bi-directional expansion possibilities
Elastomers not compressible but can be deformed	Allow for room to accommodate deformed gasket volume
Recess of gasket at product side	Max. 0.2 mm
Protrusion of gasket at product side	Max. 0.2 mm
Stress in elastomers	Avoid tensile stress Limit compression to 20–25%
Tolerances	Critical areas: – location of coupling halves – compression of gasket – inside diameters
Damage to sealing faces	Protect faces against damage

Pipe couplings should be designed to the standard DIN 11 846 (Fig. 10.3). Couplings typically consist of two metallic partners welded to the pipelines with a polymer seal in between. The two metallic partners are typically kept together by flange screws, a V-clamp or a threaded collar nut. Critical design parameters for pipe couplings are listed in Table 10.2.

An essential element in a standard pipe coupling design is the gasket. Key requirements for gaskets are as follows:

- Gasket material must not be overstressed due to mechanical limitations in the design.
- The volume of the exposed part of the gasket should be minimal to limit the effects of thermal expansion.
- As small an area of the gasket as possible should be exposed to the product.
- The gasket should be given some stiffness for handling but should have room for expansion.
- The solid shoulder should allow for easy inspection.
- Misalignment of the male part and the liner should be prevented by locating the male part in the liner.
- The gasket should be a press-fit in the male part recess. This prevents it from dropping out.
- The sealing faces should be well protected against impact damage.

10.6 Seals

Seals are needed to close gaps between individual parts. General requirements for seals are that they should be:

- resistant to processing temperature and pressures
- resistant to steam sterilisation
- made of material compatible with and resistant to product media and chemicals used for cleaning and sterilisation
- bacteria-tight under all conditions of temperature and pressure as mentioned above
- capable of a useful lifetime of approximately one year.

They are typically made of a polymer material. The material must conform with the requirements of the FDA 1770 'white list'. Typical materials for seals are described in Table 10.3. Using the correct material is essential, as is providing the right design in which the seal is placed. The thermal expansion of elastomers is very high compared with that of stainless steels. The difference may be as high as a factor of 15 in the case of silicone rubber. If thermal expansion is not properly considered in the design of the sealing system, the seal may suffer serious damage. Apart from the fact that seals will age much more quickly and become unfit for effective cleaning, they may break and the product may become contaminated by small pieces of elastomer material. Depending on the

Table 10.3 Typical materials for seals

Material	Characteristic and use
EPDM elastomer	<ul style="list-style-type: none"> • General purpose material • Good resistance against typical CIP media and steam • Not suitable for products with higher fat content, especially containing mineral oils/fats
HNBR elastomer	<ul style="list-style-type: none"> • General purpose material • Good resistance against fat, lye and steam • Mechanically strong against wear and cracks • Limited resistance against hot acids • Compression set not as good as MVQ and EPDM
MVQ (Silicon) elastomer	<ul style="list-style-type: none"> • Suitable for fat-containing products • Good compression set, especially at low temperatures • Limited resistance against hot acids
FPM (Viton) elastomer	<ul style="list-style-type: none"> • Good resistance against fat and media from industrial applications • Limited resistance in hot water, steam and hot acids
PTFE	<ul style="list-style-type: none"> • Universal resistance • Must be backed up by a resilient spring to maintain contact pressure

material, food product, CIP solutions and steam for sanitation may dissolve some polymer materials. The right materials and good sealing system design can enhance seal life considerably. Nevertheless, seals must be seen as wearable parts and must be replaced at regular intervals. A deformed resilient gasket will maintain a high enough contact pressure on the mating metal sealing faces to ensure reliable bacteria tightness. However, loss of resilience caused by ageing through slow vulcanisation necessitates regular inspection and periodic replacement. Seals also need lubrication for installation and to reduce friction. Lubricants in contact with foodstuffs must comply with the USDA H1 classification.

As well as appropriate materials, the effectiveness of the seal will depend on the conditions of the sealing faces of the parts being sealed. Surface roughness should be a maximum of $0.8 \mu\text{m } R_a$ (approx $4 \mu\text{m } R_z$). The seal must also press onto the face of the parts being sealed with sufficient pressure. The degree of pressure will depend on the resilience of the seal. As an example, a minimum contact pressure of 1.5 N/mm^2 is required when using a 70° Shore A hardness elastomer. This contact pressure is obtained when the elastomer gasket is compressed by 15% of its original thickness. It is recommended to limit the compression rate to 20–25% to achieve an acceptable degree of reliability. In this respect, the shape and design of the seal are important. Cracks will develop not only when excessive tensile stresses are present but also when the gasket geometry is such that large differences in compressive stress are present. This

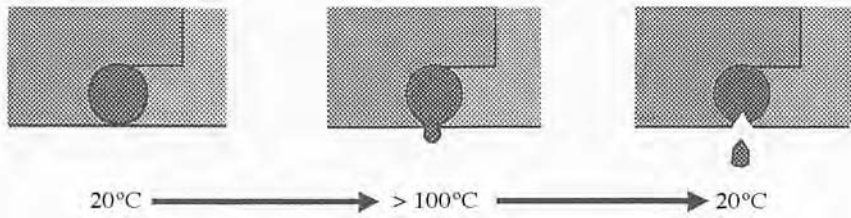


Fig. 10.4 Unhygienic seal design causing heat damage to an o-ring gasket.

usually happens at sharp inside corners. If these corners are well radiused, the transition from high to low stress takes place more gradually and the development of cracks can be prevented.

As has been noted, seal design must also take account of the higher thermal expansion of elastomers in comparison with stainless steels. Figure 10.4 illustrates the problem. If a seal has no room for expansion, an increase in temperature will result in the elastomer becoming deformed and protruding. Theoretically the elastomer will revert to the original position when the temperature is lowered, but in practice the effects of friction and loss of resilience due to temperature and deformation make this less probable with time. The protruding elastomer will either attract contaminants or break, contaminating the product itself. The effects of thermal expansion at the product side may be reduced by the possibility for expansion on the non-product side. When doing so, care must be taken that product pressure will not force the gasket into this expansion recess. This is another reason why the gasket area that is exposed to the product must be kept as small as possible. An appropriate design is shown in Fig. 10.3. The main features are:

- The maximum deformation is 20% at the product interface.
- The volume of the functional part of the gasket is minimal to limit the effects of thermal expansion.
- A small area of the gasket is exposed to the product.
- The gasket is given some stiffness for handling by a solid shoulder (which also allows the small functional part of the gasket to expand in two directions).

It is also important to design sealed joints to prevent any misalignment (see Fig. 10.5).

10.7 Valves

Every process plant is equipped with valves. Hundreds or even thousands of valves can be found in a matrix-piped, liquid conveying plant, depending on the system's size. Valves fulfil numerous functions in process plants: shut-off and opening of pipes, change-overs, control, protection against excessive or insufficient pressure or against intermixing of incompatible media at intersection

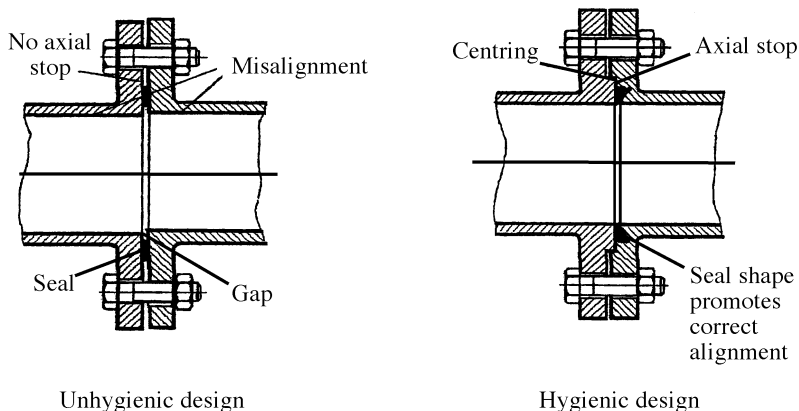


Fig. 10.5 Preventing gaps and misalignment in pipe couplings: hygienic and unhygienic designs.

points in pipes. The common key hygienic requirements for valves are summarised below (Baumbach *et al.*, 1996):

1. **Cleanability:** all surfaces in contact with product must be cleanable with special attention to the seats and seals.
2. **Surface:** surface roughness has a significant influence on cleanability. The higher the surface roughness, the longer the required cleaning time. In principle, treatment of product contact surfaces should result in a roughness of $R_a \leq 0.8 \mu\text{m}$. A rougher surface may be acceptable, but a deviating surface roughness must be clearly specified. (For instance, in the beverage industry, a surface roughness of $R_a = 1.6 \mu\text{m}$ is usually acceptable.)
3. **Materials:** the materials used for valves, including those for static and dynamic seals, must be suitable for the intended application.
4. **Geometry:** valve design must ensure full liquid exchange in all areas in contact with product. In addition to the exchange of liquids during production and cleaning, it is important that gas pockets do not remain in the valve when liquid flows through. Therefore, in the product area, pits, crevices and gaps, sharp edges, threads and dead ends should be avoided. If a dead end cannot be avoided, it must be as short as possible, in a drainable position and cleanable. If cleanability depends on a specific procedure (i.e. flow direction during CIP), this procedure must be clearly indicated.
5. **Drainability:** it must be possible to drain a valve completely in at least one installation position without need for dismantling.
6. **Seals:** the number of seals in a valve should be as few as possible. Care must be taken to ensure that the deformational properties of the sealing material are controlled under all conditions. Too low deformation of a seal is as disadvantageous as too high deformation. Seals should be adequately supported. The sealing material should project as little as possible into the product area, and should not inhibit drainage.

7. **Springs:** springs in contact with product should be avoided. Where springs are in contact with product they must have minimum surface contact. It is important to document how all soiled surfaces can be cleaned.
8. **Leak detection:** valve design should provide for quick external detection of internal leakage, e.g. by diaphragm valves and mixproof valves. In addition, it must not be possible for the liquid to transfer from actuators into product areas.
9. **Outside surfaces:** outside surfaces of valves should be easy to clean.
10. **Documentation:** comprehensive information and recommendations on valve installation, operation, cleaning and maintenance should be documented.
11. **Microbial impermeability:** for aseptic applications, the dynamic seals of moving shafts in contact with product must incorporate a barrier between the environment and the product to prevent ingress of micro-organisms. Double seal arrangements should preferably be designed in such a manner that the distance between the two seals is greater than the stroke of the shaft. If this is not the case, the ability to prevent the ingress of micro-organisms must be demonstrated. It must be possible to remove micro-organisms from all product contact surfaces and all surfaces between the two seals. For aseptic applications, moving shafts in valves must preferably be separated from the product side by either diaphragm or bellows.

Requirements for particular valve types are:

- **Diaphragm and bellows valves:** leakage should be detectable by free outlet to the atmosphere or by a specific leakage detection system.
- **Plug valves:** plug valves are not fit for cleaning in place. Instructions for use must state clearly that dismantling is necessary for cleaning.
- **Pressure relief valves:** these valves must be self-draining to the outlet side to avoid accumulation of product residues.
- **Ball valves:** the area between ball, housing and seat faces must be cleanable. Traditional ball valves are not designed for CIP. If intended for CIP, the area between ball, housing and seat faces must be positively integrated into the CIP flow.
- **Mixproof valves:** mixproof valves are defined as valves which safely exclude the intermixing of incompatible fluids between separate product lines by forming a neutral area between the product lines. The neutral area must be drainable to atmosphere, cleanable and designed in such a way that a leak cannot result in the build-up of pressure.

10.8 Mixproof valves

Food process plants now incorporate various multifunctional flows. Often one piping system is cleaned while another still contains product (Fig. 10.6). This situation can be potentially dangerous where product and cleaning liquid are

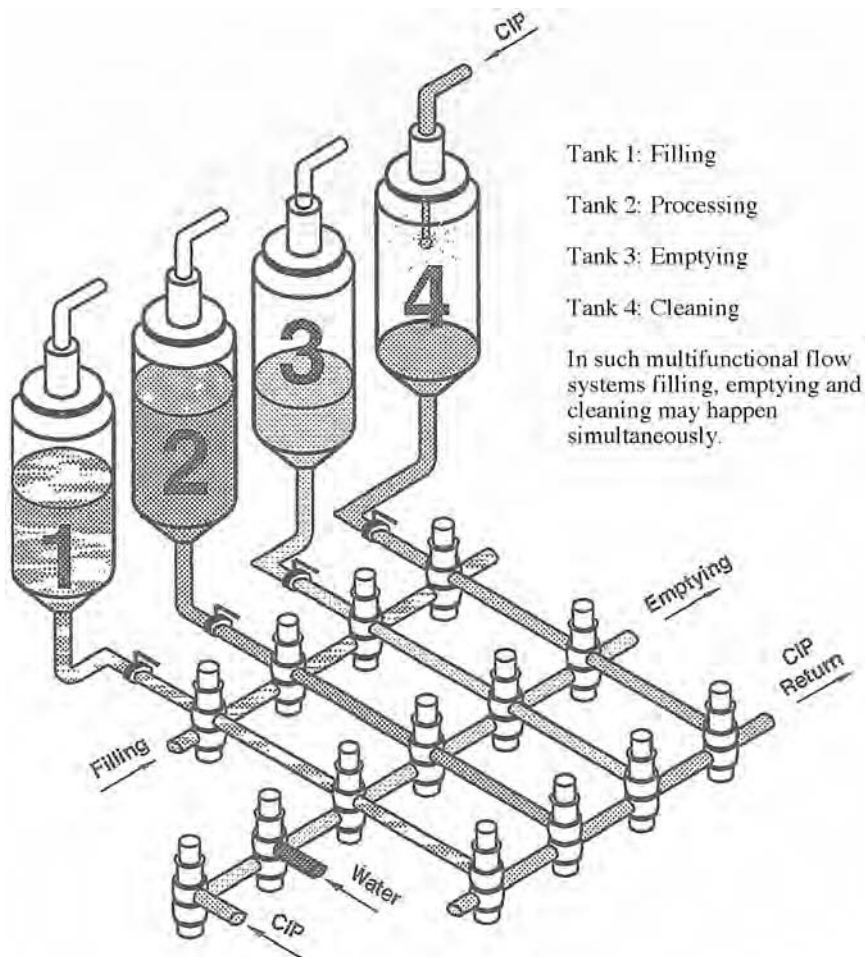


Fig. 10.6 Multifunctional use of piping systems.

separated by a single valve seat. Any cleaning liquid that leaks across such a seat will contaminate the product. To prevent such contamination, single-body double-seat mixproof valves are used.

Double-seat mixproof valves have a similar basic design. A typical design consists of a valve housing with two chambers (see Fig. 10.7). Each chamber has at least one port connected with a pipeline in the piping system. Between the two chambers the valve seat area is arranged with two seats, usually one on top of the other with a separation cavity in between. The seats consist of an upper and lower closure device, typically a disc, which are connected to independent upper and lower shafts for opening, closing and individual seat lifting. The cavity between the two seats is open to the outside (vent). Leakage from this cavity is then used for leak detection of these seals.

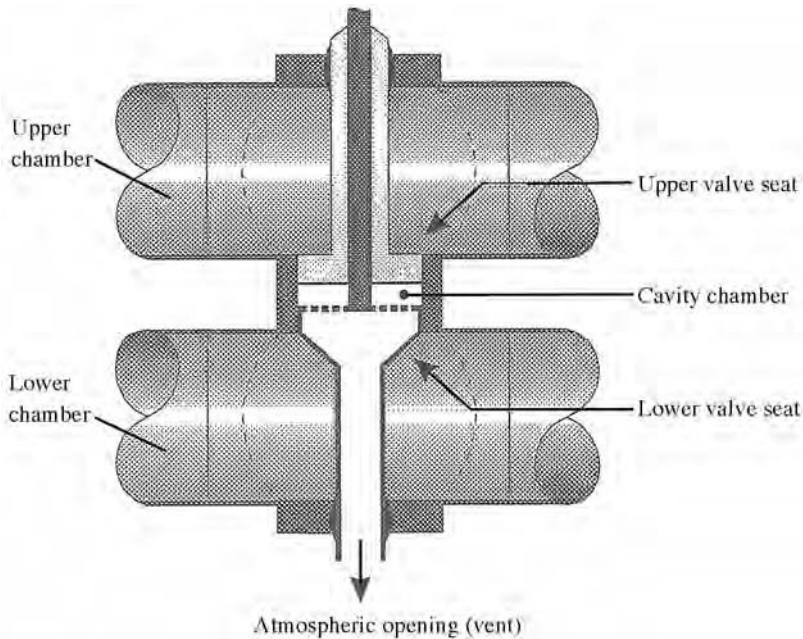


Fig. 10.7 Double-seat mixproof valve.

To limit microbial contamination the reciprocating shaft can be sealed by an elastomeric or polymer lip seal. This seal is easily cleanable, but will not prevent the ingress of micro-organisms. In aseptic process lines where ingress of micro-organisms must be prevented, the shaft must be sealed by a continuous barrier, for example a membrane or bellows. Automatic control systems for bellows are available from suppliers. A steam or sterile barrier may also be applied in the atmospheric opening (vent) to prevent ingress of micro-organisms. Defined leakage paths designed to provide immediate detection must be in place for all process seals, such as housing seals, seat seals and shaft seals. These leakage paths must also ensure minimum effect on production operations, while providing an immediate indication of seal service requirements.

During normal operation of a mixproof valve the following areas are soiled with product residues:

- The upper chamber of the valve housing by the product being conducted through the pipeline.
- The seat area between the two chambers when the valve is in the 'open' position.
- The cavity with the drainpipe in the bottom shaft due to operational leakage and leakage due to worn seat seals.
- The lower chamber of the valve housing by the product being conducted through the pipeline.

Typical methods to clean the surfaces concerned are:

- Pipeline cleaning in place for independent cleaning of the housing chambers limited by the shaft seal on the one side and the seat seal on the other side.
- Seat (plug) lifting to flush the seat seal and an eventual metallic stop (common on axial seals), the cavity and the drain pipe.
- Cavity spray cleaning to reach the leakage chamber up to the seat seals and the drainpipe.
- Shaft cleaning to reach the shaft surface and the area behind the shaft seals.

If a double-seat mixproof valve is to be operated hygienically, the following requirements should be met:

- Valve seats must be moved into the closed position and held there by a spring.
- Failure of the independent valve seat to close must be detected and alarmed.
- The valve disc seals must be individually pressed into their closed positions.
- The design must ensure that unintended movement of one disc cannot be transferred to the other.
- The neutral area must be drainable by gravity and maintained at atmospheric pressure.
- The valve must also retain its closed position during vacuum in the connecting upper or lower pipelines.
- Care must be taken of pressure surges, for instance by using valves with balanced shafts or designing the installation to prevent the valve seats from opening.
- Both seats must be in the closed position before the pipeline CIP or cavity spray process can be activated. Only on tank applications is it necessary to open the valve to drain the tank via the CIP return-line.

10.9 Further reading

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Appendix A: Determination factors for water flow velocity (*c*) and frictional resistance (*h*) in straight pipes per 100 m

Diameter (mm)	20		25		32		40		50		65		80		100		125		150		175		200	
Content	0.31		0.5		0.8		1.25		1.96		3.31		5.02		7.85		12.27		17.66		24		31	
Flow rate (m³h)	<i>c</i> (m/s)	<i>h</i> (m)	<i>c</i> (m/s)	<i>h</i> (m)	<i>c</i> (m/s)	<i>h</i> (m)	<i>c</i> (m/s)	<i>h</i> (m)	<i>c</i> (m/s)	<i>h</i> (m)	<i>c</i> (m/s)	<i>h</i> (m)	<i>c</i> (m/s)	<i>h</i> (m)	<i>c</i> (m/s)	<i>h</i> (m)	<i>c</i> (m/s)	<i>h</i> (m)	<i>c</i> (m/s)	<i>h</i> (m)	<i>c</i> (m/s)	<i>h</i> (m)	<i>c</i> (m/s)	<i>h</i> (m)
0.4	0.35	1.31	0.23	0.44	0.14	0.18																		
0.6	0.53	2.79	0.34	0.92	0.21	0.27																		
0.8	0.71	4.75	0.45	1.55	0.28	0.46																		
1	0.89	7.19	0.57	2.36	0.35	0.69	0.22	0.23																
1.2	1.06	10.10	0.68	3.29	0.42	0.96	0.27	0.32																
1.4	1.24	13.53	0.79	4.36	0.48	1.27	0.31	0.43																
1.6	1.42	17.41	0.91	5.56	0.55	1.65	0.35	0.54																
1.8	1.59	21.75	1.02	6.95	0.62	2.04	0.40	0.67																
2	1.78	26.35	1.13	8.45	0.69	2.49	0.44	0.79	0.28	0.27														
2.5			1.41	12.84	0.87	3.76	0.55	1.21	0.35	0.41														
3			1.70	18.27	1.04	5.27	0.68	1.72	0.43	0.57														
3.5			1.98	24.20	1.22	7.11	0.78	2.28	0.50	0.75														
4					1.38	9.05	0.89	2.91	0.57	0.96	0.33	0.25												
4.5					1.56	11.25	1.00	3.64	0.64	1.20	0.38	0.31												
5					1.73	13.73	1.11	4.43	0.71	1.45	0.42	0.38												
5.5					1.90	16.53	1.22	5.35	0.78	1.75	0.46	0.46												
6					2.08	19.50	1.33	6.29	0.85	2.03	0.50	0.54												
7					2.42	26.60	1.55	8.40	0.99	2.72	0.59	0.73	0.39	0.26										
8						1.77	10.85	1.13	3.50	0.67	0.94	0.44	0.33	0.28	0.11									
9						1.99	13.63	1.27	4.36	0.75	1.13	0.50	0.42	0.32	0.14									
10						2.21	16.70	1.42	5.25	0.84	1.43	0.55	0.51	0.35	0.17									
12						2.68	23.65	1.70	7.63	1.00	2.01	0.67	0.71	0.43	0.24									
14							1.98	10.21	1.17	2.70	0.78	0.95	0.50	0.31	0.32	0.10								
16							2.27	13.07	1.34	3.48	0.89	1.23	0.57	0.40	0.36	0.13								
18							2.55	16.62	1.51	4.37	1.00	1.53	0.64	0.50	0.41	0.17								
20							2.83	20.40	1.67	5.33	1.11	1.86	0.71	0.61	0.45	0.20								















Diameter (mm)	20	25	32	40	50	65	80	100	125	150	175	200
Content	0.31	0.5	0.8	1.25	1.96	3.31	5.02	7.85	12.27	17.66	24	31
Flow rate (m ³ /h)	c	h	c	h	c	h	c	h	c	h	c	h
	(m/s)	(m)	(m/s)	(m)	(m/s)	(m)	(m/s)	(m)	(m/s)	(m)	(m/s)	(m)
22			3.12	24.20	1.84	6.42	1.22	2.24	0.78	0.73	0.50	0.24
24					2.00	7.56	1.33	2.65	0.85	0.86	0.54	0.280.38
26					2.18	8.82	1.44	3.07	0.92	1.00	0.59	0.330.41
28					2.35	10.17	1.55	3.53	0.99	1.14	0.63	0.370.44
30					2.51	11.58	1.66	4.03	1.06	1.30	0.63	0.430.47
35					2.93	15.66	1.94	5.42	1.24	1.73	0.79	0.570.55
40					3.35	20.28	2.22	7.03	1.42	2.24	0.91	0.730.63
45					3.77	25.38	2.49	8.78	1.59	2.80	1.00	0.910.71
50					2.77	10.81	1.77	3.44	1.13	1.110.79.	0.45	0.58
55					3.05	12.95	1.95	4.13	1.25	1.330.87	0.53	0.64
60					3.32	15.38	2.13	4.90	1.36	1.570.94	0.63	0.69
65					3.60	18.00.	2.30	5.70	1.47	1.831.02	0.74	0.75
70					3.88	20.78	2.48	6.55	1.59	2.101.10	0.84	0.81
75					4.15	23.72	2.65	7.50	1.70	2.391.18	0.96	0.87
80					4.43	26.93	2.83	8.50	1.81	2.711.26	1.09	0.92
85								3.01	9.60	1.93	3.101.34	1.22
90								3.19	10.70	2.04	3.401.42	1.36
95								3.36	11.80	2.15	3.761.49	1.50
100								3.54	13.10	2.27	4.151.57	1.66
110								3.89	15.80	2.49	5.001.73	1.99
120								4.25	18.75	2.72	5.901.89	2.36
130								4.60	21.90	2.95	6.902.05	2.74
140											3.17	7.962.20
160											3.62	10.332.52
180											4.08	13.052.83
200											4.53	16.033.15

The frictional resistance (*h*) of the numerical table is valid for medium-rough pipelines(*k* = 0.1 mm).

New, polished pipelines (*k* = 0.05 mm) are to be multiplied by 0.9; very rough, longer working pipelines (*k* = 0.5 mm) are to be multiplied by 1.4.

Appendix B: Pressure drop values for fittings in metre equivalent pipe lengths (m)

Valid for pipe roughness $k = 0.05$ mm, flow velocity $\nu = 1\text{--}3$ m/s (error >10% for other velocities) (accuracy $\pm 5\%$)

Fitting		Nominal width (mm)								
		25	32	40	50	65	80	100	125	150
$\zeta = 0.05$ reducer		0.05	0.07	0.09	0.12	0.17	0.20	0.28	0.40	0.48
Tee										
$\zeta = 0.15$ bend 45°		0.14	0.20	0.27	0.35	0.50	0.60	0.85	1.20	1.40
$\zeta = 0.25$ bend 90°		0.25	0.35	0.45	0.60	0.80	1.00	1.35	1.90	2.4
Extension										
Butterfly valve		0.4	0.8	0.8	1.2	1.2	1.2	1.9	2.5	2.8
Inlet (tank outlet)										
$\zeta = 0.90$ tee		0.90	1.20	1.60	2.00	3.00	3.70	5.20	7.00	8.80
$\zeta = 1.30$ tee		1.20	1.80	2.30	3.00	4.30	5.40	7.40	10.00	12.50
$\zeta = 1.5$ reflux valve		1.40	2.10	2.70	3.50	5.00	6.30	8.50	11.50	14.50
Angular sieve mesh width 1.6 mm ²				6.50	8.00	13.00	14.00	22.00		
Shut-off valve		2.00	4.00	2.50	5.00	6.00	10.00	13.00	24.00	34.00
Shut-off valve										
Mixproof valve				10.50	9.50	21.00	40.00	48.00	24.00	34.00
Valve housing		0.80	1.00	1.50	1.40	1.70	2.20	3.00	4.00	5.00

11

Cleaning in place

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11.1 Introduction

Cleaning in place (CIP) may be defined as the circulation of chemical solutions and/or water through a process plant that remains assembled in its production configuration, such that all product contact surfaces are cleaned (and, if appropriate, disinfected) to an acceptably high and consistently reproducible standard. This system of cleaning is engineered to clean processing equipment without dismantling and reassembling the different units in the production process. The advantages of CIP systems include:

- **Cost savings.** CIP ensures optimum use of water, detergent, sterilant and steam to produce economy in operation.
- **Increased plant utilisation.** Tanks and pipelines can be cleaned as soon as they are empty and refilled immediately after cleaning. Thus unproductive downtime is minimised.
- **Minimum manual effort.** Manual operations can be reduced or eliminated entirely, depending upon the degree of automation designed into the plant.
- **Greater safety.** Personnel have no need to enter vessels. The risk of falls on slippery internal surfaces is eliminated and personnel do not have to enter hazardous atmospheres.
- **Improved hygiene.** Cleaning schedules are better adhered to and more consistent results are obtained. Thus product quality is improved and shelf life extended.
- Elimination of the need for reassembling equipment after cleaning, thus reducing the chance for recontamination of the cleaned plant.
- Reduced disassembly damage and wear and reduced maintenance and repair costs.

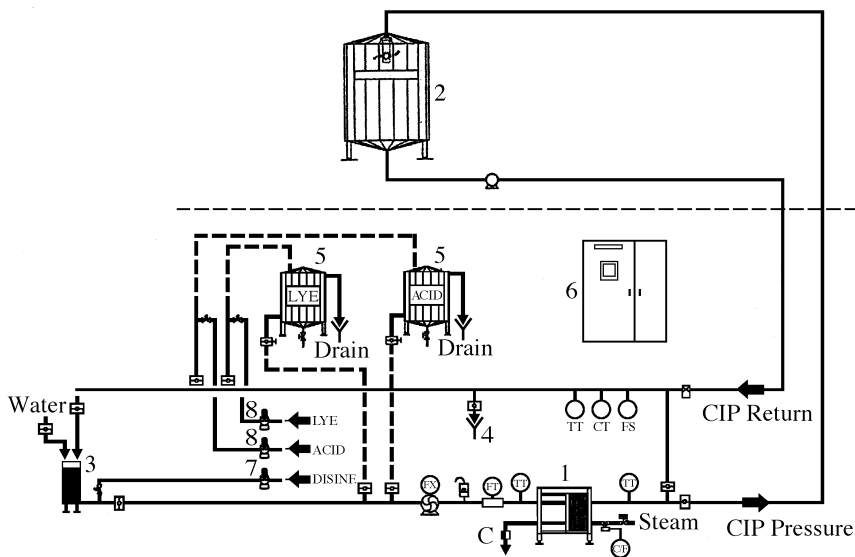
The disadvantages of CIP systems are:

- **Cost.** Because most CIP systems are custom designed, design and installation costs add to the high price of the equipment.
- **Maintenance.** More sophisticated equipment and systems tend to require more maintenance.
- **Inflexibility.** These cleaning systems can effectively clean in only those areas where equipment is installed, whereas portable cleaning equipment can cover more area. Heavily soiled equipment is not as effectively cleaned by CIP systems, and it is difficult to design units that can clean all processing equipment.

As labour costs continue to increase and hygienic standards are raised, cleaning-in-place (CIP) systems have become more important. Dairies and breweries have used CIP for many years. It has been adapted sparingly in other plants because of equipment and installation costs and the difficulty of cleaning certain processing equipment. The use of CIP systems in the meat and poultry industry, for example, is limited. This equipment is expensive and lacks effectiveness in heavily soiled areas. CIP cleaning has some application in vacuum thawing chambers, pumping and brine circulation lines, pre-blend/batch silos, and edible and inedible fat-rendering systems. CIP is regarded as the method of choice for cleaning tanks, pipelines, pumps and, where applicable, valves. It is also used for cleaning vats, heat exchangers, centrifugal machines and homogenisers. To be successful, CIP application should be designed in from the start. Attempts to fit a CIP system retrospectively to equipment which has already been designed and installed are likely to prove expensive and are often not fully effective.

11.2 Principles of CIP systems

Figure 11.1 illustrates how a CIP system operates. A system of mixing and storage tanks for cleaning chemicals and detergents together with pumps allows cleaning and sanitising fluids to be pumped to equipment. Pipelines, for example, can be cleaned by a high-velocity cleaning solution circulating through the system. Larger vessels such as storage tanks and vats can be cleaned by the use of spray-balls mounted at the top of the vessel spraying cleaning chemicals uniformly on relevant surfaces. A typical cleaning cycle for a CIP system is shown in Table 11.1. CIP may be undertaken without the addition of extra equipment. This is possible when, for example, an ingredient tank is present at the beginning of a process with a volume sufficient to contain enough cleaning solution for the whole system to be cleaned. This tank can be cleaned manually and subsequently filled with cleaning solution. If the existing pumps lack sufficient capacity for pipe cleaning and spray-ball supply, they can be supplemented by additional dedicated CIP pumps. Cleaning fluids are used only once and discharged once the cycle is terminated.



1. Plate heat exchange; 2. cleaning circuit (e.g. tank); 3. circulation tank; 4. drain; 5. detergent solution tanks; 6. control panel; 7. metering pump for disinfectant; 8. metering pump for detergent concentrate; TT: temperature transmitter; FS: flow switch; CT: conductivity transmitter; FX: frequency control; FT: flow transmitter

Fig. 11.1 CIP system for tanks and piping.

The advantage of such a basic CIP system is that hardly any investment in additional equipment is needed. However, the running costs may be high in chemicals and energy. Moreover, cleaning may take a long time because, after each cycle, a new batch of cleaning fluid has to be prepared (dissolved/diluted and optionally heated). Such a basic system is only recommended for relatively small process plants. For bigger process plants a tailor-made, dedicated CIP system is recommended that can supply the various cleaning circuits in the plant with the required cleaning solutions at the right conditions at the right time. Such a CIP system may be composed of one or more tanks, pumps and a more or less automated control system.

Table 11.1 Typical operating cycle for a CIP system

Operation	Function
<ul style="list-style-type: none">• Preliminary rinse (hot or cold water)• Detergent wash• Rinse• Sanitisation• Final rinse (optional, according to sanitiser use)	<ul style="list-style-type: none">• Remove gross soil• Remove residual soil• Remove cleaning compounds• Destroy residual microorganisms• Remove CIP solutions and sanitisers

The principle of a CIP system is to combine the benefits of the chemical activity of the cleaning compounds with the mechanical effects of soil removal. The cleaning solution is dispensed to contact the soiled surface, and the proper time, temperature, detergency and force are applied. The effectiveness of CIP systems thus depends on four main factors:

- **Time.** Too short a cleaning time will result in improperly cleaned plant, whereas too long a time involves unnecessary delays and thus a decrease of available production time. In general, a relatively high volume of solution has to be applied to soiled surfaces for at least 5 minutes and up to 1 hour.
- **Temperature.** The efficiency of cleaning is strongly influenced by the temperature of the cleaning liquids. A CIP system must keep the temperature between certain target values during all stages of the cleaning process.
- **Chemical concentration/detergency.** Depending on the type of soil and the detergents used, there is an optimal concentration for cleaning chemicals. This should be controlled either manually (measuring, diluting) or automatically.
- **Force/velocity.** CIP pumps must deliver sufficient liquid for spray-balls and pipeline cleaning. The rule of thumb is that pipelines require a linear velocity of at least 1.5 m/s, whereas for tank cleaning normally a capacity of approximately 10 m³/h per tank is sufficient. Return pumps should have at least the same or preferably a slightly higher capacity.

11.2.1 Temperature and detergent concentration

In general, the higher the temperature of the detergent solution, the more effective its cleaning action. While manual cleaning has to be carried out at around 45–50°C, CIP cleaning may well take place at 85–90°C. Higher temperatures (e.g. 100–105°C) are used during the alkaline wash of a UHT plant. Acid treatments are usually carried out at around 60–70°C. Under certain conditions, for example the use of enzyme preparation for cleaning purposes, the temperature of the CIP solution is $\leq 55^{\circ}\text{C}$.

A caustic soda solution about 1% is sufficient for cleaning storage tanks, pipelines and fermentation tanks. 1–<2% is recommended for cleaning multipurpose tanks and plate heat exchangers, and 2–3% for cleaning UHT plants. It is important to monitor the strength of the detergent solution, especially in a re-use or multi-use system, but high detergent concentrations (i.e. above 2–3%) are often not economic. However, up to 5% may be necessary to clean heavily soiled equipment.

Acid solutions are normally used in the region of <1%, since at higher concentrations corrosion of metal surfaces may occur. However, with a bench-scale tubular heat exchanger (i.e. heating milk to 72°C) the use of a single-stage acid detergent system has been shown to clean product surface both physically and chemically in half the time taken by a two-stage (i.e. alkali–acid) procedure which did not remove mineral deposits (Timperley and Smeulders, 1987, 1988).

11.2.2 Velocity

The flow characteristics of a liquid in a pipe can be either laminar or turbulent and these configurations are influenced by such factors as pipe diameter, fluid momentum and fluid viscosity. A numerical presentation of the degree of turbulence in the fluid is referred to as its Reynolds number (e.g. $Re < 2000$ = laminar, Re 2000–4000 = transitional and $Re > 4000$ = turbulent) and the higher the number, the more disturbed the flow. Thus, the physical scrubbing action in a CIP system is greatly influenced by the flow rate of the fluid, and effectiveness of the cleaning operation is greatly improved by increasing the velocity of the solution. Although the presence of any obstruction affects the flow rate of liquid through a plant, the mean velocity can still be calculated and Timperley and Lawson (1980) have substantiated that the residual bacteria on a surface are reduced to a minimum if the mean flow rate is maintained at 1.5 m/s, or as Kessler (1981) suggested $Re > 10^4$. However, the design and construction of a processing plant can affect the flow rate of liquids. The mathematical equations used to measure these losses have been detailed by Romney (1990).

The design and operation of a CIP system needs to ensure that a target velocity for the passage of cleaning fluids is maintained. When vessels and pipework are cleaned simultaneously, for example, care should be taken that the right velocity can be obtained to clean piping effectively. A tank can first be cleaned by spray-balls. The tank can then be partly filled with the cleaning liquid to create a sufficient buffer for subsequent line-cleaning. For larger-scale and more complex systems, tanks and pipes are often cleaned by individual cleaning circuits because such lines require a higher throughput to obtain the required 1.5 m/s linear velocity. Similarly, parallel flows in line-cleaning circuits must be avoided. It is very difficult or even impossible to control the fluid velocity in parallel pipelines fed by the same pump. For spray-ball cleaning of tanks, simultaneous cleaning of tanks is possible, provided that the spray-balls give a significant backpressure. Clearly the CIP supply pump must have the required capacity at this given backpressure.

11.2.3 Avoiding ‘dead areas’

To be effective the design of CIP systems needs to ensure that there are no ‘dead areas’. These include areas which cleaning fluid cannot reach at the required velocity. A good example is upward-pointing T-pieces in pipes for the installation of valves. Cleaning fluid either bypasses these areas altogether or fails to circulate with sufficient velocity to remove soil effectively. All pipelines should be free of crevices and, as much as possible, obstructions. When obstructions are unavoidable, the positioning of those items in relation to the flow direction – during both processing and cleaning – should exclude ‘shadow’ areas protected from the passage of cleaning fluids. For this reason the flow during cleaning should preferably have the same direction as the product flow during processing.

An example of a ‘dead area’ is one where either product or cleaning fluid can collect. This problem is illustrated in Fig. 11.2. In this figure, process unit 4 is

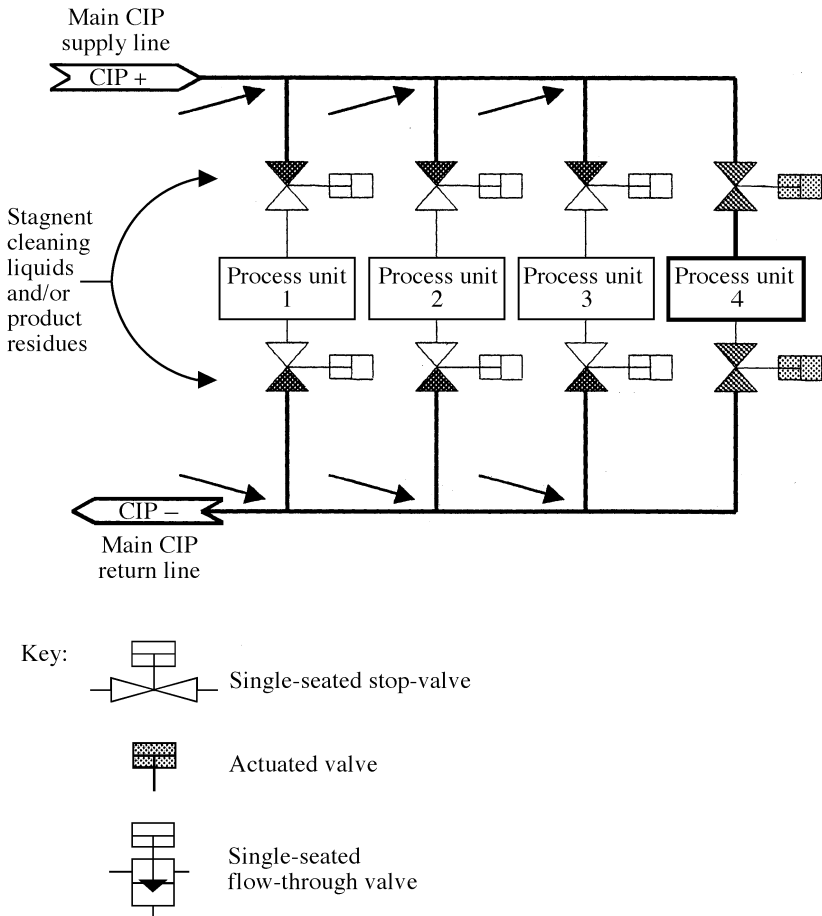


Fig. 11.2 The problem of dead areas in CIP design.

being cleaned. The CIP supply line will contain stagnant cleaning liquid in the branches to the other process units that cannot be properly removed when changing to the next cleaning stage for process unit 4. The CIP return line at the bottom also contains stagnant liquid consisting of pre-rinse water and product residues or cleaning chemicals. These problems could be reduced by placing the valves very close to the main CIP lines and/or by installing non-return valves in the CIP return branches. The latter could, however, obstruct the CIP rerun flow. An improved layout is shown in Fig. 11.3. Various types of valves are available that can branch pipelines without creating stagnant areas (for example, flow-through or cross-flow valves).

However, the configuration in Fig. 11.4 shows that this layout is still not perfect. Cleaning process unit 2, for example, will create stagnant cleaning fluid in the CIP supply line and the CIP return line that cannot be flushed between

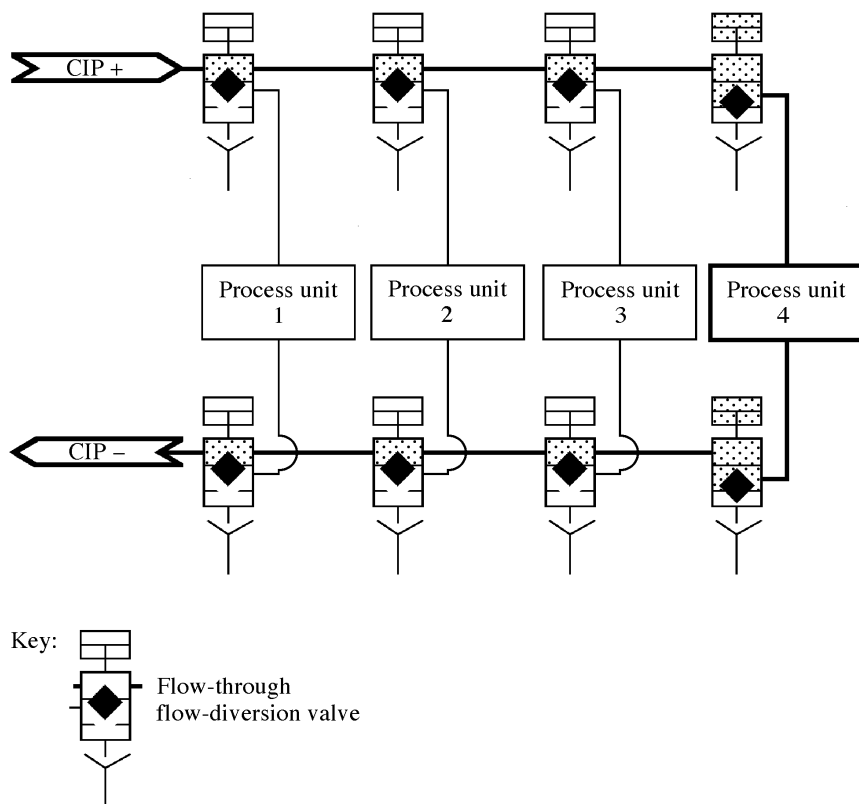


Fig. 11.3 Improved CIP design to reduce dead areas.

cleaning stages. To overcome this, cleaning circuits should preferably be loops in which the supply line is connected to the return line, separated by a block-valve. This configuration, shown in Fig. 11.5, will facilitate the replacement of a cleaning liquid by the subsequent one in the CIP supply line by opening the block valve. This will result in smaller mixing zones and thus lower chemical losses. Moreover, by circulating via the CIP return line, the CIP return line cannot remain polluted by residues from, e.g., the former pre-rinse.

11.3 Cleaning tanks

Tanks, and other large-volume pieces of equipment, are best cleaned using either rotating jets or fixed spray-balls designed to spray liquid onto vessel surfaces. Vessels need to be designed with smooth, straight walls and curved corners that can be cleaned easily by liquid spray. Spray-balls or rotating jets should produce a high-velocity jet of liquid in a 360° pattern to cover the interior of the tank and thoroughly remove residual soil or other contamination.

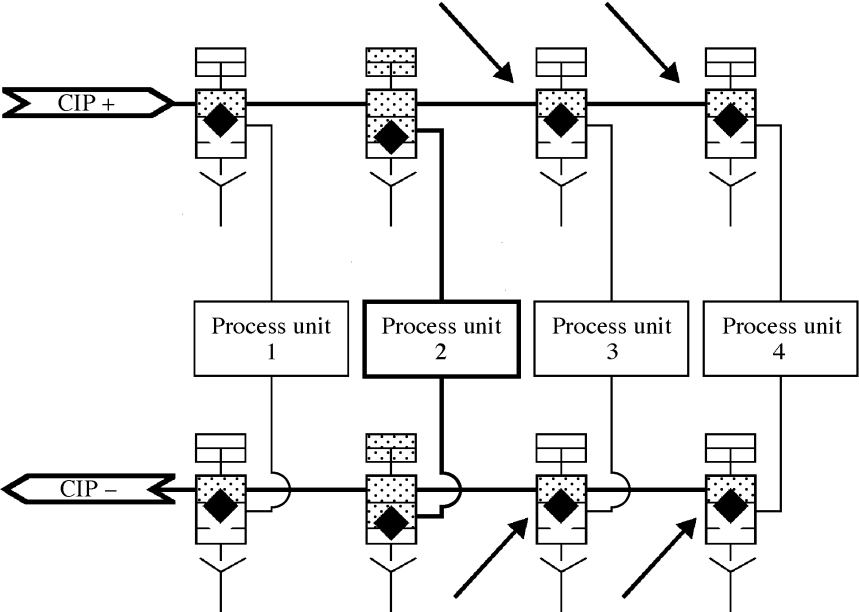


Fig. 11.4 Remaining dead areas in improved CIP design.

Tamplin (1980) has compared these two basic types. Flow rates tend to be higher using spray-balls rather than rotating jets, which could be important for achieving good results in cleaning. Romney (1990) has also detailed the various aspects involved in tank cleaning. Systems have been categorised according to their performance as follows:

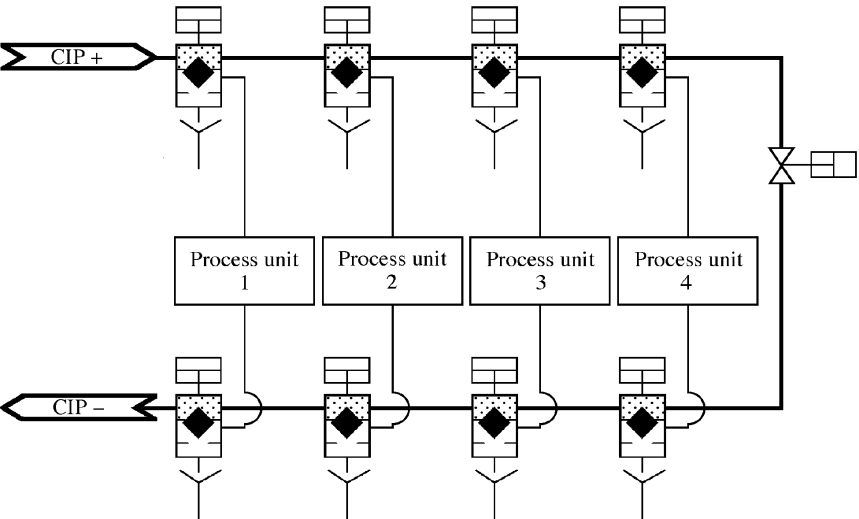


Fig. 11.5 Optimal CIP design.

- Category 1 – high pressure and low volume systems which tend to be used for tank cleaning; the heads have two nozzles as opposed to the four or eight available on large heads. The operating pressures range between 0.4 and 1 MPa, with corresponding flow rates from 3000 to 8000 l/h.
- Category 2 – high pressure and high volume systems which are based on category 1 and are suitable for larger units; the operating pressures are between 0.6 and 1.5 MPa, and the flow rates from 8000 to 35 000 l/h.
- Category 3 – low pressure and low volume systems. This category covers fixed spray-balls and fixed jets, but not the rotating types. Their application is restricted to those places where a very light cleaning duty is required.
- Category 4 – low pressure and high volume systems include the majority of tank cleaning heads, such as for milk silos and process buffer tanks; large flow, fixed spray-balls and rotating spinner-type heads which use the reaction force of the jet to rotate the head are placed in this category.

Whatever device is used, vessels should be kept empty during cleaning. Failure to do so may result in the following problems:

- Floating fat or foam cannot be removed from a tank.
- Cleaning of the bottom of the vessel will be hampered, resulting in longer cleaning times.
- Product and cleaning fluid residues are difficult to rinse out, resulting in bigger mixing zones in the CIP circuit. Separation of individual cleaning steps will be more difficult and chemical losses will increase.

There are two means of keeping a vessel empty during spray-ball cleaning:

- The pump used to remove cleaning liquids from the vessel should have a higher capacity than the required CIP supply of the spray-ball or jet. A product pump or an additional CIP return pump could fulfil this function.
- The spray-ball or jet may deliver cleaning liquid intermittently. This means that after a short time of spraying the supply valve is closed and the tank is emptied before spraying resumes.

11.4 Avoiding product contamination

To avoid cleaning liquids contaminating the final product, running CIP circuits must always be properly separated from materials that still have to be further processed. Single valves between cleaning fluids and such products is not safe enough, because occasional leakage over the valve seat cannot be observed from the outside. In Fig. 11.6, for example, it can be seen that product in process unit 1 may get contaminated with cleaning liquid from process unit 2 in four places. The danger of contamination can be removed by using one of the following systems:

- Flow selector plate
- Manual 'key pieces' or 'security flow pipes'
- Use of special valves.

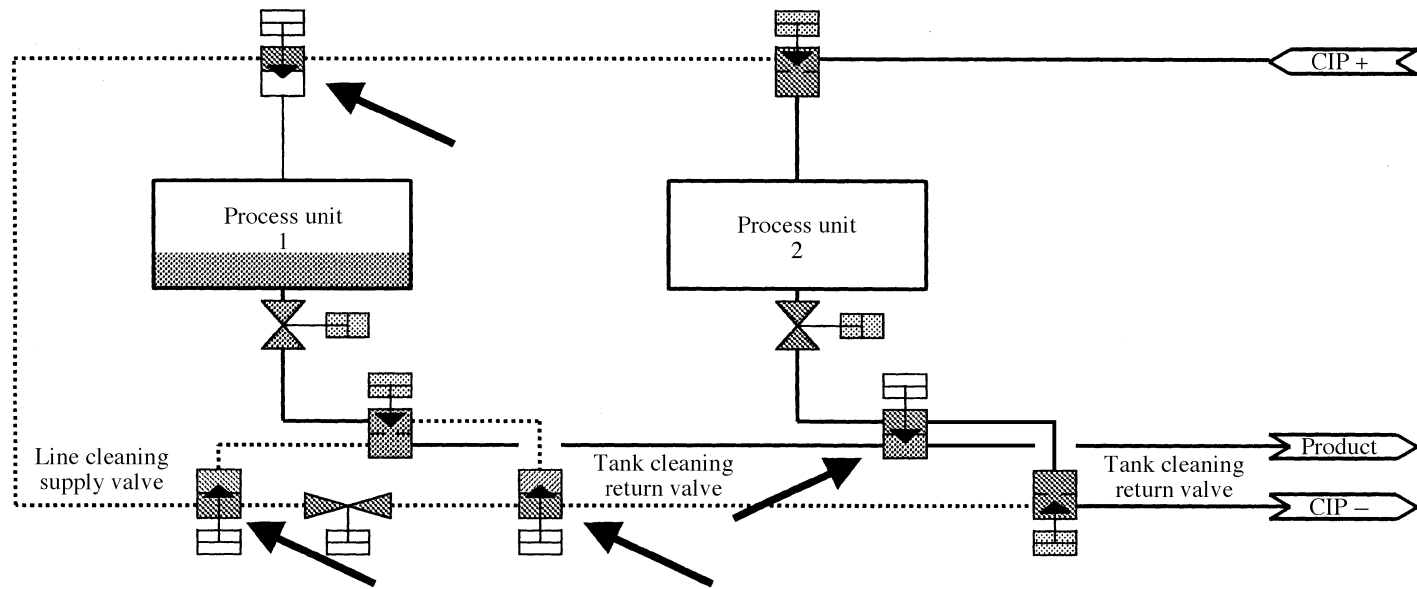


Fig. 11.6 Potential product contamination with the use of single valves.

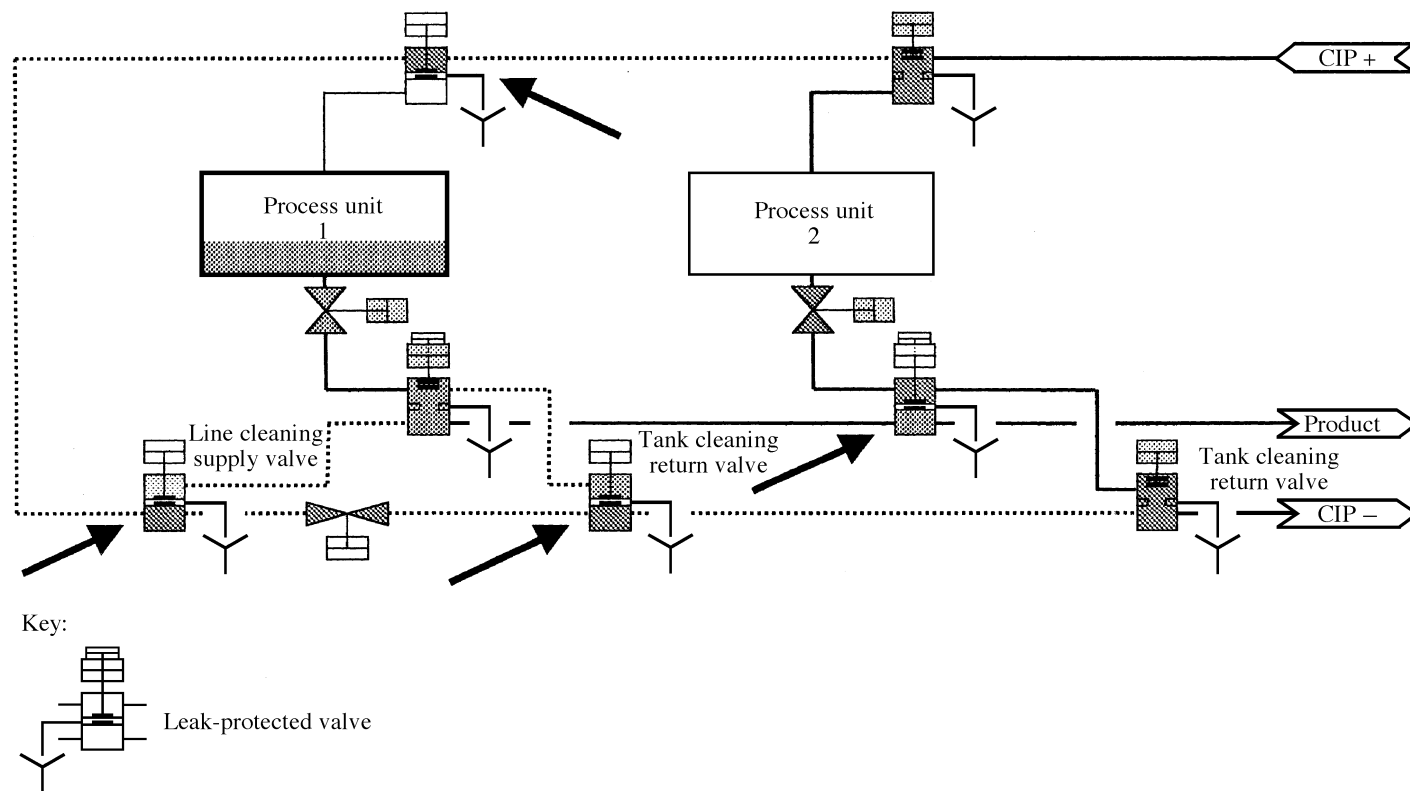


Fig. 11.7 The use of leak-proof valves in CIP systems.

The former two systems are suitable for small plant operations and, as a further precautionary measure, interlock switches are often incorporated. The use of key pieces also offers a high degree of security. If installed, for example, at two places in a tank installation (bottom fed), the first will be positioned at the bottom when the product is being handled, while the second will be positioned at the top (i.e. above spray-ball(s)) during the operation of the CIP programme.

Alternatively, different types of mixproof valve could be used. A single-seat valve with external cleaning has one seat and two valves mounted on the same plug. The area between the two seals is open to the atmosphere and this leakage drain chamber is closed by a small shut-off valve before the seat valve is activated; an external CIP line is connected to the drainage line via the small valves (see Fig. 11.7 and Bylund, 1995). A double-seated valve (with external cleaning or seat-lift cleaning) has two independent seals separating the two liquids and a drainage chamber in between (see Figs 11.8 and 11.9). This chamber must open to the atmosphere to ensure full mixproof safety in case either of the two seals should leak. When a double-seated mixproof valve is activated, the chamber between the upper and lower body is closed and then the valve opens to connect the upper and lower pipelines. When the valve is closed, first the upper plug seals and then the leakage chamber is opened to the atmosphere. This gives very small product losses during operation. It is important that the lower plug should be hydraulically balanced to prevent pressure shocks from opening the valve and allowing products to mix. During cleaning, one of the plugs lifts, or an external CIP line is connected to the leakage chamber. Some valves can be connected to an external cleaning source for cleaning those parts of the plugs which have been in contact with the product.

The three-way valve is a single valve which is arranged in such a way that, in the closed position, one part is open to the atmosphere and any leakage of the CIP solutions will fall outside the vessel; thus contamination of the product is prevented. However, a double-valve system with electric interlocks has been

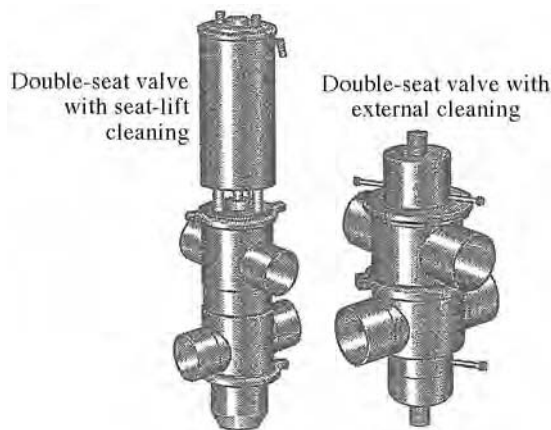
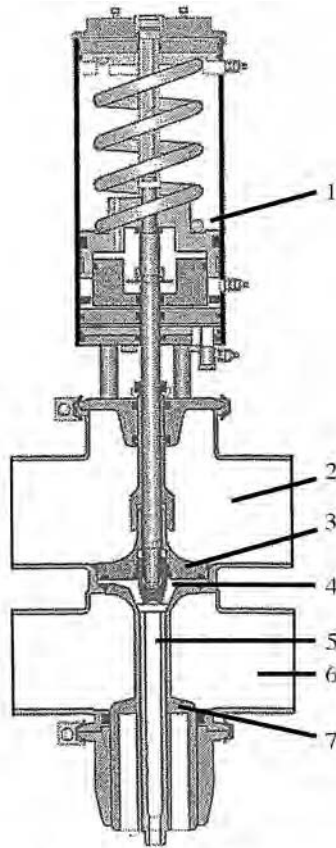


Fig. 11.8 Types of mixproof valve.



1. Actuator; 2. upper port; 3. upper plug; 4. leakage chamber with drainage;
5. hollow spindle to atmosphere; 6. lower port; 7. lower plug with balancer

Fig. 11.9 Diagram of a double-seat mixproof valve.

developed which ensures total isolation of the circuit being cleaned from the adjacent section where product could be flowing (Fig. 11.10).

Figure 11.11 shows a system with double-seated valves at critical points. Because of the rather high costs of such valves, they can be replaced at the points of connection to the CIP circuit by ordinary flow-diversion valves in combination with single-seated block valves. An additional advantage is that occasional draining of a process unit can be done independently from the CIP circuit. The same safety precautions have to be taken when formerly cleaned and rinsed parts of a line have connections with parts that are being cleaned at a later stage or by other CIP supply circuits. It is important to prevent cleaning liquids from penetrating unnoticed into already clean parts of the system. Figures 11.12 and 11.13 show examples of how to safely separate two process units that are cleaned by different CIP circuits.

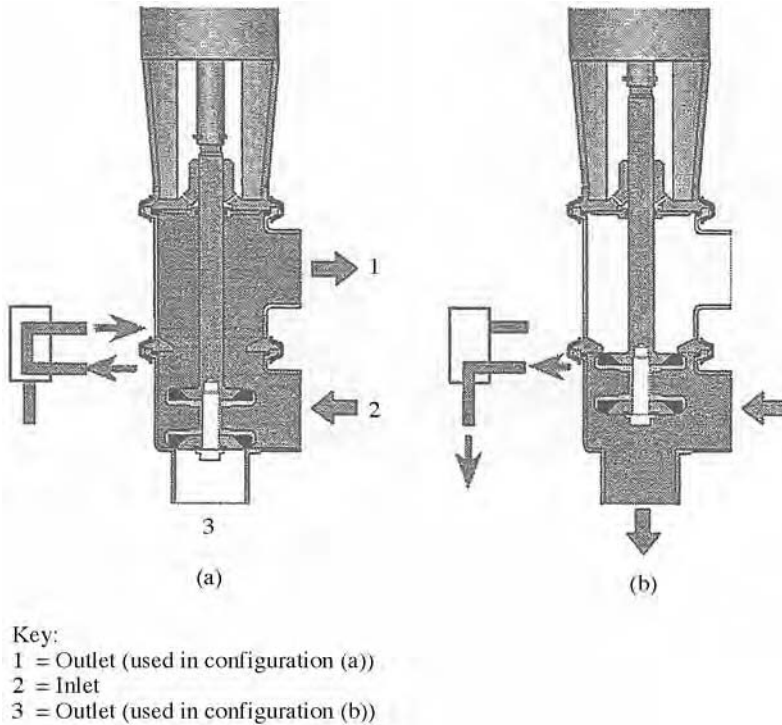


Fig. 11.10 Three-way valve configuration.

11.4.1 Drainage

A good drainage system must be in place so that the product and/or cleaning solutions can be quickly removed from the plant to prevent intermixing. Sound design of a plant is essential and the piping layout must have the following features:

- Self-drainage capability
- No dead ends.

Pipework should slope correctly to drain at a pitch of 1 in 120. Pipework must also be adequately supported to prevent sagging which allows solutions to lie static in the line.

CIP supply and return lines are usually drained when a cleaning procedure is terminated and should therefore have drain valves at appropriate places. Post-rinse water can be left in the system until the next cleaning cycle starts. This will reduce water hammer effects that may occur when the lines are filled at the start of the next cleaning. However, care should be taken that the CIP lines are kept at atmospheric pressure when not in use. When a pipeline between two closed valves is completely filled with a liquid, temperature changes may cause mechanical damage to valves and seals. Furthermore,

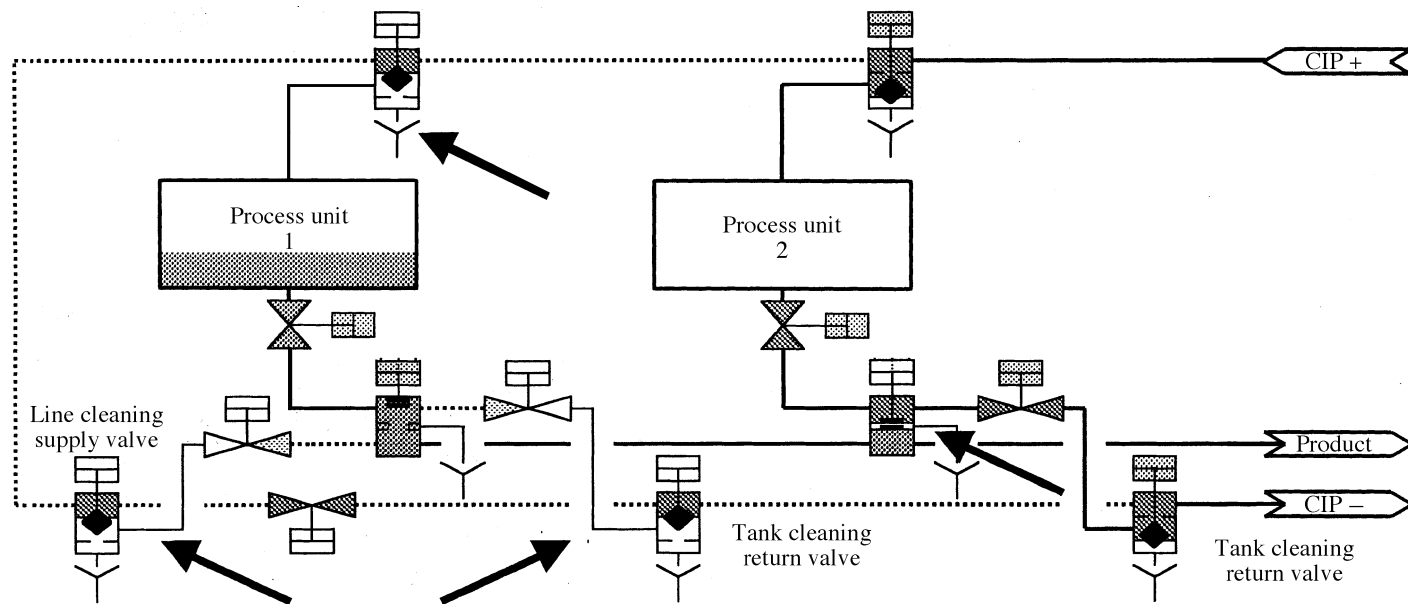


Fig. 11.11 CIP system with double-seated valves at critical points.

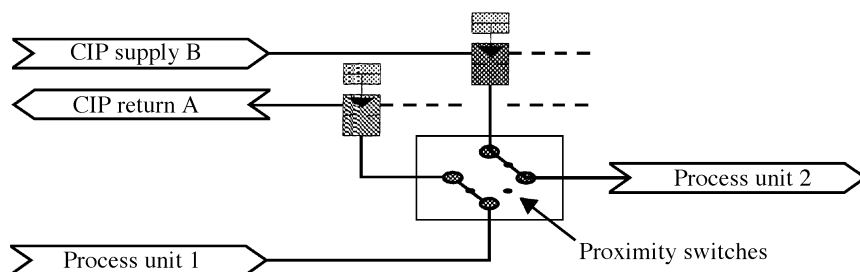


Fig. 11.12 Separation of cleaning circuits using flow plates.

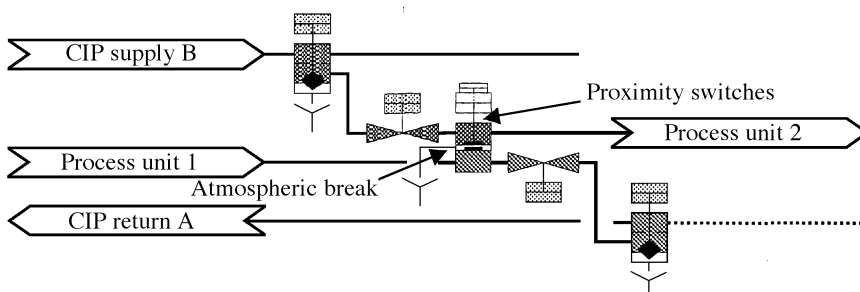


Fig. 11.13 Separation of cleaning circuits with leak-protected valves.

post-rinse water should not be continuously present against valves separating the system from product since this increases the risk of leakage and contamination.

In modern plants a 'pigging' system is employed to purge the product from the pipelines in order to improve cleaning efficiency. In older installations air purging is sometimes used. A blast of oil-free compressed air is forced into tanks and pipelines as a convenient method of evacuating residual product from the plant. The volume of air delivered and the duration of purge are calculated to empty the pipelines effectively. The result is improved product recovery, minimum soiling matter to be removed and less rinsing water required, and better utilisation of detergent since elective concentrations can be maintained for a number of runs. Incidentally, although the air purging system is mainly operated before the cleaning cycle commences, it is also used to evacuate residual rinsing water during and/or after cleaning (e.g. the preliminary rinse at the beginning of the cleaning cycle).

11.5 Types of CIP system

This section describes the three basic types of CIP system:

- Single-use systems

- Re-use systems
- Multi-use systems.

11.5.1 Single-use systems

Single-use systems use a cleaning solution only once. They are generally small units, frequently located adjacent to the equipment to be cleaned and sanitised. Heavily soiled equipment is especially suited to a single-use system because re-use of the solution is less feasible. Some single-use systems are designed to recover the cleaning solution and rinse water from a previous cycle for use as a pre-rinse cycle in the subsequent cleaning cycle. An example of this kind of system is shown in Fig. 11.14. When compared to other CIP systems, single-use units are more compact, less complex and have a lower capital cost. A typical sequence for cleaning equipment such as storage tanks or other storage containers takes about 20 minutes, with the following procedures:

1. Three pre-rinses of 20 seconds with intervals of 40 seconds each to remove the gross soil deposits are initially applied. The water is subsequently pumped by a CIP return pump for discharge to the drain.
2. The cleaning medium is mixed with injected steam (if used) to provide the preadjusted temperature directly into the circuit. This status is maintained for 10 to 12 minutes prior to discharge of the spent chemicals to the drain or recovery tank.
3. Two intermediate rinses with cold water for an interval of 40 seconds each are followed by transfer to water recovery or to the drain.
4. Another rinse and recirculation is established and may include the injection of acid to lower the pH value to 4.5. Cold circulation is continued for about 3 minutes, with subsequent drainage.

For optimal use of water and reduced effluent discharge, CIP systems are being designed to permit the final rinse to be utilised as make-up water for the

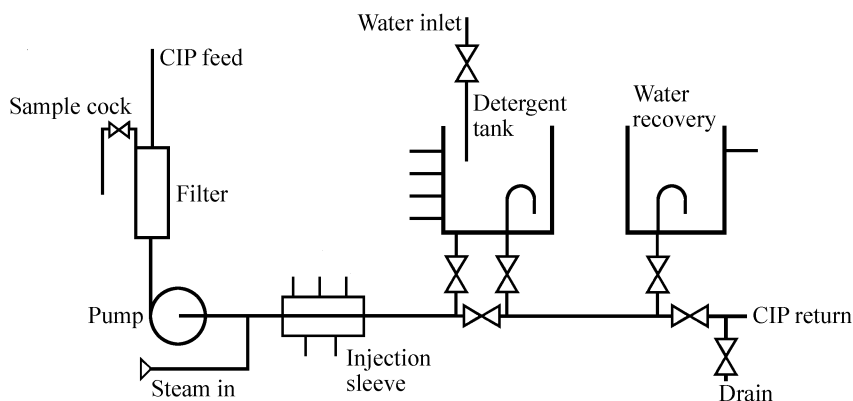


Fig. 11.14 Single-use CIP system.

next cleaning cycle. The dairy industry has attempted to recover a spent cleaning solution for further use by concentration through ultrafiltration or through use of an evaporator. Various installations have incorporated systems that integrate the advantages of single-use systems of known reliability and flexibility with water and solution recovery procedures that aid in reducing the total amount of water required for a specific cleaning operation. These installations combine the spent cleaning solution and past rinsings for temporary storage and use as a pre-rinse for the next cleaning cycle. Thus, the requirement of water, cleaning compounds and required energy are reduced.

11.5.2 Re-use systems

In this system, the detergent and/or acid solutions are recovered and re-used as many times as possible, especially in part of the plant where the equipment is not heavily soiled. The preliminary rinse of such equipment removes a high percentage of the soil. As the detergent solution circulated during the wash cycle is not then heavily polluted, it can be re-used many times. The re-use CIP can be described as having the following essential components: the detergent tank(s), acid tank, water tank, water recovery tank and heating system, all interconnected with a system of pipework fitted with CIP feeds and return pumps. An example of this kind of system is shown in Fig. 11.15. The concentration of the acid and alkali solutions is regulated via feeds from tanks containing the corresponding compounds in a concentrated form, and the unit is also fitted with neutralisation tanks in which the alkali and/or acid solutions are neutralised prior to their disposal into the effluent system. Tamplin (1980) and Romney (1990) suggest that water consumption in a re-use system can be optimised by providing a recirculation facility for the hot water and the use of a return water tank.

Tamplin (1980) has also pointed out that in a dairy operating 15–20 individual cleaning circuits per day, this CIP system becomes more efficient if another CIP feed pump is incorporated, so that two circuits can be cleaned

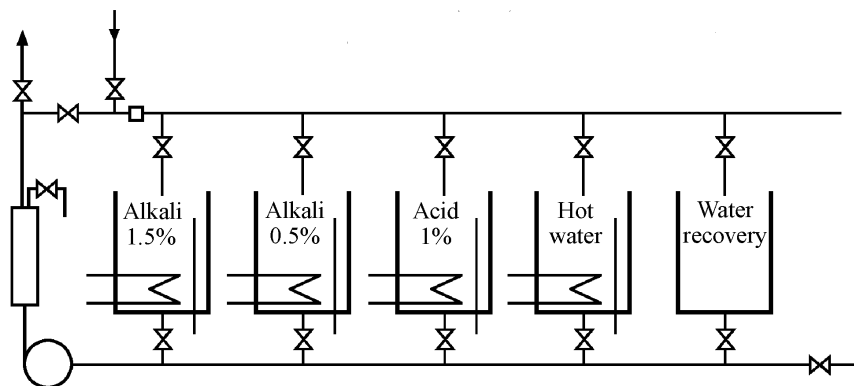


Fig. 11.15 Re-use CIP system.

Table 11.2 Typical operating cycle for a CIP re-use system

Operation	Description	Time (min.)	Temperature
Pre-rinse	Application of cold water from recovery tank with subsequent draining	5	Ambient
Detergent wash	A 1% alkaline-based cleaning compound purges remaining rinse water to drain with subsequent diversion by conductivity probe to the cleaning compound tank for circulation and recovery	10	Ambient to 85°C, depending on equipment to be cleaned and type of soil
Intermediate water rinse	Softened cold water from rinse forces out remaining cleaning solution to cleaning solution tank; water then diverted to water recovery tank	3	Ambient
Acid wash	An acid solution of 0.5–1.0% forces out residual water to drain; then this solution is diverted through a conductivity probe to acid tank for recirculation and recovery	10	Ambient to 85°C, depending on equipment to be cleaned and type of soil
Final water rinse	Cold water purges out residual acid solution with collection of water in water recovery tank; overflow diverted to drain	3	Ambient
Final flush	Pasteurising equipment tanks and pipelines may also be subjected to final flush of hot water	3	85°C

simultaneously. However, any extension of the re-use CIP system is limited, since the tank capacity is defined in advance by the circuit volume, temperature requirements and desired cleaning. The ideal CIP re-use system has the ability to fill, empty, recirculate, heat and dispense contents automatically. A typical operation of this system with a programme for storage tank and pipeline cleaning with recovery of the cleaning solution is described in Table 11.2.

11.5.3 Multi-use systems

These systems combine the features of both single-use and re-use systems and are designed for cleaning pipelines, tanks and other storage equipment. These systems function through automatically controlled programmes that entail various combinations of cleaning sequences involving circulation of water, alkaline cleaners, acid cleaners and acidified rinse through the cleaning circuits for differing time periods at varying temperatures.

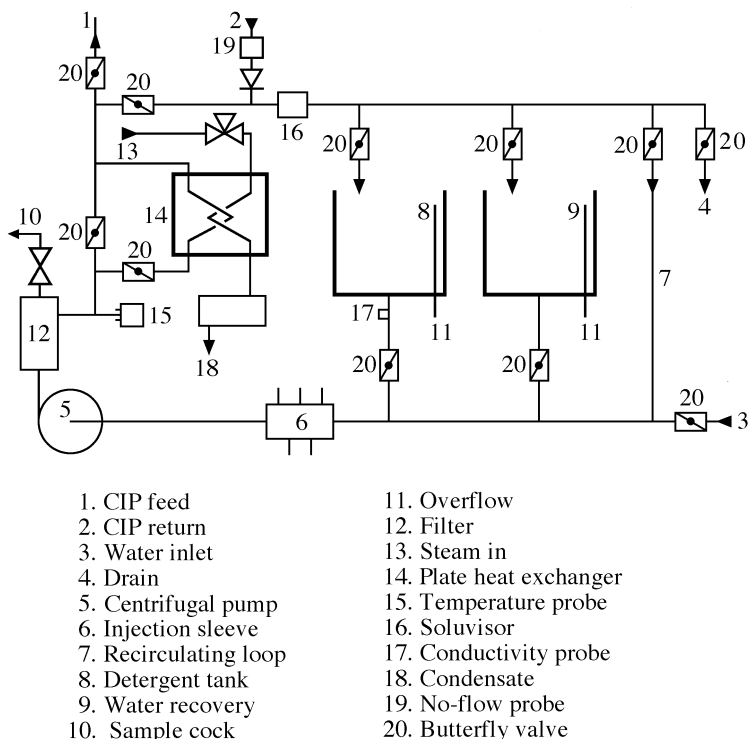


Fig. 11.16 Multi-use CIP system.

A simplified flow chart of a typical multi-use CIP system is presented in Fig. 11.16. The multi-use CIP system contains tanks for chemical and water recovery, with an associated single pump, recirculating pipe work and heat exchanger. The plate heat exchanger heats the incoming water and cleaning liquid to the required temperature. Flexibility of temperature control, optimal utilisation of tank capacity, and flexibility in heating of water or cleaning solutions can be realised through the use of a heat exchanger.

An automatic multi-use CIP system follows the following operation sequence:

1. *Pre-rinse.* This step occurs from water recovery or the water supply provided at the desired temperature. The solution from this operation can be directed to the drain or diverted by a recirculatory loop for a timed period, then transferred to the drain.
2. *Cleaning solution recirculation.* The recirculation step occurs by the cleaning compound vessel or the bypass loop. A desired combination of cleaning chemicals can be used for variable recirculation times, and the chemical injection can boost the strength or use of the solution. The plate heat exchanger or its bypass loop can contribute to the cleaning solution recirculation. With a bypass loop, variable-temperature programming

permits total detergent-tank heating. Cleaning solutions can be recovered or drained.

3. *Intermediate rinse.* This operation is similar to the pre-rinse, except that it is important to remove residual cleaning chemicals from the previous operation.
4. *Acid recirculation.* This optional operation, which is similar to the cleaning recirculation operation, may occur with or without an acid tank. With an acid tank, the recirculatory loop is established on water, either through the plate heat exchanger or via the plate heat exchanger bypass loop. The acid is injected to a preset strength base on timing for a specific circuit volume.
5. *Sanitiser recirculation.* This operation, designed to reduce microbial contamination, is similar to the acid injection operation except that heating is not normally required.
6. *Hot water sterilisation.* Variable times and temperatures are available for this operation, which involves use of a recirculation loop on fresh water via the plate heat exchanger. The spent water can be either returned to water recovery or drained.
7. *Final water rinse.* Water is pumped via the CIP route and sent to water recovery. Water rinse times and temperatures are variable.

The various strengths and weaknesses of single-use, re-use and multi-use systems are compared in Table 11.3.

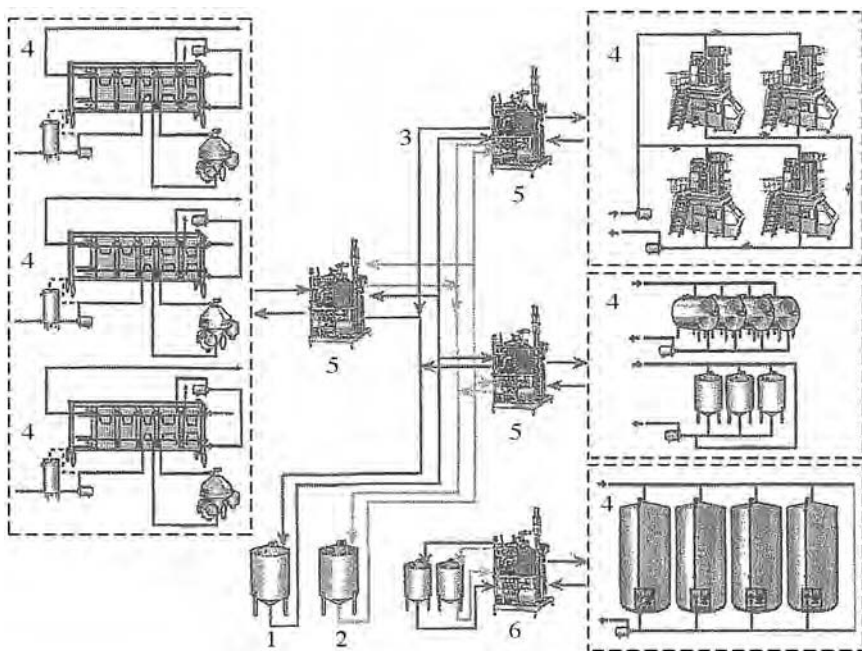
Table 11.3 Comparison of different CIP systems

Feature	Single-use	Re-use	Multi-use
Design type	Simple, often modular	Complex, 'one-off'	Complex, but modular
Addition to new equipment	Easy	More difficult	More difficult
Flexibility of detergent types	Flexible	Inflexible without modification	Flexible
Changes in detergent strength	Easy	Difficult without modification	Easy
Detergent make-up	As used	Stored hot	As used
Peak thermal load	High	Low	Moderate to high
Soil types system can deal with	Heavy	Light to moderate	Moderate to heavy
Re-use of water and detergent	Use once then throw away	Re-use where possible	Some single-use, some re-use
Costs – capital	Low	High	Lower than re-use
Costs – detergent	High	Low	Lower than single-use
Costs – heat energy	High	Low	Lower than single-use

11.6 Centralised/decentralised CIP systems and automation

Two types of CIP systems can be used: centralised and decentralised systems. The former system is normally used in small plants with relatively short CIP pipelines. A decentralised CIP is an attractive alternative for large plants where the distance between a centrally located CIP station and peripheral CIP circuits would be extremely long (see Fig. 11.17). The large CIP station is replaced by a number of smaller units located close to the specific groups of process equipment in the dairy, but there is still a central station for storage of the alkaline and acid detergents which are distributed to the individual or satellite CIP units. The supply and heating of rinsing water (and acid detergent when required) is arranged locally at the satellite stations. These stations operate on the principle that the various stages of the cleaning programme are carried out with a carefully measured minimum volume of liquid – just enough to fill the circuit to be cleaned. A powerful circulation pump is used to force the detergent through the circuit at a high flow rate.

The principle of circulating small batches of cleaning solutions has many advantages. Water and steam consumption can be greatly reduced. Residues from the first rinse are obtained in a more concentrated form and are, therefore, easier to handle. Decentralised CIP reduces the load on sewage systems



1. Alkaline storage tank; 2. acid storage tank; 3. pipelines for detergents; 4. equipment to be cleaned; 5. satellite CIP units; 6. decentralised CIP system with its own detergent tanks.

Fig. 11.17 Decentralised CIP system.

compared to centralised CIP, which uses large volumes of liquid. The concept of single-use detergents has been introduced in conjunction with decentralised CIP, as opposed to the standard practice of detergent recycling in centralised systems. The one-time concept is based on the assumption that the composition of the detergent solution can be optimised for a certain circuit. The solution is considered spent after having been used once. In some cases it may, however, be used for pre-rinsing in a subsequent programme.

11.6.1 Automation

Automatic control has been achieved during the past few decades using computers and microprocessors and, as a result, the process has become more efficient with better detergent recovery, a reduction in energy consumption and a reduction in the scope for human error. Automated systems can lower chemical costs by 15% to 20% and reduce cleaning cycle time by 10% as a result of more efficient chemical allocation. Automated units enhance cleaning effectiveness and reduce cleaning costs through precise control of the variables associated with mechanised cleaning. Some units have as many as 200 separate and variable programmes that can provide product recovery, rinse and/or cleaning compound recovery, manual rinsing, sanitising cycle, concentration of chemical strength, extended wash duration, and many other options. The quality of the cleaning solution can be controlled by conductivity transmitters. The conductivity is proportional to the concentration of the active ingredient, and at the phase of flushing with water, the concentration of the detergent solution becomes lower. At a preset value, a changeover valve routes the liquid to drain instead of to the relevant detergent tank. The unit can be designed with self-contained, on-line programming while running via an integral keypad or an off-line programming package available for use on personal computers.

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12

Verification and certification of hygienic design

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12.1 Introduction

The effectiveness of the hygienic design of food processing equipment will sometimes need to be verified. Reasons for verification include the following:

- To demonstrate compliance with relevant hygiene legislation such as the EU Machinery Directive (98/37/EC)
- As part of a quality assurance scheme used by an equipment manufacturer to check the quality of its design and manufacturing processes
- To meet the requirements of a customer contract
- To ascertain that a new or modified design does not conflict with hygienic design criteria.

The nature of verification will depend on a number of factors, including:

- The complexity of the equipment
- Whether it is 'open' processing equipment (for example a conveyor belt) or closed equipment (such as a heat exchange)
- Whether it is used before the main decontamination stage in a production process, or to decontaminate food or handle decontaminated food before it is sealed within its packaging.

Verification methods for open equipment not handling decontaminated product can be relatively simple. They may involve the following:

- Examination of two- or three-dimensional plans to check compliance with food principles of hygienic design
- Examination of the equipment itself, including dismantling it if required
- Checking materials used to manufacture the equipment are hygienic.

Verification of this kind may be sufficient for many types of open equipment to comply with the EU Machinery Directive (98/37/EC) and achieve a 'CE' mark. However, for more complex equipment, particularly closed equipment handling decontaminated product, more elaborate tests may be required. There are four main types of test:

- Pasteurisability, i.e. to test whether equipment is free of vegetative micro-organisms after a relatively mild heat treatment
- Sterilisability, i.e. to test whether equipment is free of any micro-organism, including bacterial spores, after a relatively severe heat treatment
- Bacterial tightness, i.e. the ability of the equipment to prevent the ingress of micro-organisms
- Cleanability, i.e. the relative ease with which equipment can be cleaned to prevent contamination of product with product residues, soil and micro-organisms.

12.2 Testing pasteurisability, sterilisability and bacterial tightness

The EHEDG has established methods to test the pasteurisability and sterilisability of equipment (Timperley *et al.*, 1993a; Venema-Keur *et al.*, 1993). In these methods the equipment to be tested is contaminated with a test organism: ascospores of *Neosartorya fischeri* for pasteurisation and *Bacillus subtilis* spores for sterilisation. The equipment then undergoes either pasteurisation (water at 90°C for 30 min) or sterilisation (saturated steam at 120°C for 30 min). The equipment is subsequently filled aseptically with nutrient medium to check for the test organisms which, if they survived, will remultiply and be detected.

The bacterial tightness of equipment can be tested by another standard EHEDG method following a EHEDG sterilisation test (Timperley *et al.*, 1993b). To test bacterial tightness, *Serratia marcescens* is used. This is a small, strongly motile microorganism able to penetrate through small holes and crevices which are difficult to test by other physical methods. The indicator microorganism is cultivated in sterile trypticase soy broth (TSB). TSB is also pumped into the equipment to provide a growth medium for any indicator microorganisms able to penetrate the equipment.

If not preceded by a sterilisability test, the equipment is dismantled, cleaned and then sterilised. It is then reassembled under aseptic conditions and the TSB introduced into the equipment. A freshly prepared culture containing at least 10^9 bacteria ml^{-1} is diluted in sterile TSB and spread evenly over all critical and suspected parts of the equipment. Syringes may be required to ensure that the more inaccessible areas are properly covered. All areas where leakage may occur are treated twice a day for at least 3 days. Where applicable, the equipment is operated 10 times after each treatment. To obtain sufficient mixing and ensure rapid detection of microbial growth the TSB broth in the equipment is circulated for 2 hours every day. The equipment is kept at ambient

temperature (approx 20–25°C) during the soiling procedure. If the ambient temperature fluctuates outside the stated limits, it must be confirmed experimentally that the growth and motility of *Serratia marcescens* are not adversely affected.

After the soiling procedure the system is kept at ambient temperature (approximately 20–25°C) for 5 more days. The TSB broth is circulated for 2 hours every day at the same flowrate used during the soiling procedure. If the broth remains clear after this period, the equipment is classified as bacteria tight. If the broth becomes turbid, a sample is taken and examined for the presence of *Serratia marcescens*. The broth sample is incubated at 30°C for 2 days. A red discoloration of the broth confirms the presence of *Serratia marcescens*. If *Serratia marcescens* is present in the system, the equipment has failed the test and is, therefore, not bacteria tight and hence not suitable for aseptic use. The organism is certain to have penetrated from outside, because its heat resistance is so poor that it could not survive the original sterilisation treatment of 120°C for 30 minutes. Tests should be conducted a minimum of three times. If varying results are obtained, a thorough examination of the test procedures and equipment should be conducted. If no faults are discovered, it can be concluded that the equipment is not bacteria tight. The EHEDG has developed other tests for particular pieces of equipment, including testing the bacterial retention ability of filters (Andersen *et al.*, 2000).

12.3 Testing cleanability

Food factories need regular cleaning to avoid products becoming contaminated with soil, product residues and micro-organisms. This applies to the interior of the building, the process lines and the individual pieces of equipment. A cleaning protocol for walls for instance involves detergent foaming for 20 minutes followed by spraying with potable water at 1.5 MPa for 5 seconds, where a spray lance is held approximately 200 mm from the surface at an angle of 90°. For in-place cleaning of enclosed surfaces typically a fixed flowrate (1.5 m/s) and variable detergent concentrations, temperature and contact times are used. Open equipment often requires manual activity using safe and thus very mild detergents.

To ascertain that the cleaning methods applied are effective, tests are required, but because methods applied vary greatly, there is not one single standard test. Whether surfaces of equipment can be cleaned does not only depend on the design of the equipment, but also on the soiling. A process line for mineral water is usually easier to clean than one for chocolate paste, even if in both cases the equipment is of perfect hygienic design. For that reason, methods have been developed to assess comparative cleanability (Lelieveld, 1985). These methods establish the cleanability of surfaces compared with a reference, soiled and cleaned in the same way as the surfaces under investigation.

Methods for testing the cleanability of food processing equipment involve various stages including (Lelieveld, 1985):

- ensuring that the equipment is initially clean
- soiling with organic soil mixed with indicator micro-organisms
- undertaking cleaning
- measuring residual micro-organisms still present on the surface after cleaning.

Cleaning protocols used for cleanability testing have been developed to allow some residual retention of soils and survival of the indicator micro-organisms as required for comparative analysis. One example for closed equipment is:

- A rinse with cold water (10–15°C) for 1 minute
- Circulation of a 1.0% (w/v) mild detergent solution (e.g. Lever Industrial PD332) for 10 minutes at 63°C
- A final rinse with cold water (10–15°C) for 1 minute.

It is possible to cover small open test objects by spraying microbial and organic soils with hand-held commercial compressed air driven sprayers. Uniformity of spraying is increased by the use of a repeat coating, if possible in a different spray direction, and a second spray of nutrient medium for microbial soils helps prevent viability loss on the surface. Soiling of larger size open test items by these methods may be difficult and, at best, time consuming. For equipment of large size it may be appropriate to first identify areas that could be potentially difficult to clean and soil and assess these areas only (Holah, 1995). It is unlikely that flat easily accessible surfaces would be difficult to clean, but fastenings, corners and areas of poor drainage could well be. Closed equipment of all sizes is more easily and consistently soiled by circulation of organic and microbial soils. Analytical techniques include apparatus designed to remove micro-organisms from surfaces using ultrasound, traditional microbiological swabbing and ATP hygiene testing systems, Direct Epifluorescent Microscopy (DEM) and visual and image analysis measurements of stains remaining after cleaning. There are currently about 10 independent laboratories that can test the cleanability of relatively small size equipment for closed processing such as pumps, valves and in-line sensors (Cerf *et al.*, 1995).

12.4 Particular tests for cleanability

This section covers the following tests:

- EHEDG small closed equipment test
- Beta-carotene residues test
- *P. fragi* test
- *B. thuringiensis* test
- 'Campden soil' method
- 'Buttermilk' test.

12.4.1 EHEDG small closed equipment (*B. stearothersophilus*) test

This method is described by Holah *et al.* (1992). In this method, the test item is filled with soured milk containing spores of *B. stearothersophilus*, pressurised to 5 bar, drained and dried. The test item is then cleaned, drained and dismantled in the laboratory. Test items are covered in agar as appropriate, so that all product contact surfaces are wetted, and incubated at 58°C. Spores remaining on the test item after cleaning germinate and ferment the glucose in the agar to acidic end points. A pH sensitive dye in the agar records this fermentation with a change from purple to yellow, with yellow areas indicating microbial growth and thus spore presence. The number of spores still present after cleaning is a measure of the amount of soil left. The amount left in the equipment tested can be compared to a reference piece of equipment which has been similarly treated. The method tells the equipment manufacturer whether the equipment tested can be cleaned more easily than the reference equipment or presents a greater cleaning challenge. This method also helps to identify particular unhygienic areas in a piece of equipment. If, after several tests, yellow is recorded in the same area on each occasion, this can be interpreted as a particularly difficult to clean, or unhygienic, area of the test item.

This method has been developed in a number of ways. Agar removal has been enhanced with an 'apple corer' device which removes a cylinder of agar approximately 0.5 mm thick from the surface of the pipe which can then be rolled out over a gridded surface for colour assessment by enumerating the squares that are yellow. Glass colour comparators have been made and used as training aids on colour interpretation. These have led to increased operator yellow/purple perception and thus increased the repeatability of the method (Holah, 2000).

The EHEDG method has been accepted for accreditation to various countries' National Standards (e.g. UKAS in the UK, DANAK in Denmark) and has been published in an updated version by the EHEDG (Timperley *et al.*, 2000). The method has been particularly successful and is used by many European liquid handling equipment manufacturers (e.g. pumps, valves, couplings, sensors) as a means of independently assessing equipment cleanability.

12.4.2 EHEDG β -carotene residues test for closed equipment

In this method a test item is filled with a commercially available soft margarine, containing 80% fat with a viscosity of less than 60 mPa.s at room temperature, and pressurised to 5 bar. After cleaning, the test item is removed from the test rig and dismantled. All product contact surfaces of the test item can then be examined for the presence of residual soil by visual inspection and by swabbing the surface with a cotton wool tipped swab. The relative amount of residual soil is recorded on a relative number (RN) scale from 0 to 4 where 0 represents no visible yellow soil and 4 indicates soil being highly visible. One difference from the EHEDG microbiological method is that instead of a bacterial spore, a

colorant (β -carotene) is used as soil residue indicator (Venema-Keur *et al.*, 1997).

This method is easier to apply and gives results faster, but is less sensitive than the microbiological method. The method is also cheap and suitable as a means of reducing the number of the more expensive microbiological tests required during the development of new food processing equipment. The detection of β -carotene in margarine soils is dependent on visual observation, since automated colour recognition systems have been found to be less sensitive than the human eye. In addition, techniques based on absorbance spectrophotometry after extraction of the β -carotene into hexane have also proved less sensitive. As test results are thus recorded on an arbitrary (RN) scale, statistical analysis of repeatability studies by the RN scale is difficult. Visual comparison of results does, however, suggest that similar results can be obtained. Further work is required on the quantification of the level of β -carotene remaining in margarine on the surfaces of large pieces of equipment after cleaning. If no suitable automated system can be found, appropriate colour charts to enhance the RN scoring system could be considered to allow reproducible results between partners.

12.4.3 *P. fragi* test method for exposed surfaces

In this method, overnight cultures of *P. fragi* are resuspended in phosphate buffer and sprayed onto test surfaces using a small compressed air based sprayer (Merck) with spraying in a zigzag pattern to give even coverage. The surfaces or equipment are allowed to dry for 15 minutes and then sprayed with growth media (0.1% bacteriological peptone, 0.07% yeast extract) prior to cleaning. After cleaning, surfaces are swabbed, the swabs processed traditionally or the swab resuspension fluid assessed by TVC, ATP or DEM/DEFT as appropriate.

Those using *P. fragi* as a test organism have found it to be easy to use and results are repeatable. The measurement of *P. fragi* by TVC also has the largest range of detection in that cleaning can remove >5 log orders of the organism attached to surfaces. This range allows even small differences in the cleanability of surfaces to be detected, though such small differences may not be relevant practically. Further work, however, needs to concentrate on the method's reproducibility, i.e. how to standardise its methodology and interpretation between partners, as the principles of the method (choice of organism, method of soiling, cleaning variables and detection methods) currently vary between individual users. This method is currently used only in laboratories. In the future it may be possible to use edible micro-organisms, such as lactic acid bacteria, which would make the method acceptable for use in factories.

12.4.4 *B. thuringiensis* test method for exposed surfaces

In this method spores of *B. thuringiensis* are suspended in saline and sprayed onto surfaces with sweeping movements using a compressed air 'artist's brush' type paint sprayer or by filling the item of equipment with the spore suspension.

Immediately after cleaning, surfaces are covered with molten nutrient agar containing 2,3,5-triphenyltetrazoliumchloride (TTC). The agar is incubated on the surface for a variable time period (up to 5 h) at 30°C and then removed from the surface and incubated overnight. TTC salts, which are water soluble in the oxidised state, are reduced to water-insoluble formazans by cellular respiration. When growing using this TTC solid medium, colonies appear red and small, offering an easier visualisation of the contaminated areas.

The detection of *B. thuringiensis* by TTC is limited by the ability to differentiate colonies on an agar surface. This probably covers a range of 1–100 colonies/cm², above which colonies become indistinguishable (i.e. 2 log orders). This range is, however, sufficient to determine cleanability differences either by means of colony counts or by visual assessment. Methods using spores such as *B. thuringiensis* offer greater repeatability and reproducibility than vegetative bacterial-based tests, as spores have high resistance to heat and chemicals as well as strong adhesive properties. They are less susceptible, therefore, to viability loss within the soiling and cleaning process. Difficulties arise, however, particularly for open surfaces, with the detection of spores if an agar overlay technique is used on large pieces of equipment, because it is impractical to cover them totally with agar and it may be difficult to cover only areas of the equipment identified as likely to be unhygienic. What is not known at this stage of development of the TTC methods is the ability of the agar to fully wet the surface and thus come in contact with all surface-bound spores and subsequently what proportion of spores are removed by the agar and are thus enumerated. The ability of the agar to enter into surface irregularities, e.g. crevices, and remove any spores present will clearly influence the sensitivity of the technique, though results to date have shown the method to be among the most sensitive of the five currently developed.

12.4.5 'Campden soil' method for exposed surfaces

In this method, a soil is prepared containing 'Coldflo' modified starch, whole milk powder and vegetable oil and spiked with calcium carbonate (final concentration 1.25M). This 'Campden soil' is then diluted 1:2 for spraying to excess onto equipment surfaces using, for example, a Merck TLC sprayer. After cleaning, surfaces are swabbed by sponges which are resuspended in nitric acid. Diluted samples are aspirated into a Perkin Elmer 3300 atomic absorption spectrophotometer using an air/acetylene flame at 422.7 nm and results calculated as mg calcium/cm².

This technique has proved very easy to use and is repeatable. Its detection is dependent, however, on access to atomic absorption spectroscopy which imposes a cost limitation to its widespread use. Alternative calcium detection methods are available and it may be possible for cheaper analyses to be undertaken. The simplicity, safety and repeatability of the calcium technique makes it particularly suitable for routine use outside the laboratory, especially in areas in which microbiological testing would be impossible, and it is certainly

recommended for future study. The difference between cleaned and control surfaces as measured by calcium is approximately 1 log order. This range makes an assessment of the cleanability very difficult but is sufficient to detect areas of poor cleanability at a gross scale within individual test items.

12.4.6 The 'Buttermilk' test for filling machines

This test has been assessed by the EHEDG and is appended to the EHEDG guidelines on the evaluation of packing machines (Mostert *et al.*, 2000). The objective of the test is to assess the interior cleanability (CIP) of filling machines. The machine is soiled with buttermilk containing a fluorescent dye. After cleaning, the product contact parts of the filling machine are inspected for any residual fluorescence with ultraviolet light. The residues are then confirmed by an ATP test. In addition, a selected number of 'critical' parts are tested for ATP. This test is mainly intended for investigating the hygienic design of filling machines, but can in principle be used also to evaluate and document the effect of an existing cleaning programme, optimising cleaning programmes or comparing various cleaning agents. This test, however, may only be done at the location of the equipment manufacturer, using the required safety precautions. The fluorescent dye is not safe and should not be used in any food environment. For the same reason, it must be ascertained beyond any doubt that there are no residues left when the equipment is shipped to the user.

12.5 Certification of equipment in Europe: the EHEDG

Long before the first legislation on the subject appeared, food processors started to negotiate with equipment manufacturers about the hygienic design and cleanability of the equipment provided. In the USA this resulted in the foundation of the 3-A organisation as early as 1927. In most countries food processors are now legally responsible for the safety of their products. Manufacturers specify the quality of the raw materials purchased and carefully define the process conditions needed to obtain a safe product of the right quality. Manufacturers are also responsible for ensuring the equipment they use is of the right standard. This need has led to demands for ways of certifying the hygienic quality of products.

There are two organisations that provide a certification scheme for the hygienic design of equipment. The oldest is the 3-A Sanitary Standards Symbol Administrative Council in the USA. The 3-A council has been providing a self-certification scheme for hygienic equipment for the dairy industry for many years. Currently, the 3-A certification scheme is under revision with the objective of providing a higher confidence level in the 3-A certified equipment. Self-certification will be replaced by third-party accreditation.

In the late 1990s the European Hygienic Equipment Design Group (EHEDG) initiated the development of a certification scheme in Europe. The objective is to

certify equipment that complies with hygienic design criteria, specified and discussed in the EHEDG publication *Hygienic Design Criteria* (EHEDG Document no. 8). The scheme has operated since 2001 and is executed on behalf of EHEDG by 'EHEDG Authorised Organisations'. To obtain a certificate of compliance, the applicant must provide clear evidence that the equipment for which certification is wanted complies with EHEDG hygienic design criteria. Detailed drawings must be provided. The material provided is evaluated by an expert from an authorised organisation. The evaluation report forms the basis of a contract with the applicant, which, if duly signed by both parties, allows the use of the EHEDG Certification Logo in connection with the equipment evaluated. Certification applies for one year.

There may be reasons why a particular feature of equipment cannot comply with one of the EHEDG hygienic design criteria. If measures have been devised that compensate for the lack of compliance and evidence has been provided that these measures are effective, certification is still possible provided that the applicant agrees to describe these measures clearly in any promotional material and documentation belonging to the equipment. To ensure correct use, the EHEDG logo may only be placed on, or used in relation to the product(s) as identified. The applicant is fully responsible for its correct use. Certification becomes invalid if the product has been significantly altered or is used for any other purpose or end use other than that certified. The applicant is contractually bound to inform EHEDG of any changes in the design of a certified product that may affect its compliance with the hygienic design criteria. Abuse of the Certification Logo is subject to legal action.

The actual evaluation of the evidence provided is done by qualified experts working at the organisations that have been authorised by contract to certify on behalf of EHEDG. To ensure that they are competent, the EHEDG contract with the Authorised Organisation includes the following conditions:

- The organisation will notify the EHEDG of the competent staff with the required experience needed to correctly judge compliance with the hygienic design criteria of the EHEDG. Typically, such staff will have undertaken appropriate courses on hygienic design and/or been trained by EHEDG recognised experts.
- The EHEDG will be allowed to interrogate staff responsible for evaluation for compliance with the hygienic design criteria of the EHEDG.
- Changes in staff responsible for EHEDG evaluation will be reported immediately to the secretariat of the EHEDG.

The organisation will not accept requests for certification:

- from closely related organisations (such as daughter, parent and sister organisations)
- if the expert has been involved in the design or improvement of the product for which certification is requested

- if the expert or the organisation has financial interest in the company requesting certification
- if the expert or the organisation might benefit commercially from certification of the product, other than by enhancement of the reputation, recognition and fame of the organisation.

To guard the quality of the certification scheme, a User Committee randomly inspects documents and evidence relevant to EHEDG certification. These documents include test reports, drawings and correspondence discussing the evaluation (including testing, where relevant) of the product for which certification is required. Evidence may be, for example, the actual product, pictures of the product, or records of measurements (such as measurement of surface roughness). To protect the interest of the applicant, the User Committee has no members who are affiliated with the applicant or its competitors.

12.6 Certification of equipment in the United States: the 3-A Symbol Council

Organised in 1956, the 3-A Sanitary Standards Symbol Administrative Council – known in the industry as the 3-A Symbol Council – grants authorisations to use the 3-A Symbol on equipment that meets 3-A Sanitary Standards for design and fabrication. The 3-A symbol on food equipment serves three important purposes:

- It assures processors that equipment meets sanitary standards.
- It provides accepted criteria to equipment manufacturers for sanitary design.
- It establishes guidelines for uniform evaluation and compliance by those responsible for inspection.

The 3-A Symbol Council consists of eight trustees (members), including a Chairman, Vice-Chairman and Secretary-Treasurer. Two trustees are appointed to represent processor interests, two to represent the International Association of Food Industry Suppliers (IAFIS) and four to represent regulatory bodies and appointed by the International Association for Food Protection (IAFP). Symbol Council trustees authorise and administer use of the 3-A symbol, but do not participate in preparing the 3-A standards. In order for food equipment manufacturers to use the 3-A symbol, they must file an application with the 3-A Symbol Council office. A company executive is required to sign the application for authorisation to use the symbol, initialing each paragraph of the standard to signify that the equipment is compliant with all provisions of that standard. A statement of the quality controls in place must be submitted along with drawings or pictures of the equipment. The council may also request additional materials to ensure compliance on complex subassemblies. The council reviews the application and, if all areas are in compliance under that specific 3-A standard, the manufacturer is permitted to use the 3-A symbol. Equipment manufacturers

are required to place the serial number of the 3-A standard with which it complies adjacent to the 3-A symbol on their equipment.

Authorisations to use the 3-A symbol are renewable each year. Amendments to an authorisation can be made if a manufacturer desires to change design or add new models to the line. A manufacturer may do so by submitting an application for amendment, in which the changes are specifically designated. All records are maintained by the Council's Administrative Officer and kept at the 3-A Symbol Council office. If equipment in use in the dairy and food industry bears the 3-A symbol but does not comply with the 3-A Sanitary Standards, it should be reported to the 3-A Symbol Council office. The 3-A Symbol Council will investigate reports of non-compliance or unauthorised use and take appropriate action to resolve the inquiry.

At the present time, the 3-A Symbol Council is considering moving from a supplier self-certification to third-party certification as currently used by the EHEDG. A joint committee composed of 3-A trustees and 3-A Sanitary Standards Committee members is crafting the plan for the 'New 3-A Way'. The new way will provide criteria for auditor qualifications, the audit process and how to recertify used and refurbished equipment. Qualified auditors will be selected by the 3-A Symbol Council, based on the developed protocol, who will conduct equipment examination. An auditors report will be submitted to the 3-A Symbol Council for council approval. The joint committee expects to have the new programme operating by 2003.

The 3-A Sanitary Standards Committees and NSF International have joined forces to develop a family of standards for the hygienic design of meat and poultry processing equipment. NSF/3-A 14159-2 and 14159-3 will provide specifics for hand-held tools and modular conveyors. These three NSF/3-A standards contain verbatim requirements from ISO 14159 (Safety of machinery: Hygienic requirements of the design of machinery) plus additional clauses needed to meet the hygienic design expectation of the US meat and poultry industry.

Review of dairy equipment may be done by an individual state regulatory agency, the FDA, the USDA Dairy Grading Branch or a combination. The review is applied mostly to pasteurisation equipment and especially to the controls used for high-temperature short-time (HTST) and higher-heat shorter-time (HHST) pasteurisation processes, ultra-high temperature (UHT) and aseptic processing of milk and fluid milk products. Through a memorandum of understanding (MOU) with the states, the states have the authority to accept or reject equipment.

The Food Safety and Inspection Service (FSIS) of the USDA traditionally carried out 'prior approval' inspections of meat and poultry processing equipment. This programme has been replaced by the mandatory implementation of HACCP systems by meat processors in which they assume responsibility for the suitability of equipment. The USDA has subsequently developed a voluntary fee-based meat and poultry equipment inspection programme using the NSF/3-A family of standards on the hygienic design requirements of meat and poultry processing equipment.

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Part III

Hygienic practices

13

Cleaning and disinfection

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13.1 Introduction: principles

Cleaning and disinfection is undertaken to:

- remove microorganisms, or material conducive to microbial growth. This reduces the chance of contamination by pathogens and, by reducing spoilage organisms, may extend the shelf-life of some products
- remove materials that could lead to foreign body contamination or could provide food or shelter for pests
- remove food materials left on production lines which may deteriorate and re-enter subsequent production runs, damaging product quality
- extend the life of, and prevent damage to, equipment and surfaces
- provide a safe and clean working environment for employees
- present a favourable image to visitors. On audit, for example, the initial impression of an 'untidy' or 'dirty' processing area creates an impression of poor management which is subsequently difficult to overcome.

Cleaning and disinfection can be divided up into a number of stages, building on the pioneering work of Jennings (1965), Koopal (1985) and Holah (2000a). These are described below.

- The wetting and penetration by the cleaning solution of both the soil and the equipment surface.
- The reaction of the cleaning solution with both the soil and the surface, to facilitate peptisation of organic materials, dissolution of soluble organics and minerals, emulsification of fats and the dispersion and removal from the surface of solid soil components.

- The prevention of redeposition of the dispersed soil back onto the cleansed surface.
- The wetting by the disinfection solution of residual microorganisms to facilitate reaction with cell membranes and/or penetration of the microbial cell to produce a biocidal or biostatic action.
- Depending on whether the disinfectant contains a surfactant and the disinfectant practice chosen (i.e. with or without rinsing), this may be followed by dispersion of the microorganisms from the surface.

To undertake these stages, sanitation programmes employ a combination of four major factors:

- Mechanical or kinetic energy
- Chemical energy
- Temperature or thermal energy
- Time.

The combinations of these four factors vary for different cleaning systems and, generally, if the use of one energy source is restricted, this shortfall may be compensated for by utilising greater inputs from the others.

Mechanical or kinetic energy is used to remove soils physically. The mechanics and kinetics of these interactions have been discussed by a number of authors (Jennings, 1965; Schlusser, 1975; Loncin, 1977; Corrieu, 1981; Koopal, 1985; Bergman and Tragardh, 1990). Methods may include scraping, manual brushing and automated scrubbing (physical abrasion) and pressure jet washing (fluid abrasion). Of all four factors, physical abrasion is regarded as the most efficient in terms of energy transfer (Offiler, 1990). The efficiency of fluid abrasion and the effect of impact pressure has been described by Anon. (1973) and Holah (1991). Mechanical energy has been demonstrated to be the most efficient for biofilm removal (Blenkinsopp and Costerton, 1991; Wirtanen and Mattila-Sandholm, 1993, 1994; Mattila-Sandholm and Wirtanen, 1992; Gibson *et al.*, 1999).

In cleaning, chemical energy is used to break down soils to render them easier to remove and to suspend them in solution to aid rinsability. At the time of writing, no cleaning chemical has been marketed with the benefit of aiding microorganism removal. In chemical disinfection, chemicals react with microorganisms remaining on surfaces after cleaning to reduce their viability.

The chemical effects of cleaning and disinfection increase with temperature in a linear relationship and approximately double for every 10°C rise. For fatty and oily soils, temperatures above their melting point are used to break down and emulsify these deposits and so aid removal. Elevated temperature is the best disinfectant as it penetrates into surfaces, is non-corrosive, is non-selective to microbial types, is easily measured and leaves no residue (Jennings, 1965). However, for open surfaces, the use of hot water or steam is uneconomic, hazardous or impossible, and reliance is therefore placed on chemical biocides. The influence of detergency in cleaning and disinfection has been described by

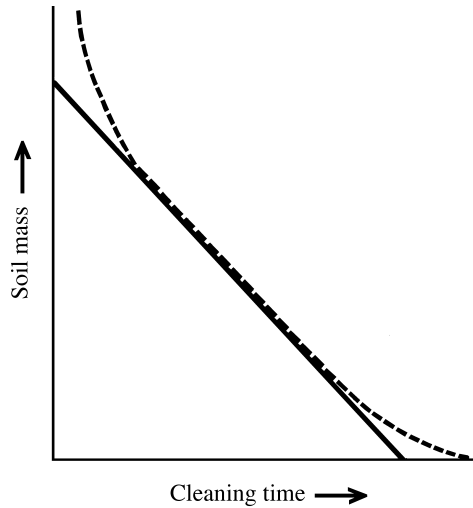


Fig. 13.1 Removal of soil with cleaning time.

Dunsmore (1981), Shupe *et al.* (1982), Mabesa *et al.* (1982), Anderson *et al.* (1985) and Middlemiss *et al.* (1985).

For cleaning processes using mechanical, chemical and thermal energies, generally the longer the time period employed, the more efficient the process. When extended time periods can be employed in sanitation programmes, e.g. soak-tank operations, other energy inputs can be reduced (e.g. reduced detergent concentration, lower temperature or less mechanical brushing).

Soil removal from surfaces decreases such that the log of the mass of soil per unit area remaining is linear with respect to cleaning time (Fig. 13.1) and thus follows first-order reaction kinetics (Jennings, 1965; Schlusser, 1975). This approximation, however, is only valid in the central portion of the plot and, in practice, soil removal is initially faster and ultimately slower (dotted line in Fig. 13.1) than that which a first-order reaction predicts. The reasons for this are unclear, though initially, unadhered gross oil is usually easily removed (Loncin, 1977), whilst ultimately, soils held within surface imperfections or otherwise protected from cleaning effects would be more difficult to remove (Holah and Thorpe, 1990).

Routine cleaning operations are never, therefore, 100% efficient, and over a course of multiple soiling/cleaning cycles, soil deposits (potentially including microorganisms) will be retained. As soil accumulates, cleaning efficiency will decrease and, as shown in plot A in Fig. 13.2, soil deposits may for a period grow exponentially. The timescale for such soil accumulation will differ for all processing applications and can range from hours (e.g. heat exchangers) to typically several days or weeks. In practice it is controlled by the application of a 'periodic' clean (Dunsmore *et al.*, 1981). Periodic cleans are employed to return the surface-bound soil accumulation to an acceptable base level (plot B in Fig. 13.2) and are achieved by increasing cleaning time and/or energy input, e.g.

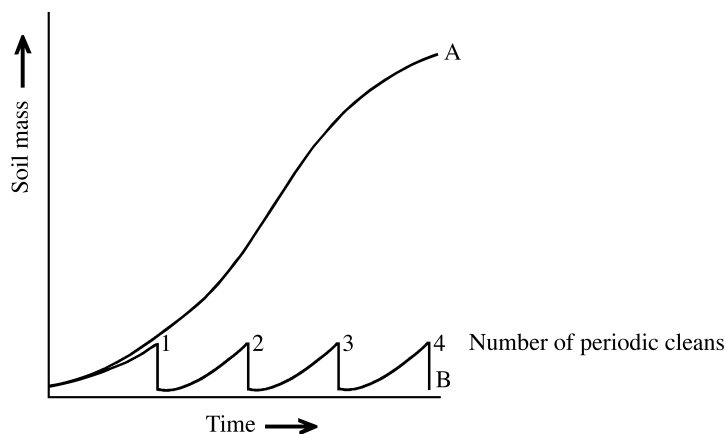


Fig. 13.2 Build-up of soil over time: (A) without periodic cleaning; (B) with periodic cleaning.

higher temperatures, alternative chemicals or manual scrubbing. A typical example of a periodic clean is the 'weekend clean down' or 'bottoming'.

13.2 Cleaning chemicals

Cleaning should not just remove soil but also reduce the number of microorganisms present. A number of studies have shown how cleaning can reduce bacterial numbers (Schmidt and Cremling, 1981; Mrozek, 1982). The efficacy of cleaning and disinfection, following well-planned and executed sanitation programmes on food processing equipment in eight chilled food factories, is shown in Table 13.1 (Holah, 2000a). The results suggest that both cleaning and disinfection are equally responsible for reducing the levels of adhered microorganisms. It is important, therefore, not only to purchase quality cleaning chemicals for their soil removal capabilities but also for their potential for microbial removal. In addition, there are likely to be sufficient viable microorganisms remaining on the surface to warrant the application of a disinfectant. The aim of disinfection is therefore to further reduce the surface population of viable microorganisms, via removal or destruction, and/or to prevent surface microbial growth during the inter-production period.

Table 13.1 Arithmetic and log mean bacterial counts on food processing equipment before and after cleaning and after disinfection

	Before cleaning	After cleaning	After disinfection
Arithmetic mean	1.32×10^6	8.67×10^4	2.5×10^3
Log mean	3.26	2.35	1.14
No. of observations	498	1090	3147

No single cleaning agent combines soil and microbial removal properties. A cleaning solution or detergent is blended from a number of components:

- Water
- Surfactants
- Inorganic alkalis
- Inorganic and organic acids
- Sequestering agents.

The range of chemicals and their purposes is well documented (Anon., 1991; Elliot, 1980; ICMSF, 1980, 1988; Hayes, 1985; Holah, 1991; Koopal, 1985; Russell *et al.*, 1982). Water is the base ingredient of all 'wet' cleaning systems and must be of potable quality. Water provides the cheapest readily available transport medium for rinsing and dispersing soils, has dissolving powers to remove ionic-soluble compounds such as salts and sugars, will help emulsify fats at temperatures above their melting point, and, in high-pressure cleaning, can be used as an abrasive agent. On its own, however, water is a poor 'wetting' agent and cannot dissolve non-ionic compounds.

Organic surfactants (surface-active or wetting agents) are amphipolar and are composed of a long non-polar (hydrophobic or lyophilic) chain or tail and a polar (hydrophilic or lyophobic) head. Surfactants are classified as anionic (including the traditional soaps), cationic or non-ionic, depending on their ionic charge in solution, with anionics and non-ionics being the most common. Amphipolar molecules aid cleaning by reducing the surface tension of water and by emulsification of fats. If a surfactant is added to a drop of water on a surface, the polar heads disrupt the water's hydrogen bonding, reduce the surface tension of the water and allow the drop to collapse and 'wet' the surface. Increased wettability leads to enhanced penetration into soils and surface irregularities and hence aids cleaning action. Fats and oils are emulsified as the hydrophilic heads of the surfactant molecules dissolve in the water whilst the hydrophobic end dissolves in the fat. If the fat is surface-bound, the forces acting on the fat/water interface are such that the fat particle will form a sphere (to obtain the lowest surface area for its given volume), causing the fat deposit to 'roll-up' and detach itself from the surface.

Alkalis are useful cleaning agents as they are cheap, break down proteins through the action of hydroxyl ions, saponify fats and, at higher concentrations, may be bactericidal. Strong alkalis, usually sodium hydroxide (or caustic soda), exhibit a high degree of saponification and protein disruption, though they are corrosive and hazardous to operatives. Correspondingly, weak alkalis are less hazardous but also less effective. Alkaline detergents may be chlorinated to aid the removal of proteinaceous deposits, but chlorine at alkaline pH is not an effective biocide. The main disadvantages of alkalis are their potential to precipitate hard water ions, the formation of scums with soaps, and their poor rinsability.

Acids have little detergency properties, although they are very useful in making soluble carbonate and mineral scales, including hard water salts and

proteinaceous deposits. As with alkalis, the stronger the acid the more effective it is, though, in addition, the more corrosive to plant and operatives. Acids are not used as frequently as alkalis and tend to be used for periodic cleans.

Sequestering agents (sequestrants or chelating agents) are employed to prevent mineral ions precipitating by forming soluble complexes with them. Their primary use is in the control of water hardness ions and they are added to surfactants to aid their dispersion capacity and rinsability. Sequestrants are most commonly based on ethylene diamine tetraacetic acid (EDTA), which is expensive. Although cheaper alternatives are available, these are usually polyphosphates which are environmentally unfriendly.

A general-purpose food detergent may, therefore, contain the following:

- A strong alkali to saponify fats
- Weaker alkali 'builders' or 'bulking' agents for saponification and protein disruption
- Surfactants to improve wetting, dispersion and rinsability
- Sequestrants to control hard water ions.

In addition, the detergent should ideally be safe, non-tainting, non-corrosive, stable, environmentally friendly and cheap. The choice of cleaning agent will depend on the soil to be removed and on its solubility characteristics, and these are summarised for a range of products in Table 13.2 (modified from Elliot, 1980).

Alcohol-based products are commonly used for mid-shift cleaning and disinfection in high-risk areas. This is primarily to restrict the use of water for cleaning during production as a control measure to prevent the growth and spread of any food pathogens that penetrate the high-risk area barrier controls. Ethyl alcohol (ethanol) and isopropyl alcohol (isopropanol) have bactericidal

Table 13.2 Solubility characteristics and cleaning procedures recommended for a range of soil types

Soil type	Solubility characteristics	Cleaning procedure recommended
Sugars, organic acids, salt	Water-soluble	Mildly alkaline detergent
High-protein foods (meat, poultry, fish)	Water-soluble Alkali-soluble Slightly acid-soluble	Chlorinated alkaline detergent
Starchy foods, tomatoes, fruits	Partly water-soluble Alkali-soluble	Mildly alkaline detergent
Fatty foods (fat, butter, margarine, oils)	Water-insoluble Alkaline-soluble	Mildly alkaline detergent; if ineffective, use strong alkali
Heat-precipitated water hardness, milk stone, protein scale	Water-insoluble Alkaline-insoluble Acid-soluble	Acid cleaner, used on a periodic basis

and virucidal (but not sporicidal) properties (Hugo and Russell, 1999), though they are active only in the absence of organic matter, i.e. the surfaces need to be wiped clean and then alcohol reapplied. Alcohols are most active in the 60–70% range, and can be formulated into wipe and spray based products. Alcohol products are used on a small, local scale because of their well-recognised health and safety issues.

13.3 Disinfectants

The ideal disinfectant should have the following characteristics:

- Microbial destruction properties of uniform, broad-spectrum activity against vegetative bacteria, yeasts and moulds to produce rapid kill
- Environmental resistance (effective in the presence of organic matter, detergent and soap residues, and water hardness and pH variability)
- Good cleaning properties
- Non-toxic and non-irritating properties
- Water solubility in all proportions
- Non-tainting, particularly for 'non-rinse' disinfectants
- Stability in concentrated and use dilution
- Ease of use
- Ready availability
- Inexpensive
- Ease of measurement in solution.

Whilst there are many chemicals with biocidal properties, many common disinfectants are not used in food applications because of safety or taint problems, e.g. phenolics or metal-ion-based products. In addition, other disinfectants are used to a limited extent only in food manufacture and/or for specific purposes, e.g. biguanides, formaldehyde, glutaraldehyde, organic acids, ozone, chlorine dioxide and bromine compounds. Of the acceptable chemicals, the most commonly used products are:

- Chlorine-releasing components
- Quaternary ammonium compounds (quats)
- Amphoterics
- Iodine compounds (iodophors)
- Peracetic acid
- Acid anionic compounds.

Chlorine is the cheapest disinfectant and is available as hypochlorite (or occasionally as chlorine gas) or in slow-release forms (e.g. chloramines, dichlorodimethylhydantoin). Chlorine is known to be effective as a sanitiser for mechanically polished stainless steel, unabraded electropolished stainless steel, and the polycarbonate surfaces, reducing self-populations to less than $1.0 \log \text{CFU/cm}^2$. This disinfectant is less effective on abraded electropolished stainless

steel and mineral resin surfaces, where populations exceed $1.0 \log \text{CFU/cm}^2$ (Frank and Chmielewski, 1997). The most common chlorine compounds are hypochlorite and the slow-releasing chloramines and dichlorodimethylhydantoin. These have a wide range of activity, including some effect against spores, and are relatively inexpensive. However, they are readily inactivated by organic matter, and potentially can have an adverse effect on the environment. Chlorine compounds in the undiluted form are corrosive to equipment, can be hazardous to health and should always be handled with care and at the correct concentrations.

Quaternary ammonium compounds (Quats or QACs) are amphipolar, cationic detergents, derived from substituted ammonium salts with a chlorine or bromine anion. Although having little effect on spores, they are both relatively environmentally and operative friendly. It should be noted that certain alkaline compounds (anionic wetting agents) can reduce the bacteriocidal action of QACs. It should also be noted that:

- QACs are stable in concentrated form and have a long shelf life.
- In concentrated form they are much safer to handle than hypochlorite solutions and they are relatively non-corrosive to metals.
- Owing to their high surface activity, excessive foam can be produced during circulation through the plant and hence QACs are sometimes difficult to rinse away.
- Factors that can impair their bacteriocidal effectiveness are the presence of organic matter, water hardness which can reduce their activity and the type of organism. Gram-negative bacteria like coliforms and psychotrophic organisms may be less affected, especially at low concentrations (e.g. at $<50 \text{ ppm}$ of QAC at 10°C), than Gram-positive bacteria (e.g. staphylococci and streptococci).

Amphoterics are based on the amino acid glycine, often incorporating an imidazole group. They share similar activities and benefits with the quaternary ammonium compounds. Amphoterics are known to have good detergent/sterilising properties, but due to their high foaming characteristics, they are not recommended for cleaning in place (CIP). However, they are used for manual cleaning, since they are non-corrosive and non-irritant to skin.

The major iodine compounds used for disinfection are iodophors, alcohol-iodine solutions, and aqueous iodine solutions. In iodophors iodine is combined with a suitable non-ionic surfactant to provide a usable product. The iodine complex is acidified with, for example, phosphoric acid for better stability and improved bacteriocidal effect. Iodophors are often considered as detergent/sterilisers due to the presence of surface-active agents together with the acid. In general:

- Hard water can neutralise the acid in the iodophore.
- Iodophores have a good shelf life at ambient temperatures, but some iodine may vaporise; however, excessive loss occurs at temperatures above 50°C .

- Some plastic materials, e.g. gaskets, can react with iodine and the product can acquire an iodine taint.
- Iodine stains any residual soiling matter on the surfaces of equipment and visual inspection of the plant can indicate the standard of hygiene.
- Some residues like milk can inactivate the iodine. An early indication of this loss is the fading of the amber colour. It is important to check the strength of the iodophor, especially if the solution is recirculated.

Peracetic acid, which provides a rapid, broad-spectrum kill, works on the oxidation principle through the reaction with the components of cell membranes. It is particularly effective against spores but is hazardous to use. It is one of a family of acid disinfectants which are considered to be toxicologically safe and biologically active. They include other organic acids, such as acetic, lactic, propionic and formic acid. Acid anionic disinfectants are formulated with anionic surfactants (negatively charged) acids, phosphoric acid and organic acids. They act rapidly and kill a broad spectrum of bacteria. The general characteristics of these disinfectants are summarised in Table 13.3. General and particular applications are summarised in Tables 13.4 and 13.5.

The efficacy of disinfectants is generally controlled by five factors:

- Interfering substances (primarily organic matter)
- pH
- Temperature
- Concentration
- Contact time.

To some extent, and particularly for the oxidative biocides, the efficiency of all disinfectants is reduced in the presence of organic matter. Organic material may react chemically with the disinfectant such that it loses its biocidal potency, or spatially such that microorganisms are protected from its effect. Quaternary ammonium compounds are, for example, incompatible with calcium and magnesium salts and should not be used with over 200 parts per million (ppm) of calcium in water or without a sequestering or chelating agent. As water hardness increases, the effectiveness of these sanitisers decreases. Other interfering substances, e.g. cleaning chemicals, may react with the disinfectant and destroy its antimicrobial properties, and it is therefore essential to remove all soil and chemical residues prior to disinfection.

Disinfectants should be used only within the pH range specified by the manufacturer. Perhaps the classic example of this is chlorine, which dissociates in water to form HOCl and OCl^- ion. Over pH 3–7.5, chlorine is predominantly present as HOCl, which is a very powerful biocide, though the potential for corrosion increases with acidity. Above pH 7.5, however, the majority of the chlorine is present as the OCl^- ion which has about 100 times less biocidal action than HOCl.

In general, the higher the temperature, the greater the disinfection. A higher temperature generally lowers surface tension, increases pH, decreases viscosity, and creates other changes that may help bactericidal action. For

Table 13.3 Characteristics of some common disinfectants

Property	Chlorine	QAC	Amphoterics	Iodophors	Peracetic acid	Acid anionics
<i>Microorganism control</i>						
Gram-positive	++	++	++	++	++	++
Gram-negative	++	++	++	++	++	++
Spores	+	—	—	+	++	—
Yeast	++	++	++	++	++	++
Developed microbial resistance	—	+	+	—	—	—
<i>Other characteristics</i>						
Inactivation by organic matter	++	+	+	+	+	+
Water hardness	—	+	—	—	—	—
Detergency properties	—	++	+	+	—	++
Surface activity	—	++	++	+	—	—
Foaming potential	—	++	++	—	—	+
Problems with taints	±	—	—	+	±	—
Stability	±	—	—	±	±	—
Corrosion	+	—	—	+	—	—
Safety	+	—	—	+	++	—
Other chemicals	—	+	—	—	—	+
Potential environmental impact	++	±	±	±	—	—
Cost	—	++	++	+	+	+

— No effect/poor effectiveness

+ Effect/medium effectiveness

++ Large effect/strong effectiveness

Table 13.4 General applications of disinfectants

Detergent	Application
Chlorine	All food contact surfaces, spray, CIP, fogging
QAC	All food contact surfaces, mostly used for environmental control; walls, drains, tiles
Iodophors	All food contact surfaces, approach as a hand dip
Peracetic acid	All food contact surfaces, usually restricted to CIP, especially cold temperature and carbon dioxide environments
Acid anionics	All food contact surfaces, spray, combines sanitising and acid rinse into one operation

most food manufacturing sites operating at ambient conditions (around 20°C) or higher this is not a problem, as most disinfectants are formulated (and tested) to ensure performance at this temperature. This is not, however, the case in the chilled food industry. Taylor *et al.* (1999) examined the efficacy of 18 disinfectants at both 10°C and 20°C and demonstrated that for some chemicals, particularly quaternary ammonium-based products, disinfection was much reduced at 10°C; they recommended that in chilled production environments, only products specifically formulated for low-temperature activity should be used.

The relationship between disinfectant concentration and microbial death concentration is not linear but follows a sigmoidal curve. Microbial populations are initially difficult to kill at low concentrations, but as the biocide con-

Table 13.5 Particular applications of disinfectants (adapted from Lentsch, 1979)

Application	Recommended disinfectants
Film formation, prevention of	Acid sanitiser, iodophor, chlorine, paracetic acid
Bacteriostatic film	QAC, acid-quat, acid-anionic
CIP cleaning	Acid sanitiser, chlorine, iodophor
Concrete floors	Chlorine, QAC
Fogging, atmosphere	Chlorine, QAC, amphoteric
Hand-dip (production)	Iodophor
Hand sanitiser (washroom)	Iodophor, QAC, chlorhexadine
Odour control	Quat
Plastic crates	Iodophor, QAC, amphoteric
Wood crates	Chlorine
Porous surfaces	Chlorine
Processing equipment (aluminium)	QAC, iodophor, amphoteric
Processing equipment (stainless steel)	Acid sanitiser, acid-quat, chlorine, iodophor, amphoteric
Rubber belts	Iodophor, QAC, amphoteric
Tile walls	Iodophor, QAC, amphoteric
Walls	Chlorine, QAC, acid-quat, amphoteric
Water treatment	Chlorine, ozone, chlorine dioxide

centration is increased a point is reached where the majority of the population is reduced. Beyond this point the microorganisms become more difficult to kill (through resistance or physical protection) and a proportion may survive regardless of the increase in concentration. It is important, therefore, to use the disinfectant at the concentration recommended by the manufacturer. Concentrations above this recommended level may thus not enhance biocidal effect and will be uneconomic, whilst concentrations below this level may significantly reduce biocidal action.

Sufficient contact time between the disinfectant and the microorganisms is perhaps the most important factor controlling biocidal efficiency. To be effective, disinfectants must find, bind to and transverse microbial cell envelopes before they reach their target site and begin to undertake the reactions which will subsequently lead to the destruction of the microorganism (Klemperer, 1982). Sufficient contact time is therefore critical to give good results, and most general-purpose disinfectants are formulated to require at least 5 minutes to reduce bacterial populations by 5 log orders in suspension. This has arisen for two reasons. Firstly, 5 minutes is a reasonable approximation of the time taken for disinfectants to drain off vertical or near-vertical food processing surfaces. Secondly, when undertaking disinfectant efficacy tests in the laboratory, a 5-minute contact time is chosen to allow ease of test manipulation and hence timing accuracy. For particularly resistant organisms such as spores or moulds, surfaces should be repeatedly dosed to ensure extended contact times of 15–60 minutes. The reaction time of chlorine-based sanitisers is temperature-dependent. Up to 52°C, the reaction rate doubles for each 10°C increase in temperature. Although hypochlorites are relatively stable, Cl₂ solubility decreases rapidly above 50°C.

The practice of rinsing or not rinsing has yet to be established. The main reason for leaving disinfectants on surfaces is to provide an alleged biocide challenge (this has not been proven) to any subsequent microbial contamination of the surface. It has been argued, however, that the low biocide concentrations remaining on the surface, especially if the biocide is a QAC, may lead to the formation of resistant surface populations. There is evidence that *Pseudomonas aeruginosa* can become adapted by repeated exposure to QACs and amphoteric (Adair *et al.*, 1969; Jones *et al.*, 1989; Langsrud and Sundheim, 1997). Plasmid-mediated resistance has also been described for Gram positive *Staphylococci* spp. involving the *qacA-D* genes (McDonnell and Russell, 1999) and *qacG-H* genes (Heir *et al.*, 1999). The presence of QAC resistant staphylococcal strains has been shown to be common in food processing environments by Heir *et al.* (1999) who identified 25 from 191 isolates to be resistant to benzalkonium chloride. In laboratory disinfectant challenge tests, these authors demonstrated an increase in minimum inhibitory concentration (MIC) from 0–2 mg/l to 4–11 mg/l. Similarly, Mereghetti *et al.* (2000) demonstrated a MIC increase in resistance from 3–13 mg/l for strains of *Listeria monocytogenes* isolated from a range of environmental, food, animal and clinical sources. None of these workers

demonstrated *Staphylococcus spp.* or *L. monocytogenes* strain resistance to disinfection concentrations approaching disinfectant manufacturers' in-use recommended concentrations. Good quality QACs have a concentration of approximately 1000 mg/l, indicating no problems with resistant vegetative bacteria if appropriate disinfectants are chosen and used properly.

Leaving disinfectants on surfaces also increases the risk of tainting food. In Europe, legislation is confusing surrounding whether or not disinfectants can be left on surfaces without rinsing. The Meat Products Directive (95/68/EC) allows disinfectants to remain on surfaces (no rinse status) 'when the directions for use of such substances render such rinsing unnecessary', whilst the Egg Products (89/437/EEC) and Milk Products (92/46/EEC) Directives require that disinfectants must be rinsed off by potable water. There is no specific guidance for other food product categories, although the general Directive on the hygiene of foodstuffs (93/43/EEC) requires that 'Food business operators shall identify any step in their activities which is critical to ensuring food safety and ensure that adequate safety procedures are identified, implemented, maintained and reviewed ...'.

It is important to be aware of microbial resistance to disinfectants that are not used correctly. Some bacteria have innate chlorine resistance, including bacterial spores and *Cryptosporidium*. Pathogens such as *Salmonella* may also develop chlorine resistance either in response to the use of sub-lethal concentrations or because compounds are neutralised in use (Mokgatla *et al.*, 2002). Studies of the use of chlorine in the washing of minimally processed fruits and vegetables have shown that such pathogens may not be completely eliminated (Zhuang *et al.*, 1995). The disinfection activity of hypochlorites is significantly reduced by a high pH and the presence of organic matter (Cords and Dychdala, 1993). It is essential to ensure that cleaning is effective prior to disinfection and that concentrations of chlorine are sufficient to eradicate bacteria.

Pathogens also have the potential to develop resistance to other disinfectants. As an example, Pickett and Murano (1996) exposed *L. monocytogenes* to sub-lethal concentrations of various disinfectants. The pathogen developed resistance to the acidic anionic disinfectant used. It also demonstrated resistance to the use of citric acid when the pH was raised to 5.0. Other studies have shown that *L. monocytogenes* can also develop resistance to quaternary ammonium sanitisers (Lemaitre *et al.*, 1998). As has already been noted, biofilms significantly inhibit the effectiveness of disinfectants (Oh and Marshall, 1996; Bower and Daeschel, 1999). It has also been suggested that the development of resistance to antibiotics used therapeutically may be linked to resistance to biocides. Studies by Russell and Day (1996) and Russell (1997) have shown that antibiotic-resistant *Staphylococcus aureus* and *S. epidermidis* developed increased resistance to chlorhexidine, iodophors and quaternary ammonium compounds. All these studies confirm the importance of using disinfectants correctly and at the recommended concentrations.

13.4 Testing disinfectants

Due to the wide range of food soils likely to be encountered and the influence of the food manufacturing site (temperature, humidity, type of equipment, time before cleaning, etc.), there are currently no officially recognised laboratory methods for assessing the efficacy of cleaning compounds. This is not the case for disinfectants, however, as it is possible to assess a wide spectrum of activity against microorganisms, including bacteria, fungi, spores and viruses in laboratory tests. The range of currently available disinfectant test methods was reviewed by Reybrouck (1998). They fall into two main classes: suspension tests and surface tests.

Suspension tests are useful for indicating general disinfectant efficacy and for assessing environmental parameters such as temperature, contact time and interfering matter such as food residues. In reality, however, microorganisms disinfected on food contact surfaces are those that remain after cleaning and are therefore likely to be adhered to the surface. A surface test is thus more appropriate.

A number of authors have shown that bacteria attached to various surfaces are generally more resistant to biocides than are organisms in suspension (Dhaliwal *et al.*, 1992; Frank and Koffi, 1990; Holah *et al.*, 1990a; Hugo *et al.*, 1985; Le Chevalier *et al.*, 1988; Lee and Frank, 1991; Ridgeway and Olsen, 1982; Wright *et al.*, 1991; Andrade *et al.*, 1998; Das *et al.*, 1998). In addition, cells growing as a biofilm have been shown to be more resistant (Frank and Koffi, 1990; Lee and Frank, 1991; Ronner and Wong, 1993). The mechanism of resistance in attached and biofilm cells is unclear but may be due to physiological differences such as growth rate, membrane orientation changes due to attachment and the formation of extracellular material which surrounds the cell. Equally, physical properties may have an effect, e.g. protection of the cells by food debris or the material surface structure or problems in biocide diffusion to the cell/material surface. To counteract such claims of enhanced surface adhered resistance, it can be argued that surface tests do not consider the environmental stresses the organisms may encounter in the processing environment prior to disinfection (action of detergents, variations in temperature and pH and mechanical stresses) which may increase susceptibility to disinfectants. Both suspension and surface tests have limitations, however, and research-based methods are being developed to investigate the effect of disinfectants against adhered microorganisms and biofilms *in situ* and in real time. Such methods have been reviewed by Holah *et al.* (1998).

In Europe, CEN TC 216 is currently working to harmonise disinfectant testing and has produced a number of standards. The current food industry disinfectant test methods of choice for bactericidal and fungicidal action in suspension are EN 1276 (Anon., 1997), EN 1650 (Anon., 1998a) and (on surfaces) EN 13697 (Anon., 2001) respectively. Food manufacturers should ensure that the disinfectants they use conform to these standards as appropriate. Because of the limitations of disinfectant efficacy tests, however, food

manufacturers should always confirm the efficacy of their cleaning and disinfection programmes by field tests either from evidence supplied by the chemical company or from in-house trials.

As well as having demonstrable biocidal properties, disinfectants must also be safe (non-toxic) and should not taint food products. In terms of the demonstration of non-toxicity, legislation will vary in each country, although in Europe this has been clarified with the implementation of Directive 98/9/EC concerning the placing of biocidal products on the market, which contains requirements for toxicological and metabolic studies. Traditionally, a recognised acceptable industry guideline for disinfectants is a minimum acute oral toxicity (with rats) of 2000 mg/kg bodyweight.

Approximately 30% of food taint complaints are thought to be associated with cleaning and disinfectant chemicals. These taints are described by sensory scientists as 'soapy', 'antiseptic' or 'disinfectant' (Holah, 1995). Disinfectants can enter food products accidentally, e.g. from aerial transfer or poor rinsing, or deliberately, e.g. from 'no rinse status' disinfectants. CCFRA have developed two taint tests in which foodstuffs which have and have not been exposed to disinfectant residues are compared by a trained taste panel using the standard triangular taste test (Anon., 1983a). For assessment of aerial transfer, a modification of a packaging materials odour transfer test is used (Anon., 1964) in which food products, usually of four types (high moisture, e.g. melon; low moisture, e.g. biscuit; high fat, e.g. cream; high protein, e.g. chicken), are held above disinfectant solution of distilled water for 24 hours. To assess surface transfer, a modification of a food container transfer test is used (Anon., 1983b) in which food products are sandwiched between two sheets of stainless steel and drained off, to simulate no rinse status, or can be rinsed off prior to food contact. Control sheets are rinsed in distilled water only. The results of the triangular test involve both a statistical assessment of any flavour differences between the control and disinfectant-treated sample and a description of any flavour changes.

13.5 Water quality

There are many uses of water in food processing, including cleaning raw materials, cleaning of machinery and premises, as a heat transfer medium for pasteurisation and cooking as liquid or steam, as a medium for cooling, as an essential product ingredient, in extracting a key material for further processing or as a diluent for concentrated extracts. Table 13.6 illustrates the different grades and uses of water typically used in food processing, including cleaning.

Current EU regulation lays down mandatory standards for potable water quality (Table 13.7). These standards set out limits for potential contaminants such as pesticides and disinfection by-products as well as characteristics such as pH (Griffiths, 2000). As well as these standards, there are widely accepted microbiological standards for water quality (IDF, 1979; Dawson, 2000):

Table 13.6 Different grades and uses of water in food processing operations

Grade of water	Uses
Treated potable water	Product Cleaning of product containers (high-risk) Cleaning of raw materials (high-risk) Cleaning of process machinery (high-risk) Boiler feed water CIP feed water
Potable water	Product Washing of containers Washing of raw materials Washing of machinery Washing of production areas Transporting product Processing product Washing facilities for staff and visitors Drinking Prewash and final rinse of materials and containers Heating and cooling
Recycled treated or potable water	Secondary washing of materials or containers Secondary heating or cooling
Recovered water	Flushing of toilet Heating or cooling Washing of non-production areas Vehicle washing Fire fighting Garden irrigation

- Throughout any year, 95% of samples should not contain any coliform organisms or *Escherichia coli* in 100 ml.
- No sample should contain more than 10 coliform organisms per 100 ml.
- No sample should contain more than two cells of *E. coli* per 100 ml.
- No sample should contain more than one or two cells of *E. coli* per 100 ml in conjunction with a total coliform count of three or more per 100 ml.
- Coliform organisms should not be detectable in 100 ml of any two consecutive samples.

In addition, the degree of hardness must be taken into account in assessing water quality. This latter aspect is important, since detergents are formulated in relation to the degree of water hardness, and the presence of excess inorganic salts, mainly calcium and magnesium, can reduce their effectiveness. In addition, these salts can leave deposits on the surfaces of equipment which are difficult to remove. Water hardness is measured according to the mass of dissolved calcium and magnesium salts in the water. Other general measures of water quality include pH, conductivity or chlorine concentration (Anon., 1993). Whilst the main responsibility for meeting these standards lies with those

Table 13.7 Selected parameters of water quality

Parameter	Units	Limit
Temperature	°C	20
pH	pH units	6.5–9.0
Conductivity	mS/cm	2500
Chloride	mg/l	250
Sulphate	mg/l	250
Sodium	mg/l	200
Aluminium	mg/l	0.2
Nitrate	mg/l	50
Nitrite	mg/l	0.1
Ammonium	mg/l	0.5
Permanganate oxidation	mg/l O ₂	5
Boron	mg/l	1
Iron	mg/l	0.2
Manganese	mg/l	0.05
Copper	mg/l	2
Fluoride	mg/l	1.5
Arsenic	mg/l	0.01
Cadmium	mg/l	0.005
Cyanide	mg/l	0.05
Chromium	mg/l	0.05
Mercury	mg/l	0.001
Nickel	mg/l	0.02
Lead	mg/l	0.01
Antimony	mg/l	0.005
Selenium	mg/l	0.01
Pesticides, individual	mg/l	0.1
Pesticides, total	mg/l	0.5
Benz 3,4 pyrene	µg/l	0.01
Trichloroethane	µg/l	14
Tetrachloroethane	µg/l	8
Total THMs	µg/l	100
Acrylamide	µg/l	1
Epichlorhydrin	µg/l	0.1
Aldrin	µg/l	0.03
Dieldrin	µg/l	0.03
Heptachlor	µg/l	0.03
Heptachlor epoxide	µg/l	0.03
Benzene	µg/l	1
Bromate	µg/l	10
1,2 Dichlorethane	µg/l	3
Vinyl chloride	µg/l	0.5

supplying water to the food industry, food processors need to be aware of them, partly to ensure they are included in contractual agreements with water suppliers, and partly because many food processors undertake additional disinfection processes which may alter water composition and quality (Dawson, 1998).

There are a large number of options for water treatment in terms of physical filtration, ion exchange, chemical coagulation and use of nanofiltration or reverse osmosis systems, usually undertaken by the water supplier to remove impurities. There is also a wide range of disinfection techniques, some chemical and some physical, more often used by food processors. The chemical processes include the use of chlorine, sodium hypochlorite, chlorine dioxide, chloramines, bromine, bromamines, ozone and sonically produced copper and silver ions. The physical techniques include micro-filtration and the action of UV light. It is important to be aware that disinfection techniques can affect other materials, particularly organics, present in the water. This can lead to the formation, albeit at low levels, of disinfection by-products, some of which are not only toxic but carcinogenic. The control of the disinfection process is essential to ensure minimisation of risks from these products.

The water used in a food processing plant for cleaning and other purposes must be properly stored and managed. Storage systems should be designed with no dead ends so that water may circulate or flow freely (Imholte, 1984). Water should not be allowed to stagnate. In an old plant with extensive pipe runs, 'dead ends' or 'dead sections' can present real problems and have been known to be the explanation of sudden and unacceptably high numbers of microorganisms and taints. Water supplies should therefore be installed or modified to eliminate dead ends. Water lines no longer in use should be removed. Contamination from rust, scale and grease can also occur and pipes and pumps must be regularly inspected and properly maintained. New water piping installations should be made of corrosion-resistant materials.

All potable water storage tanks should be fitted with closely fitting covers to exclude contamination from dust, insects, birds or rodents. They should also be fitted with a means of access to permit cleaning not less than once a year. Water in tanks should be sampled for microbiological and other contamination at regular intervals. In general, storage tanks and pipes should meet the same hygienic design criteria as other equipment in such areas as drainability and cleanability (see Chapters 8 and 10). It is important to keep accurate records of the water supply system to anticipate or resolve any contamination problems.

Temperature control is also important: to maintain cold water lines below the recommended 20°C (68°F) insulation may be needed. In a large plant, the 'potable water' system may include heat-regenerating units and heat exchangers to provide a piped hot water system, as well as high-pressure hot and/or cold hose lines for cleaning purposes. It is good practice to keep the length of 'spurs' or 'branches' to less than 6 m, and to lag hot water lines. This will mean that they can deliver water consistently at the required temperature and/or pressure.

Both cross-connections and backflows can cause unexpected problems in a processing plant. A cross-connection is a physical connection, either temporary or permanent, between systems such that the water can flow between them. A backflow or back-siphonage occurs when contaminated water is drawn back by reduced pressure into a potable water line. Backflow preventers or vacuum-breakers should be used where required.

It is very important that non-potable water supplies should always be recognised as a source of potential danger. Potable and non-potable water should be in separate, independent distribution systems. It is not acceptable to rely on separation or isolation by valve arrangements. Valves can and do leak and pressure differentials may be momentarily altered or reversed. Potable water used to supplement any non-potable supply must always be positively protected against contamination from back-pressure or siphonage, e.g. by an adequate air-gap. Non-potable lines must be clearly and readily identified as such.

13.6 Applying detergents and disinfectants

Cleaning and disinfection can be undertaken by hand using simple tools, e.g. brushes or cloths (manual cleaning), though as the area of open surface requiring cleaning and disinfection increases, specialist equipment becomes necessary to dispense chemicals and/or provide mechanical energy. Chemicals may then be applied via the following means:

- Mechanical means using high- and low-pressure water jets, or water-powered or electrically powered scrubbing brushes
- Low-pressure mists
- Foams
- Gels
- Fogging systems.

These techniques have been well documented (Anon., 1991; Marriott, 1985; Holah, 1991) and this section considers their use in practice. The use of cleaning techniques can perhaps be described schematically following the information detailed in Fig. 13.3. The figure details the different energy source inputs for a number of cleaning techniques and shows their ability to cope with both low and high (dotted line) levels of soiling.

For the manual cleaning of small items a high degree of mechanical energy can be applied directly where it is needed, and with the use of soak tanks (or clean-out-of-place techniques) contact times can be extended and/or chemical and temperature inputs increased such that all soil types can be tackled. Alternatively, dismantled equipment and production utensils may undergo manual gross soil removal and then be cleaned and disinfected automatically in tray or tunnel washers. As with soak tank operations, high levels of chemical and thermal energy can be used to cope with the majority of soils. The siting of tray washes in high-risk production areas should be carefully considered, however, as they are prone to microbial aerosol production which may lead to aerial product contamination. In manual cleaning of larger areas, for reasons of operator safety, only low levels of temperature and chemical energy can be applied, and as the surface area requiring cleaning increases, the technique becomes uneconomic with respect to time and labour. Labour costs amount to 75% of the total sanitation programme and for most food companies the cost of extra staff is

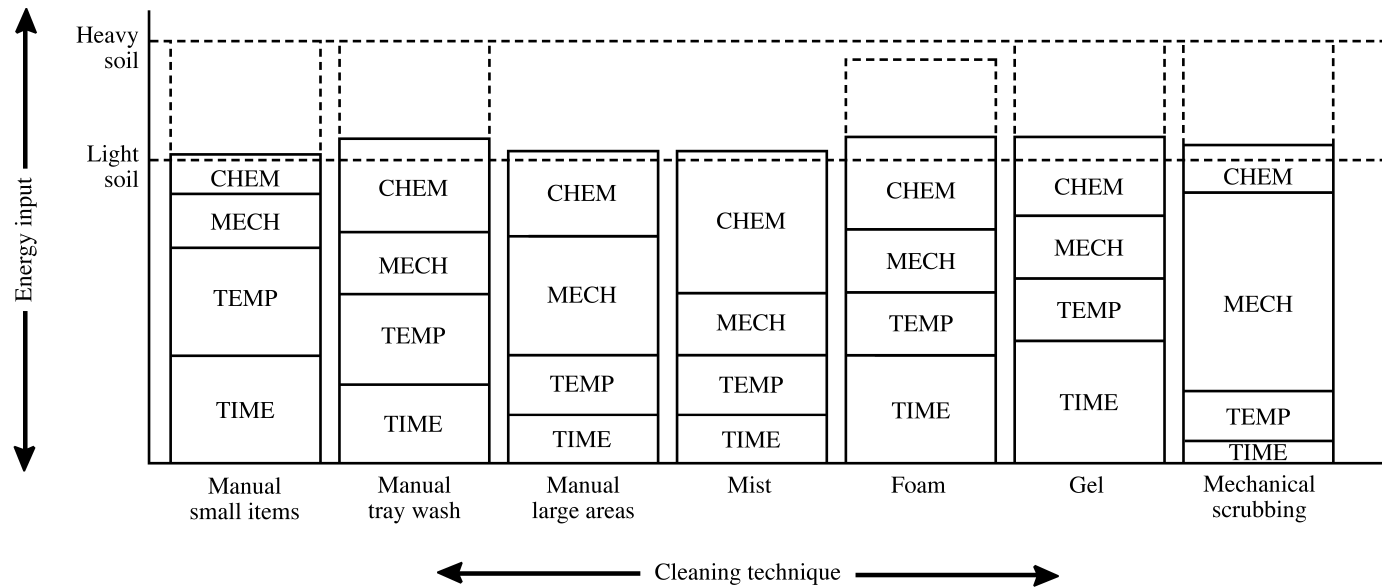


Fig. 13.3 Relative energy source inputs required by different cleaning techniques.

prohibitive. Only light levels of soiling can be economically undertaken by this method.

Mechanical scrubbers range from traditional floor scrubbers and scrubber/driers (automats) for floors to high pressure systems and electrically operated small-diameter brushes that can be used on floors, walls and other surfaces. Contact time is usually limited with these techniques (though it can be increased), but the combination of detergency with high mechanical input allows them to tackle most soil types. The main limitation is that food-processing areas have not traditionally been designed for their use, though this can be amended in new or refurbished areas.

The main difference between mist, foam and gel techniques is in their ability to maintain a detergent/soil/surface contact time. For all three techniques, mechanical energy can be varied by the use of high- or low-pressure water rinses. Temperature effects for these techniques are minimal. Mist spraying is undertaken using small hand-pumped containers, 'knapsack' sprayers or pressure washing systems at low pressure. Misting will only 'wet' vertical smooth surfaces. Only small quantities can be applied and these will quickly run off to give a contact time of 5 minutes or less. Because the technique forms aerosols that could be an inhalation hazard, only weak chemicals can be applied. Misting is therefore useful only for light soiling. On cleaned surfaces, however, misting is the most commonly used method for applying disinfectants.

Foams can be generated and applied by the entrapment of air in high-pressure equipment or by the addition of compressed air in low-pressure systems. Foams work on the basis of forming a layer of bubbles above the surface to be cleaned which then collapses and bathes the surface with fresh detergent contained in the bubble film. The critical element in foam generation is for the bubbles to collapse at the correct rate: too fast and the contact time will be minimal; too slow and the surface will not be wetted with fresh detergent. Gels are thixotropic chemicals which are fluid at high and low concentrations but become thick and gelatinous at concentrations of approximately 5–10%. Gels are easily applied through high- and low-pressure systems or from specific portable electric pumped units and physically adhere to the surface.

Foams and gels are more viscous than mists, are not as prone to aerosol formation and thus allow the use of more concentrated detergents, and can remain on vertical surfaces for much longer periods (foams 10–15 minutes, gels 15 minutes to an hour or more). Foams and gels are able to cope with higher levels of soils than misting, although in some cases rinsing of surfaces may require large volumes of water, especially with foams. Foams and gels are well liked by operatives and management; because of the nature of the foam, a more consistent application of chemicals is possible and it is easier to identify areas that have been 'missed'.

Cleaning chemicals are removed from surfaces by low-pressure/high-volume hoses operating at mains water pressure or by high-pressure/low-volume pressure pumped washing systems. Pressure washing systems typically operate at between 25–100 bar through a 15° nozzle and may be mobile units, wall

mounted units or centralised ring-mains. Water jets confer high mechanical energy, can be used on a wide range of equipment and environmental surfaces, will penetrate into surface irregularities and are able to mix and apply chemicals.

Fogging systems have been traditionally used in the food industry to create and disperse a disinfectant aerosol to reduce airborne microorganisms and to apply disinfectant to difficult-to-reach overhead surfaces. The efficacy of fogging was recently examined in the UK and has been reported (Anon., 1998b). Providing a suitable disinfectant is used, fogging is effective at reducing airborne microbial populations by 2–3 log orders in 30–60 minutes. Fogging is most effective using compressed air-driven fogging nozzles producing particles in the 10–20 micron range. For surface disinfection, fogging is effective only if sufficient chemical can be deposited onto the surface. This is illustrated in Fig. 13.4 which shows the log reductions achieved on horizontal, vertical and upturned (underneath) surfaces arranged at five different heights from just below the ceiling (276 cm) to just above the floor (10 cm) within a test room. It can be seen that disinfection is greatest on surfaces closest to the floor and that disinfection is minimal on upturned surfaces close to the ceiling. To reduce inhalation risks, sufficient time (45–60 minutes) is required after fogging to allow the settling of disinfectant aerosols before operatives can re-enter the production area.

The hygienic implications of the design and use of cleaning equipment should be carefully considered. Sanitation equipment should be constructed out of smooth, non-porous, easily cleanable materials such as stainless steel or plastic. Mild steel or other materials subject to corrosion may be used but must be suitably painted or coated, whilst the use of wood is unacceptable. Frameworks should be constructed of tubular or box-section material, closed at either end and properly jointed, e.g. welds should be ground and polished and there should be no metal-to-metal joints. Crevices and ledges where soil could collect should be avoided and

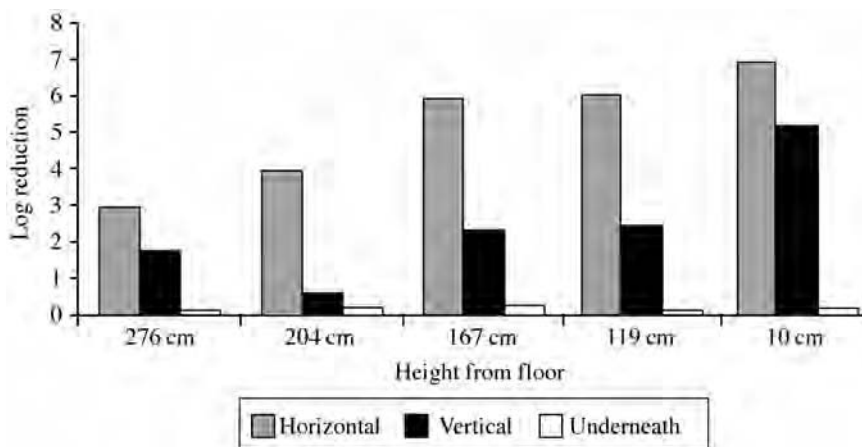


Fig. 13.4 Log reductions of microorganisms after fogging of horizontal, vertical and underneath surfaces at differing heights from the floor.

exposed threads should be covered or dome nuts used. Tanks for holding cleaning chemicals or recovered liquids should be self-draining, have rounded corners and should be easily cleaned. Shrouds around brush heads or hoods and rotary scrubbing heads should be easily detachable to facilitate cleaning. Brushes should have bristles of coloured, impervious material, e.g. nylon, embedded into the head with resin so no soil trap points are apparent. Alternatively, brushes with the head and bristles moulded as one unit may be used.

Cleaning equipment is prone to contamination with *Listeria* spp. and other pathogenic microorganisms and, by the nature of its use, provides an excellent way in which contamination can be transferred from area to area. Cleaning equipment should be specific to high-risk areas. After use, equipment should be thoroughly cleaned and, if appropriate, disinfected and dried. The potential for cleaning equipment to disperse microbial contamination by the formation of aerosols has been reported (Holah *et al.*, 1990b). It was shown that all cleaning systems tested produced viable bacterial aerosols from test surfaces contaminated with attached biofilms. The degree of water droplet contamination impinging on a surface was graded from total average to the minimum level thought likely to give concern if a proportion of the droplets contained viable microorganisms. The maximum height and distance travelled by this contamination level is shown in Table 13.8. Assuming an average food contact surface height of 1 m, the results suggest that both the high-pressure low-volume (HPLV) and low-pressure high-volume (LPHV) techniques disperse a significant level of aerosol to this height and should not, therefore, be used during production periods. The other techniques, however, are acceptable for use in clean-as-you-go operations as the chance of contamination to product is low, though care is needed when using floor scrubber/driers (these are useful in that the cleaning fluid is removed from the floor) if product is stored in racks close to the floor. After production, HPLV and LPHV techniques may be safely used (and are likely to be the appropriate choice), but it must be recognised that aerosols will be formed and that these will take time to fall back on to surfaces. However, disinfection of food contact surfaces should be the last operation to be performed within the sanitation programme. Subsequent work has shown that reducing water pressure or changing impact angle made little difference to the degree of aerosol spread for HPLV and LPHV systems, dispersal to heights >1 m still being achieved.

Table 13.8 Maximum height and distance of aerosol impingement for a number of cleaning techniques

Cleaning technique	Height (cm)	Distance (cm)
High-pressure/low-volume spray lance	309	700
Low-pressure/high-volume hose	210	350
Floor scrubber/drier	47	80
Manual brushing	24	75
Manual wiping	23	45

13.7 Other disinfection techniques

13.7.1 Steam

Elevated temperature is the best disinfectant as it (Jennings, 1965):

- penetrates into surfaces
- is non-corrosive
- is non-selective to microbial types
- is easily measured
- leaves no residue.

As a result, disinfection with steam in closed production processes is widely used in certain sectors of the food industry, particularly aseptic food production. However, for open surfaces, the use of hot water or steam is uneconomic, hazardous, corrosive to materials, difficult to control and therefore ineffective. In these circumstances reliance is placed on other methods such as the use of chemical biocides.

Sanitising open surfaces with steam is expensive because of high energy costs, and is usually ineffective. Workers frequently mistake water vapour for steam. The temperature is often not high enough to sterilise that which is being cleaned. If the surface being treated is highly contaminated, a cake may form on the organic residues and prevent sufficient heat penetration to kill the microbes. Experience in the industry has shown that steam is not amenable to continuous sanitising of machinery such as conveyors. In fact, condensation from this operation and other steam applications has actually complicated cleaning operations.

13.7.2 Hot water

Immersion of small components (i.e. knives, small parts, eating utensils and small containers) into water heated to 80°C or higher is another thermal method of sterilisation. The microbicidal action is thought to be due to the denaturation of some of the protein molecules in the cell. Pouring 'hot' water into containers is not a reliable sterilising method because of the difficulty of maintaining a water temperature high enough to ensure adequate sterilisation. Hot water can be an effective, non-selective sanitising method for food-contact surfaces; however, spores may survive for more than an hour at boiling temperature. This sterilising method is frequently used for plate heat exchangers and eating utensils.

The temperature of the water determines the time of exposure needed to ensure sterilisation. An example of time-temperature relationships would be combinations adopted that utilise 6 seconds of exposure time at 80°C or 30 seconds at 75°C. A shorter time requires a higher temperature. The volume of water and its flow rate will also influence the time taken by the components to reach the required temperature. If water hardness exceeds 60 mg/l, water scale is frequently deposited on surfaces being sanitised unless the water is softened. Disinfection can be accomplished either by pumping the water through assembled equipment or by immersing equipment in the water.

13.7.3 Irradiation

Radiation at a wavelength of approximately 2500 Å in the form of ultraviolet light or high-energy cathode or gamma rays will destroy microorganisms. Ultraviolet light has been used in the form of low-pressure mercury vapour lamps to destroy microorganisms in hospitals. Ultraviolet light units are now commonly used in Europe to disinfect drinking and food processing waters and are being installed in the United States. However, this method of sanitising has been restricted to fruits, vegetables and spices and has not been widely used in food plants and food service facilities because of its limited total effectiveness. Dose is a combination of intensity and time. The resistance to ultraviolet light varies between microorganisms, though the viability of all microorganisms will be reduced given sufficient dose. To be effective the light rays must actually strike the microorganisms. Dust, thin films and opaque or turbid solutions can absorb them. Some practical applications include sterilising the air entering a processing area or sterilising packaging materials before filling. It must be emphasised that it is important to protect eyes from UV radiation, because the microbiological wavelengths can cause damage.

13.7.4 Ozone

Ozone (O₃) is a water-soluble naturally occurring gas that is a powerful oxidising agent. It is also very unstable: on exposure to air and water it rapidly decomposes to form oxygen. Therefore it needs to be generated at the point of use. In general, bacteria are more susceptible than yeasts or moulds; Gram-positive bacteria are more sensitive than Gram-negative; bacterial spores are more resistant than vegetative cells. Temperature, relative humidity, pH, stage of microbial growth and organic matter present have all been shown to affect ozone antimicrobial action. Research with ozone at CCFRA has been quite promising. It has proved effective at killing both microorganisms attached to surfaces and those contained in an aerosol to approximately the same degree. A general rule of a 2 log reduction in viable organisms in 2 hours with 2 ppm ozone has been suggested (Taylor and Chana, 2000). Additional potential advantages over chemical disinfectants include its ability to penetrate areas inaccessible to chemical fogs; reduced storage problems (it could be produced when required); and flexibility (it could be used to deodorise vehicles and storage areas). Little is known, however, about the persistence of ozone in the air and thus when, after ozonation of a food processing plant, it is safe for operatives to re-enter.

13.7.5 Dry cleaning

Dry cleaning methods are used where the products are hygroscopic or where water can react to form hard deposits which are difficult to remove. The principal risk is that failure to control moisture can permit the growth of pathogens, e.g. *Salmonella* spp., in the processing environment which then contaminate any food being processed. Environments usually dry cleaned

include plants producing flour, chocolate, peanut butter, dry milk products, dry soup and snack mixes, and dry infant formulae. Dry cleaning is essentially the mechanical removal of soils using sweeping, brushing, wiping and vacuuming. Compressed air can be used to remove 'caked-on' residues, but it has the disadvantage that it moves the soil from one area of the equipment or environment to another. Vacuuming does not spread dirt and dust but picks it up. It is therefore, in principle, the desirable system to use though it must be specified with a suitable exhaust filter. Disinfection following dry cleaning is not easy, although 70% ethanol may be used and allowed to dry off before equipment is reassembled.

13.8 Sanitation programmes

Sanitation programmes are concerned with both the timing of cleaning and disinfection and the sequence in which equipment and environmental surfaces are cleaned and disinfected within the processing area. Sanitation programmes are so constructed as to be efficient with water and chemicals, to allow selected chemicals to be used under their optimum conditions, to be easily managed and to reduce manual labour. In this way an adequate level of sanitation will be achieved economically and with due regard to environmental friendliness.

A sanitation sequence should be established in a processing area to ensure that the applied sanitation programme is capable of meeting its objectives and that cleaning programmes are implemented on a routine basis. In particular, a sanitation sequence determines the order in which the product contact surfaces of equipment and environmental surfaces (walls, floors, drains, etc.) are sanitised, such that once product contact surfaces are disinfected, they should not be recontaminated. Based on industrial case studies, the following basic sanitation sequence has been demonstrated to be useful in controlling the proliferation of undesirable microorganisms (Holah, 2000a).

1. Remove gross soil from production equipment.
2. Remove gross soil from environmental surfaces.
3. Rinse down environmental surfaces (usually to a minimum of 2 m in height for walls).
4. Rinse down equipment and flush to drain.
5. Clean environmental surfaces, usually in order of drains, walls then floors.
6. Rinse environmental surfaces.
7. Clean equipment.
8. Rinse equipment.
9. Disinfect equipment and rinse if required.
10. Fog (if required).
11. Clean the cleaning equipment.

The sequence must be performed at a 'room' level such that all environmental surfaces and equipment in the area are cleaned at the same time. It is not

acceptable to clean and disinfect one line and then move onto the next and start the sequence again as this merely spreads contamination around the room. These and other stages in a sanitation sequence are discussed in more detail below.

Before sanitation. Production staff should be encouraged to consider the implications of production practices on the success of subsequent sanitation programmes. Product should be removed from lines during break periods and this may be followed by manual cleaning, usually undertaken by wiping with alcohol (to avoid the use of water during production periods). Production staff should also be encouraged to operate good housekeeping practices (this is also an aid to ensuring acceptable product quality) and to leave their workstations in a reasonable condition. Soil left in hoppers and on process lines is wasted product and should be avoided. Sound sanitation practices should be used to clean up large product spillages during production.

Preparation. As soon as possible after production, equipment should be dismantled as far as is practicable or necessary to make all surfaces that microorganisms could have adhered to during production accessible to the cleaning fluids. All unwanted utensils/packaging/equipment should be covered or removed from the area. Dismantled equipment should be stored on racks or tables, not on the floor. Machinery should be switched off, at the machine and at the power source, and electrical and other sensitive systems protected from water/chemical ingress. Production should not occur in the area being cleaned, but in exceptional circumstances if this is not possible, other lines or areas should be screened off to prevent transfer of debris by the sanitation process.

Gross soil removal. Where appropriate, all loosely adhered or gross soil should be removed by brushing, scraping, shovelling, vacuum, etc. Wherever possible, soil on floors and walls should be picked up and placed in suitable waste containers rather than washed to drains using hoses.

Pre-rinse. Surfaces should be rinsed with low-pressure cold water to remove loosely adhered small debris to at least 2 m in height for walls. Hot water can be used for fatty soils, but too high a temperature may coagulate proteins.

Cleaning. A selection of cleaning chemicals, temperature and mechanical energy is applied to remove adhered soils.

Inter-rinse. Both soil detached by cleaning operations and cleaning chemical residues should be removed from surfaces by rinsing with low-pressure cold water.

Disinfection. Chemical disinfectants (or occasionally heat) are applied to remove and/or reduce the viability of remaining microorganisms to a level deemed to be of no significant risk. In exceptional circumstances and only when light soiling is to be removed, it may be appropriate to combine stages 5–7 by using a chemical with both cleaning and antimicrobial properties (detergent-sanitiser).

Post-rinse. Disinfectant residues should be removed by rinsing away with low-pressure cold water of known potable quality. Some disinfectants, however, are intended to be left on surfaces until the start of subsequent production periods and are thus so formulated to be both surface-active and of low risk, in terms of taint or toxicity, to foodstuffs.

Completion. A number of final procedures may be undertaken, including the removal of excess water and/or equipment drying, to prevent the growth of microorganisms on production contact surfaces in the period up until the next production process. Alternatively, the processing area may be evacuated and fogged with a suitable disinfectant.

Clean the cleaning equipment. Following their use for cleaning, cleaning equipment should itself be cleaned and disinfected. Cleaning equipment should be visually checked for damage and any areas where microorganisms could reside, or loose parts which might become a foreign body hazard, should be replaced. Cleaning equipment should be stored in racks to dry or kept in disinfectant solution until their use is required.

A key issue is timing of sanitation programmes. The frequency with which areas are cleaned will depend in part on the type of processing area and the nature of run times (e.g. is the production line run on a continuous shift system, and is there a weekend shutdown?). Periodically (e.g. weekly or monthly) procedures should be undertaken to thoroughly clean equipment to a level beyond that undertaken, say, on a daily basis. This normally involves additional equipment dismantling and/or the application of increased cleaning energy. Periodic practices also include the more infrequent tasks of cleaning ceilings and overhead fittings above 2 m (Holah, 2000b). In practice the content and timing of daily and periodic sanitation procedures will be a balance between the nature of production operations and an assessment of the hygienic quality of the processing environment. If the processing environment is not clean, a more frequent and rigorous sanitation programme may be required. Table 13.9 lists some common causes of poor sanitation procedures and how they can be addressed.

13.9 Managing sanitation programmes

The manager who assumes responsibility for the sanitation programme must have technical hygiene expertise and has a range of job functions including the following:

- Selection of a suitable chemical supplier
- Selection of sanitation chemicals, equipment and methodology
- Training of cleaning operatives
- Development of cleaning schedules

- Implementation of sanitation programme monitoring systems
- Representation of hygiene issues to senior management.

Good chemical suppliers are able to do much more than simply supply detergents and disinfectants. They should be chosen on their abilities to undertake site hygiene audits, supply suitable chemical dosing and application equipment, undertake operative training and help with the development of cleaning schedules and sanitation monitoring and verification systems. Good chemical companies respond quickly to their customers' needs, periodically review their customers' requirements and visit during sanitation periods to ensure that their products are being used properly and are working satisfactorily. The cleaning manager may also need to visit the chemical supplier's site to audit their quality systems and so help ensure quality of the chemicals supplied.

Whilst in theory common sanitation systems and/or chemicals could seem appropriate for particular products and processes, every factory, with its water supply, food products, equipment, materials of construction and layout, etc., is unique. All sanitation chemicals, equipment and methodology must, therefore, be proven in the processing environment. New products and equipment are always being produced and a good working relationship with hygiene suppliers is beneficial. Only disinfectants that have been approved to the relevant European or other internationally recognised standards should be used. Three types of sanitation programme can be implemented by management:

- Production operatives form a cleaning crew and undertake the sanitation programme.
- A separate, dedicated cleaning gang completes the sanitation programme.
- Cleaning and disinfection are undertaken by contract cleaners.

The cleaning operatives' job is both technical and potentially hazardous, and all steps should be undertaken to ensure that sufficient training is given. By the nature of the job, training is likely to be comprehensive and should include the following:

- Knowledge of basic food hygiene
- Importance of maintaining low/high-risk barriers during cleaning
- Implications to product safety/spoilage of poor sanitation practices
- Understanding of the basic function and use of sanitation chemicals and equipment and of their sequence of operation
- Thorough knowledge of the safe handling of chemicals and their application and the safe use of sanitation equipment.

For each piece of equipment or for each processing area, a cleaning or sanitation schedule should be developed. This should preferably be in a loose-leaf format so that it can be readily updated, and should always be available for inspection by cleaning operatives or auditors. The schedule must show clearly each stage of the cleaning and disinfection process (diagrammatically if this would help), all pertinent information on safety, and the key inspection points

Table 13.9 Some causes and control of poor sanitation (Source: Shapton and Shapton, 1991)

Cause	Effect	Detection	Control
Water too hard	‘Stone’ or ‘fur’ formation or thin white deposit	Visual	Use periodic acid wash, more water conditioning materials in detergent mix or softened water
Unsanitary cleaning equipment, e.g. brushes, mops, cloths	Spread of microorganisms	Microbiological tests; smell bad or visual in bad instances	Use cleaning equipment of sanitary design or include a cleaning and sanitation step for this equipment
Insufficient frequency of cleaning	Build-up of soil, which becomes hard and difficult to remove	Visual; microbiological tests	Shorten cleaning intervals; include partial cleaning between existing cleaning periods
Unsatisfactory cleaning	Soil (food residues) remain after cleaning; reduced sanitiser (disinfectant) efficiency	Visual; microbiological tests	Reclean and then: (a) check that written procedures exist, and (b) that they are understood and are followed. Repeat clean under comparable conditions of soiling. If still inadequate, review and improve procedures to give proven satisfactory results. Alternatively, if correct procedures are <i>not</i> followed, investigate why. If there is no good reason why they cannot be followed, disciplinary action should be taken

Water too hot	Coagulation of protein soils	Visual	}	Provide an adequate supply of water at appropriate temperature(s)
Water too cold	Fat not removed	Visual		
Inadequate rinsing (pre-rinse)	Detergents less effective leaving residual soil	Visual; microbiological tests		Apply correct rinse procedure or increase flow or rinse time
Sanitiser (disinfectant) contact time too short	Sanitiser less effective	Microbiological tests		Check procedure is correctly applied. Increase contact time if necessary
Sanitiser too dilute	Sanitiser less effective; possibility that strains of organisms may be selected, or become adapted to sanitiser, e.g. pseudomonads	Microbiological tests		Check procedure for dispensing sanitiser and way in which use dilution is made; change procedure if necessary
Wrong sanitiser (disinfectant) used	Sanitiser less effective	Microbiological tests		Revise procedure for issue of disinfectant, e.g. use colour code or symbol
Residual moisture	Local multiplication of microorganisms, e.g. in 'pools'	Microbiological tests; visual		Check slope of pipework and/or design and installation of equipment

and how these should be assessed. It is difficult to produce a list of requirements that should be found in a cleaning schedule, but the following is a typical, non-exhaustive list:

- A description, hazard code, in-use concentration, method of make-up, storage conditions, location and amount to be drawn of all chemicals used
- Type, use, set parameters (pressure, nozzle type, etc.), maintenance and location of sanitation equipment
- Description of the equipment to be cleaned, need to disconnect from services, dismantling and reassembly procedures
- Full description of the cleaning process, its frequency and requirement for periodic measures
- Staff requirements and their responsibilities
- Key points for assessment of the sanitation procedure and description of evaluation procedures for programme monitoring and verification.

When new equipment is purchased or processing areas designed or refurbished, insufficient attention is usually placed on sanitation requirements. Equipment or areas of poor hygienic design will be more expensive to clean (and maintain) and may not be capable of being cleaned to an acceptable standard in the time available. If improperly cleaned, adequate disinfection is impossible and thus contamination will not be controlled. Hygiene management must be strongly represented to senior management, thus ensuring that hygiene requirements are considered alongside those of engineering, production and finance, for example.

13.10 Assessing the effectiveness of a sanitation programme

Assessment of the effectiveness of the sanitation programme's performance is part of day-to-day hygiene testing and, as such, is linked to the factory environmental sampling plan. The control of the environmental routes of contamination is addressed via the development of a thorough risk analysis and management strategy, typically undertaken as part of the factory HACCP study, resulting in the development of the factory environmental sampling plan. The development of environmental sampling plans has recently been established by a CCFRA industrial working party and is reported in Holah (1998). Environmental sampling can be used at three different stages:

1. Process development to determine whether a contamination route is a risk and assess whether procedures put in place to control the risk identified are working
2. Routine hygiene assessment
3. Troubleshooting to identify why products (or occasionally environmental samples) may have a microbiological count that is out of specification or may contain pathogens.

Routine hygiene testing is an important aspect of due diligence and is used for two purposes: monitoring to check sanitation process control, and verification to assess sanitation programme success. Monitoring is a planned sequence of observations or measurements to ensure that the control measures within the sanitation programme are operating within specification and are undertaken in a time frame that allows sanitation programme control. Verification is the application of methods in a longer time frame to determine compliance with the sanitation programme's specification.

The four main issues in routine hygiene assessment are:

- What to sample
- When to sample
- How to sample
- How to interpret the results.

13.10.1 What to sample

This very much depends on what activity is being monitored. To monitor the effectiveness of general cleaning regimes, it is necessary to sample walls, floors, the processing line and specific pieces of equipment. As an example, a misting disinfection technique may result in effective sanitation of horizontal surfaces, but be inefficient at cleaning vertical surfaces. Specific sampling of equipment should fit in with what the HACCP analysis has indicated are the critical points with reference to final product quality and safety. As an example, the cleaning of meat slicing machines in high-risk areas is often critical to limit the microbial contamination of the product, and will therefore need to be monitored closely. It is more useful to sample the points on the machine that directly contact the product, and those that are most difficult to clean for example, the shear edge, the 'gripper box' or the meat feed conveyor, rather than flat surfaces on the exterior of the machine. If a particular problem has been identified, then extra specific sampling may be carried out to identify both the nature of the problem and its source. Where there is the potential for microorganisms remaining after (poor) cleaning and disinfection to infect large quantities of product via, e.g. direct product contact, these sources require sampling much more frequently than other sites which, whilst they may be more likely to be contaminated, pose less of a direct risk to the product. Highly sophisticated analytical techniques and equipment are now available to assist in this process. Ribotyping, a type of genetic fingerprinting, is one such technique. This involves the automatic analysis of the DNA coding for the ribosomal RNA of a microorganism at the molecular level, to yield a genetic fingerprint. This allows not only the species of organism to be identified, but also the specific isolate (see Jones, 2000).

The food production/process environment can be a source of general contamination. Many surfaces not directly in contact with food may harbour microorganisms, e.g. non-food contact equipment surfaces, walls, floors, drains or overhead structures. These microorganisms can then be transferred to the food

in the air via water droplets and dust. Sampling of this environment can provide information on the likely presence and incidence of pathogens, their distribution in relation to processing lines and thus the risk of product contamination (Cordier, 2002). This allows preventative measures to be established in the framework of GHP, such as layout of processing lines and zoning within the factory.

Sampling the cleaning equipment is a very useful index of what is actually present in a production environment, because cleaning 'collects' dirt and bacteria from all parts of the factory, e.g. floor mops, brushes and vacuums (Fraser, 2002). In a similar way sampling of drains also gives a better chance of determining whether a particular pathogen is present in the production environment, e.g. *Listeria*. This can often be a better approach than sampling end products. In addition, other wet areas such as sinks, taps, cleaning cloths and brushes, and bootwashing baths should also be checked routinely. Aerosols can be created from such areas and then find their way into products on the manufacturing line. Testing for indicator organisms generally gives the most useful information on the environmental hygiene, an exception to this being the testing for *Listeria* in high-risk environments.

13.10.2 When to sample

Sampling can be undertaken before, during and after production, depending on its purpose. Sampling is generally taken after production (and after cleaning) to verify that a cleaning programme is effective. Monitoring the performance of a bootwasher, for example, by sampling the floor, may be taken during production. Occasionally, the level of contamination prior to cleaning is sampled. Sampling both before and after cleaning helps assess the effectiveness of the sanitation programme.

13.10.3 How to sample

The sanitation programme is monitored via physical, sensory and microbiological testing methods. Physical tests are centred on the critical control measures of the performance of sanitation programmes and include, for example:

- Measurement of detergent/disinfectant contact time
- Rinse water, detergent and disinfectant temperatures
- Chemical concentrations
- Surface coverage of applied chemicals
- Degree of mechanical or kinetic input
- Cleaning equipment maintenance and chemical stock rotation.

Sensory evaluation is usually undertaken after each of the sanitation programme stages and involves visual inspection of surfaces under good lighting, smelling for product or offensive odours, and feeling for greasy or

encrusted surfaces. Ultraviolet (UV) light may be useful if soil deposits fluoresce. For some product soils, residues can be more clearly observed by wiping the surface with paper tissues.

Microbiological sampling is typically for the total number of viable microorganisms remaining after cleaning and disinfection, i.e. total viable count (TVC), both as a measurement of the ability of the sanitation programme to control all microorganisms and to maximise microbial detection. Sampling targeted at specific pathogens or spoilage organisms, which are thought to play a major role in the safety or quality of the product, is undertaken to verify the performance of the sanitation programme designed for their control. Microbiological assessments have also been used to ensure compliance with external microbial standards, as a basis for cleaning operatives' bonus payments, in hygiene inspection and troubleshooting exercises, and to optimise sanitation procedures.

Traditional microbiological techniques appropriate for food factories involve the removal or sampling of microorganisms from surfaces, and their culture using standard agar plating methods (Holah, 1998). Microorganisms may be sampled via sterile cotton or alginate swabs and sponges, after which the microorganisms are resuspended by vortex mixing or dissolution into suitable recovery or transport media, or via water rinses for larger enclosed areas (e.g. fillers). Representative dilutions are then incubated in a range of microbial growth media, depending on which microorganisms are being selected for, and incubated for 24–48 hours. Alternatively, microorganisms may be sampled directly onto self-prepared or commercial ('dip slides') agar contact plates.

13.10.4 Rapid microbiological methods

Rapid hygiene methods are defined as monitoring methods whose results are generated in a time frame (usually regarded as within approximately 10 minutes) sufficiently quick to allow process control. Current methodology allows the quantification of microorganisms (ATP), food soils (ATP, protein) or both (ATP). No technique is presently available which will allow the detection of specific microbial types within this time frame. The most popular and established rapid hygiene monitoring technique is that based on the detection of adenosine triphosphate (ATP) by bioluminescence and is usually referred to as ATP testing. ATP is present in all living organisms, including microorganisms (microbial ATP), in a variety of foodstuffs and may also be present as free ATP (usually referred to together as non-microbial ATP). The bioluminescent detection system is based on the chemistry of the light reaction emitted from the abdomen of the North American firefly *Photinus pyralis*, in which light is produced by the reaction of luciferin and luciferase in the presence of ATP. For each molecule of ATP present, one photon of light is emitted; these are then detected by a luminometer and recorded as relative light units (RLU). The reaction is very rapid and results are available within seconds of placing the sample to be quantified in the luminometer. The result, the amount of light

produced, is also directly related to the level of microbial and non-microbial ATP present in the sample and is often referred to as the 'hygienic' status of the sample.

ATP has been successfully used to monitor the hygiene of surfaces for approximately 15 years and many references are available in the literature citing its proficiency and discussing its future potential, e.g. Bell *et al.* (1994), Griffiths *et al.* (1994) and Hawronskyj and Holah (1997). It is possible to differentiate between the measurement of microbial and non-microbial ATP, but for the vast majority of cases the measurement of total ATP (microbial and non-microbial) is preferred. As there is more inherent ATP in foodstuffs than in microorganisms, the measurement of total ATP is a more sensitive technique to determine remaining residues. Large quantities of ATP present on a surface after cleaning and disinfection, regardless of their source, is an indication of poor cleaning and thus contamination risk (from microorganisms or materials that may support their growth).

Several studies have compared the results obtained by standard microbiological techniques and ATP bioluminescence for assessing surface cleanliness. Some reported a good correlation between these methods (Seeger and Griffiths, 1994; Kyriakides *et al.*, 1991; Bautista *et al.*, 1992). Others have obtained a poor correlation (Griffith *et al.*, 1997; Poulis *et al.*, 1993; Carrick *et al.*, 2001). Such discrepancies in the findings could be explained either by the different nature of the surface and surface contamination (presence of spores, for example) or by the inability or inconsistency of swabs to pick up microorganisms effectively. Loss in bacterial viability during drying could also have an impact on both ATP bioluminescence and plate count results. In addition, the presence of detergents, sanitisers or other chemicals may interfere with bioluminescent reaction (Velazquez and Feirtag, 1997) leading to false-positive or false-negative results. Whilst it is possible to differentiate the measurement of microbial and non-microbial ATP, for the vast majority of cases the measurement of total ATP (microbial and non-microbial) is preferred. As there is more inherent ATP in foodstuffs than in microorganisms, the measurement of total ATP is a more sensitive technique to determine residues remaining after cleaning. Large quantities of ATP present on a surface after cleaning and disinfection, regardless of their source, is an indication of poor cleaning and thus contamination risk (from microorganisms or materials that may support their growth).

Although the existing ATP bioluminescence assays are sufficient for the needs of 90% of the food industry, in certain situations there is a demand to detect low levels of bacteria that may still be present. For these cases, an ATP recycling system that uses a cocktail of enzymes to amplify low ATP levels has been developed (Hawronskyj *et al.*, 1994). The amplification reagent consists of a mixture of firefly luciferase, myokinase and pyruvate kinase together with their substrates (luciferin, AMP and phosphoenolpyruvate) and effectively 'amplifies' all AMP to ATP. The time for the reaction to reach half of the maximum light output is directly related to the log of ATP and can be used as an indicator of cleanliness. A combined index of ATP, AMP and PNA was proposed by Sakakibara *et al.* (1999) for hygiene monitoring. Simultaneous

bioluminescent detection of all these metabolites was achieved by coupling the reaction catalysed by pyruvate orthophosphate dikinase (PPDK) with firefly luciferase. The sensitivity of the detection of food residues on surfaces was several hundred times better than with the usual methods using ATP as an index. Adenylate kinase (AK) amplification of ATP bioluminescence has also been used for hygiene monitoring in the food industry (Corbitt *et al.*, 2000). It was shown that AK could be used not only as a bacterial cell marker as was proposed by Squirrell and Murphy (1995) but as a marker of food residues as well. The technique is particularly applicable to the meat and vegetable industry and to certain dairy products (milk, yoghurt, cottage cheese). Further research is required to implement this method in a fruit processing environment.

Many food processors typically use the rapidity of ATP to allow monitoring of the cleaning operation such that if a surface is not cleaned to a predetermined level it can be recleaned prior to production. Similarly, pieces of kit can be certified as being cleaned prior to use in processing environments where kit is quickly recycled or when the manufacturing process has long production runs. Some processors prefer to assess the hygiene level after the completion of both the cleaning and disinfection phases, whilst others monitor after the cleaning phase and only go on to the disinfection phase if the surfaces have been adequately cleaned.

Techniques have also been developed which use protein concentrations as markers of surface contamination remaining after cleaning operations. As these are dependent on chemical reactions, they are also rapid, but their applicability is perhaps less widespread as they can only be used if protein is a major part of the food product processed. As with the ATP technique, a direct correlation between the degree of protein remaining after a sanitation programme has been completed and the number of microorganisms remaining as assessed by traditional microbiological techniques is not likely to be useful. They are cheaper in use than ATP-based systems as the end point of the tests is a visible colour change rather than a signal which is interpreted by an instrument, e.g. light output measured by a luminometer. As an example, one method detects the presence of protein on a surface by an enhanced Biuret reaction, the end point of which is a colour change from green through to purple. The surface to be assessed is swabbed and the swab placed into a tube of resuspension fluid containing the reagents necessary to activate the Biuret reaction. After 10 minutes any colour change is compared to a supplied colour card and the degree of colour change is used as an indication of the hygienic nature of the surface. However, there is currently little published data on both the efficacy of this system (Griffith *et al.*, 1997) and the food-processing environments to which it is best suited.

13.10.5 Interpreting the results of hygiene monitoring

In relation to microorganism numbers, it is difficult to suggest what is an 'acceptable' number of microorganisms remaining on a surface after cleaning

and disinfection as this is clearly dependent on the food product, process, 'risk area' and degree of sanitation undertaken. A number of figures have been quoted in the past (as total viable count per square decimetre) including 100 (Favero *et al.*, 1984), 450 (Thorpe and Barker, 1987) and 1000 (Timperley and Lawson, 1980) for dairies, canneries and general manufacturing respectively. The results in Table 13.1 show that in chilled food production, sanitation programmes should achieve levels of around 1000 microorganisms per swab, which on flat surfaces approximately equates to a square decimetre. Expressing counts arithmetically is always a problem, however, as single counts taken in areas where cleaning has been inadequate (which may be in excess of 10^8 per swab) produce an artificially high mean count, even over thousands of samples. It is better, therefore, to express counts as log to the base 10, a technique that places less emphasis on a relatively few high counts..

Because of the difficulty in setting external standards, it is best to set internal standards as a measurement of what can be achieved by a given sanitation programme. A typical approach would be to assess the level of microorganisms or ATP present on a surface after a series of 10 or so carefully controlled sanitation programmes in which detergent and disinfectant concentrations are correct, contact times are adhered to, water temperatures are checked, pressure hoses are set to specified pressures, sanitation schedules are followed, etc. The mean result will provide an achievable standard (or standards if specific areas differ significantly in their cleanability) which can be immediately used and can be reviewed as subsequent data points are obtained in the future. A review of the standard would be required if either the food product or process or the sanitation programme were changed.

As part of the assessment of sanitation programmes, it is worth looking at how the programme is performing over a defined time period (weekly, monthly, quarterly, etc.) as individual sample results are only an estimate of what is happening at one specific time period. This may be to ensure that the programme remains within control, to reduce the variation within the programme or, as should be encouraged, to try to improve the programme's performance. An assessment of the performance of the programme with time, or trend analysis, can be undertaken simply, by producing a graphical representation of the results on a time basis, or can be undertaken from a statistical perspective using Statistical Process Control (SPC) techniques as described by Harris and Richardson (1996). Generally, graphical representation is the most widely used approach, though SPC techniques should be encouraged for more rigorous assessment of improvement in the programme's performance.

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14

Detecting taints from cleaning and disinfecting agents

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14.1 Introduction

The processing of foods requires regular cleaning of equipment in order to ensure that food products are safe for the consumer and of consistent quality. The cleaning process consists essentially of two stages:

- Cleaning: removal of organic and inorganic deposits
- Disinfection: sanitising the equipment to kill pathogenic and spoilage bacteria.

Depending on the nature and amount of the deposits, cleaning and disinfecting can be performed in one or two steps. After cleaning, the cleaning and disinfecting agents are usually removed.

Although the purpose of cleaning and disinfecting agents is to improve food safety and quality, such agents can, potentially, become a hazard themselves if residues are left, either because they are toxic or because they cause taints. It has been estimated that up to 30% of food taint complaints are associated with cleaning and disinfecting chemicals, producing taints variously described as 'soapy', 'antiseptic' or 'disinfectant' (Holah, 1995). They can enter food products accidentally, for example from poor rinsing or aerial transfer. However, they can also result from 'no rinse' disinfectants designed to be left on surfaces to provide more lasting protection against recontamination. This chapter looks at the various cleaning and disinfectant agents used in food processing, how they can be tested for toxicity and potential to cause taints, and the methods available for detecting their presence in rinse water or food products.

14.2 Cleaning and disinfecting agents

There exists a large variety of cleaning and disinfecting products on the market. However, the majority are based on one or more of the ingredients listed in Table 14.1. These are divided into cleaning and disinfecting agents. In practice, some ingredients combine both functions. As an example, although active chlorine-containing agents are mainly used for disinfection, they also remove certain deposits. Similarly, alkaline solutions are used to remove organic deposits but also have a disinfecting action.

Most cleaning agents are composed of chemical ingredients which are not reactive. The cleaning is based on a physical interaction between, for example, surfactants and the deposited material which results in a solubilisation of the deposit. As a result, whenever residues of these ingredients come into contact with the food their impact on the product can vary from modest to negligible, depending on the concentration of the residual cleaning agent. The risk of toxicity or taint at normal levels of use is usually low. The relative safety and risk of taint from cleaning and disinfectant agents is summarised in Table 14.2.

The situation is different when disinfectants are used. Disinfectant agents themselves are more likely, if residues survive in sufficient concentrations, to present a potential safety risk and risk of taint. Some disinfectants, particularly those based on active chlorine, iodine or oxygen, present additional problems. These are reactive chemicals which can react with food components to form new

Table 14.1 Basic ingredients of cleaning and disinfecting agents

Ingredient	Function	Concentration
Acid (e.g. nitric, phosphoric acid)	Removal of inorganic deposits	
Alkaline (e.g. sodium hydroxide)	Removal of organic deposits (proteins, fat, carbohydrates)	
Sequestrants (e.g. EDTA)	Removal of inorganic deposits	
Quaternary ammonium compounds (e.g. didecyl-dimethylammonium chloride, alkyl-dimethyl-benzylammonium chloride)	Disinfecting, removal of fat	0.05–2%
Active chlorine (e.g. sodium hypochlorite, Chloramine T, sodium dichloroisocyanurate)	Disinfecting	0.015–0.03% (active chlorine)
Active iodine (iodophor)	Disinfecting	0.005–0.01% (active iodine)
Active oxygen (e.g. hydrogen peroxide with/without peracetic acid)	Disinfecting	0.03–0.5% (active oxygen)

Table 14.2 Cleaning and disinfecting agents: relative toxicity and risk of taint

Ingredient	Toxicity	Risk of taint
Acid	low	medium
Alkaline	low	medium
Sequestrants	low	low
Quaternary ammonium compounds	low	low
Active chlorine	medium	medium
Active iodine	medium	medium
Active oxygen	medium	medium

components. Some of those new components can then cause off-flavours. As an example, chlorine- and iodine-based disinfectants can react with food components to form chlorophenols and iodophenols. These generate off-flavours and have very low sensory threshold. Concentrations of a few parts per million (ppm) produce serious off-flavours.

Active chlorine and iodine react particularly with methylketones in food to form, respectively, chloroform and iodoform. This is the so-called Haloform reaction (Roberts, 1967). Methylketones are present in low concentrations in most foods where they often contribute to the characteristic flavour of the product. The Haloform reaction is often rapid and is dependent on the pH of the food (Tiefel, 1997). The formation of chloroform is also influenced by other components of the disinfecting agent such as quaternary ammonium and sequestering compounds. The sequestering agents nitrilotriacetic acid (NTA) and ethylene diamine tetraacetic acid (EDTA), in combination with hypochlorite, decrease the formation of chloroform. Quaternary ammonium compounds increase the formation of chloroform (Tiefel, 1997). Chloroform is considered a potential carcinogen. In Germany, for example, the maximum allowable concentration of halogenated hydrocarbons in food products is limited to 0.1 mg/kg (LHmV, 1989).

14.3 Testing the safety of cleaning and disinfecting agents

As far as demonstrating the non-toxicity of cleaning agents is concerned, legislation in Europe has in the past varied between member states. A recognised industry guideline for disinfectants is a minimum acute oral toxicity (with rats) of 2000 mg/kg bodyweight. The implementation of the Biocidal Products Directive (98/9/EC) in 2000 has introduced greater consistency between European member states.

Annexe I of the Directive lists all the permitted biocidally active substances known to the European market. Annexes II and III list the data and tests required for a biocidal product to be authorised for inclusion in Annex I. These include the following:

- Formulation
- Data on physical and chemical properties
- Intended uses
- Classification and labelling
- Effectiveness against target organisms
- Effect of residues on food
- Toxicological profile and health-related studies
- Ecotoxicological profiling.

The Directive also establishes a product authorisation scheme for new products not already included in Annexe I. The Directive states that 'Member states shall prescribe that a biocidal product shall not be placed on the market and used in their territory unless it has been authorised in accordance with the Directive.' Authorisation involves submitting data on formulation, physical and chemical properties, and proving the suitability of a biocidal product according to the criteria set out in Annexes II and III. Food processors should ensure that the biocidal products they use have been registered according to the terms of the Directive.

14.4 Testing cleaning and disinfecting agents for their capacity to cause taints

There are a number of ways of testing whether disinfectant residues may cause taints. The Campden and Chorleywood Food Research Association has developed two taint tests in which foodstuffs that have been exposed to disinfectant residues are compared with control samples using a standard triangular taste test (Anon., 1983a). The results of these tests are statistically assessed to isolate any flavour difference and to describe the nature of the taint.

To assess the potential aerial transfer of a taint from a disinfectant to a foodstuff, a modification of a standard packaging materials odour transfer test is used (Anon., 1964). This involves using samples of four types of food with differing levels of susceptibility to aerial taint:

- High moisture (e.g. fruit)
- Low moisture (e.g. biscuits)
- High fat (e.g. cream)
- High protein (e.g. chicken).

Samples are suspended over a disinfectant solution using distilled water for 24 hours before being assessed by the taint panel.

A modification of the standard food container transfer test is used to test surface transfer (Anon., 1983b). This involves one of the following procedures:

- Spraying disinfectants onto two sheets of stainless steel followed by rinsing
- Spraying disinfectants onto the stainless steel sheets and draining the disinfectant residue off to simulate a 'no rinse' application.

Food samples are sandwiched between the two stainless steel sheets and left for 24 hours before being compared by the taint panel to control sheets rinsed in distilled water only.

14.5 Detecting cleaning and disinfecting agents in rinse water

Detecting cleaning and disinfecting agents in rinse water requires particular techniques. As cleaning and disinfecting agents lack chromophores that adsorb visible light, a simple visual inspection or *in situ* spectrophotometric measurement of the rinse water is not effective. In the case of cleaning with alkali- or acid-based cleaning agents, pH measurement of the rinse water provides a simple indication of how successful rinsing has been.

Since the majority of cleaning agents have ionic properties, conductometry techniques can be used to monitor rinse water for cleaning agents. The rinsing of the system is successful if the conductivity of the rinse water effluent is below a certain threshold. Conductometric probes are of rugged design and can be easily integrated into food processing operations to check rinse water for the presence of residual cleaning agents. In some cases manufacturers add additional salt to the cleaning agent in order to make monitoring by conductometry more sensitive.

Conductometry techniques are not suitable for measuring traces of active chlorine-, iodine- and oxygen-containing detergents. Off-line photometric methods are appropriate to the determination of active chlorine, active oxygen, quaternary ammonium compounds, halogenated acids and formaldehyde, and are used, for example, in the brewing industry (Treetzen, 1989).

14.6 Detecting cleaning and disinfecting agents in food

Detection by conductometry of residual cleaning agents in a food product is more difficult than in rinse water, because the conductivity of the product is generally higher than that of the water used for rinsing. An increase in conductivity, which would clearly indicate the presence of residual cleaning agents in rinse water, is difficult to detect against the background of natural variation in conductivity in the food product. Another problem is fouling of the conductivity probe.

Detecting residues of disinfecting agents in food products is even more difficult. Detection of traces of strong alkaline or acid agents is often limited by the presence of the same cations or anions in the sample food matrix. A similar problem affects some active chlorine compounds. Hypochlorite decomposes to chloride which is often present in the matrix. Hydrogen peroxide decomposes to water and is therefore also not easily detectable. Peracetic acid decomposes to acetic acid which is often present in the matrix, limiting the detection of this component.

The situation is easier for quaternary ammonium compounds, Chloramine T, dichloroisocyanurate and iodophors. These agents leave behind specific residues, which can be detected by methods based on high performance liquid chromatography (HPLC). Para-toluenesulphonamide is the decomposition product of Chloramine T. It has been determined by reversed-phase HPLC in fish fillets (Meinertz *et al.*, 1999, 2001) and by a combination of continuous flow and liquid chromatography in ice cream (Beljaars, 1994). Iodophors decompose to iodide which is present as a trace element in most food products. However, measurement is possible after anion-exchange chromatography in combination with suppressed conductivity detection, followed by pre-column derivatisation and reversed phase HPLC (Verma *et al.*, 1992). Measurement has also been undertaken for milk by reversed-phase ion-pair separation in combination with electrochemical detection at a silver electrode (Sertl *et al.*, 1993).

14.7 Measurement of chloroform

Of all possible components which can be formed by the action of active chlorine in a food product, chloroform is probably the most abundant and it can be relatively easily measured. Chloroform is a lipophilic substance. In whole milk (fat content of approximately 3.5%), for example, chloroform resides mainly in the fat phase. However, it forms with water an azeotrope with a boiling point of 56.3°C and a composition of 97% of chloroform in the vapour phase (Weast, 1980). This means that on heating a whole milk sample in a closed vial to about 56°C an appreciable amount of the chloroform is present in the vapour phase, making a simple sampling procedure possible. Gas chromatography in combination with a halogen-specific detector enables a sensitive measurement of chloroform and other chlorinated hydrocarbons down to about 0.1 µg/l.

The formation of chloroform and other chlorinated hydrocarbons has been studied for milk in an experimental set-up simulating practical CIP conditions (Linderer *et al.*, 1994). The study used different concentrations of disinfectant with and without rinsing with water. Although the study did not specify which type of active chlorine disinfectant was used, chloroform concentrations of 1.5–5.4 µg/l were found for whole milk, 0.7–2.2 µg/l for skim milk and 13–40 µg/l for cream. Using this method, an overview of concentrations of chloroform in commercial butter and milk samples is given by Westermair (Westermair, 1998).

Recent developments in the detection of chloroform include mass spectrometry. Mass spectrometry has evolved rapidly as a technique during the last 20 years towards simple-to-use laboratory systems and rugged process gas analysers. Direct head-space measurement of chloroform is now possible, for example, with the Food-sense, a further development of the Air-sense 2000 manufactured by V&F and Absam in Austria. This apparatus uses a patented soft chemical ionisation technique which controls the contact of the moist sample

gas with the delicate filament. The ions are formed in a charge-exchange chamber and subsequently separated on their mass over charge ratio (m/z) by a quadrupole. This set-up results in a highly stable and sensitive mass spectrometer, showing detection limits to low ppb-values for all kinds of volatile or gaseous substances. At NIZO Food Research the measurement of chloroform by direct head-space sampling has been successfully evaluated using the Food-sense.

Chlorine atoms exist as two isotopes having masses of 35 (75.5%) and 37 (24.5%). On ionisation chloroform loses a chlorine atom. The residual positive ion CHCl_2^+ shows up at masses 83, 85 and 87 in decreasing intensity due to the isotopic composition of the chlorine. In principle, measurement at mass 83, the most abundant signal, would suffice. However, when dealing with complex samples of natural origin, it is possible that another component might form an ion or ion-fragment having the same mass as the one monitored for chloroform. If chloroform is monitored at more than one mass, the likelihood of a false positive result diminishes rapidly. The Food-sense uses mercury vapour (the system is completely closed, using special filters in the exhaust of the vacuum pump) or xenon gas as ionisation gases, having ionisation energies of 10.4 eV and 12.1 eV, respectively. Most organic substances can be ionised using mercury, whereas xenon often induces more fragmentation. The instrument can switch within a second between ionisation with mercury or xenon. Both can be used to ionise chloroform, enabling the measurement at masses 83 and 85 using mercury and 85 and 87 using xenon (measurement at mass 83 using xenon is hampered by residual krypton in the xenon). Chloroform is judged to be present if all four results are positive. In this way false positive results are very unlikely.

The system is calibrated by adding known amounts of chloroform to the type of product to be measured (e.g. whole or partially skimmed milk). The result of the addition of sodium hypochlorite, Chloramine T (Halamid, *N*-chloro-*p*-toluenesulphonamide sodium salt) and sodium dichloroisocyanurate to whole milk is shown in Fig. 14.1. The horizontal dashed line shows the detection limit ($5 \mu\text{g/l}$) of the system. Chloroform is detected at $5 \mu\text{g/l}$ when approximately 0.004% of active chlorine is present. The similar results obtained for the different isotopes and ionisation methods show that no interfering components have been formed. It is notable that at high concentrations of active chlorine, Chloramine T and dichloroisocyanurate generate considerably more chloroform than hypochlorite (Olieman *et al.*, in press). Since measurement takes less than one minute per sample, it provides an effective means of measuring large numbers of samples of raw milk quickly.

14.8 Future trends

Active chlorine disinfectants are being increasingly replaced by hydrogen peroxide with or without peracetic acid, because these disinfectants are less corrosive for stainless steel. Contact of these disinfectants with the food product

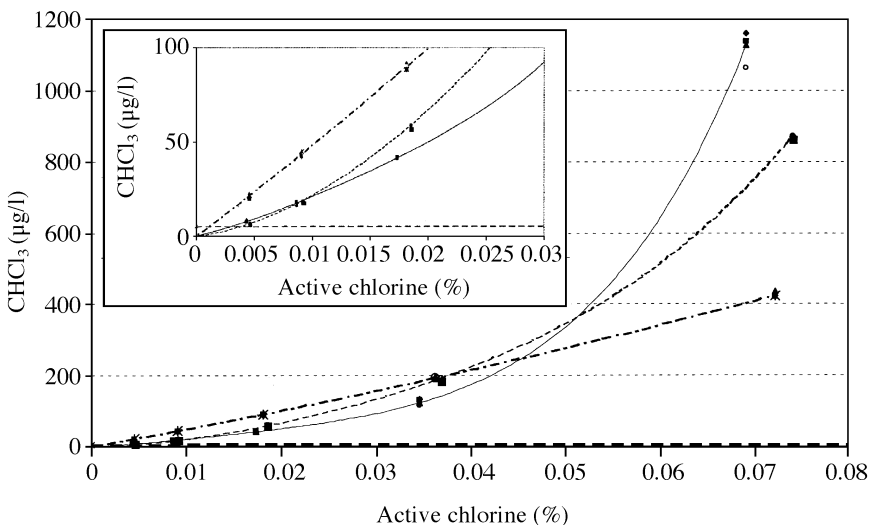


Fig. 14.1 Head-space measurement of chloroform in whole milk with the Food-sense. Chloroform formation was induced by the addition of sodium hypochlorite (short-long dashed line), dichloroisocyanurate (small dash line), and Chloramine T (continuous line) to whole milk. Chloroform was measured at mass 83 using Hg (◆), mass 85 using Hg (■), mass 85 using Xe (▲) and mass 87 using Xe (◐). Horizontal dashed line indicates detection limit (5 µg/L). The insert shows in greater detail the graph at low active chlorine and chloroform levels.

could lead to taints and off-flavours. In principle it should be possible to detect in-line off-flavours or deviations in the normal pattern of volatiles by sensitive mass spectrometry or by using fast gas chromatography in combination with mass spectrometric detection. These techniques are now becoming available as on-line process control instruments.

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15

Personal hygiene

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15.1 Introduction: sources of contamination

Personnel are both reservoirs and vectors of microorganisms and can act as a source of microbial contamination to food products. This chapter deals with the mechanisms of such product contamination and the ways in which it can be reduced by sound employee hygiene practices. The subject of personal hygiene is constantly evolving and, by its very nature of being 'personal', is influenced by a range of ethnic, cultural and personal views. Advice on personal hygiene is always available, both for food handlers and within the medical field, from government agencies, and recent technical reviews include Guzewich and Ross (1999a, 1999b), Paulson (2000) and Taylor and Holah (2000).

In the food industry the term 'personnel' is often taken to mean only operatives employed on the factory floor, but should also include managers, engineers and visitors. Successful training and control measures for these operatives, who routinely handle food products, can be negated if other people passing through the processing area do not adhere to the same control measures. Personal hygiene should apply to everybody – there is often an impression by engineers, contractors, managers, visitors, etc., that the rules do not apply to them!

The different activities and the range of movement patterns that people undertake during their working day, their perceptions and attitudes, mean that contamination from people can be complex and therefore difficult to identify and control. Direct contamination may arise by contact between the body, which acts as a reservoir of microorganisms, and the food product. The face, neck, hands and hair contain both a higher proportion of transient microorganisms and a higher general bacterial density (Troller, 1993). The reservoir of contaminating

microorganisms on the body consists of both naturally occurring organisms and those acquired on the body through normal daily activities. Indirect contamination involves people acting as vectors, transferring contamination from one area or surface to another, for example transferring product soil and microorganisms on the sole of footwear to different parts of the food factory. This indirect mode also includes poor practice such as using the same equipment, e.g. chopping boards or knives, for both raw and cooked meats.

The reservoir of microorganisms on and in the body can be divided into two broad categories; those found on the external surface, i.e. on the skin and hair, and in the nose, mouth, ears and eyes, and those found in the alimentary tract, which are excreted in the faeces. The skin microorganisms are the most important and can be further divided into two categories: transients and residents. Transient organisms are acquired in the process of normal everyday activities, e.g. every time the hands come into contact with a surface. In the food industry, microorganisms can be acquired from handling raw materials, processed foods, contaminated equipment and contaminated clothing, touching other body parts or poor toilet hygiene. If the hands have been handling raw materials of animal origin then the transient organisms could include pathogens. Generally, transient organisms do not have sufficient residence time to multiply, and they are easy to remove by, e.g., simple hand hygiene procedures. Localised lesions on the skin surface may harbour transients for a longer time period (sometimes becoming a temporary resident, e.g. *Staphylococcus aureus*) until the lesion has healed. Examples of transient organisms are Gram-negative bacteria such as *Salmonella* spp., *Escherichia coli*, *Pseudomonas aeruginosa* and *Klebsiella* spp.

The resident microorganisms live and multiply on the skin and constitute the normal microflora of the skin. The balance of residents is influenced by the presence of skin diseases or systemic illness. Generally, resident skin microorganisms are not food pathogens with the exception of *Staphylococcus aureus* which is often found on people as a temporary resident. The categories of residents and transients is useful but not always clear cut; for example, a transient organism may reside on the skin for long enough to be defined as a temporary resident.

Resident microflora are able to resist desiccation and the antibacterial properties of skin substances. The concentration of organisms varies over the body and on the hands, is greatest on the fingertips and under the nails. The organisms reside as micro-colonies often attached to skin squames, which are constantly shed into the environment through normal everyday activities. The predominant resident skin organism is coagulase-negative *Staphylococcus epidermidis*, which is not normally a pathogen. The coagulase-positive organism *Staph. aureus* can sometimes be a temporary resident, usually in the nose, or where the skin is damaged or infected. In the moist areas of the skin, Gram-negative bacteria are more common and include *Acinetobacter* spp. and sometimes *Klebsiella* and *Enterobacter* (usually transient). Corynebacteria and propionic bacteria are other residents (Newsom, 1999). In general, resident

bacteria are not usually pathogenic and therefore with some exceptions are not an issue when considering contamination of food from personnel.

15.2 Direct and indirect routes of contamination

15.2.1 Direct routes

Direct contamination involves the transfer of microorganisms from people to the food product by direct physical contact. The contamination may be a result of the transfer of microorganisms naturally harboured on or in the body acting as a reservoir or it may result from translocation of transient organisms. Translocation occurs by people acting as a vector, picking up pathogens from one activity (most likely by the hands) which are then transferred to another surface (which may be food) in a subsequent handling activity.

Gastrointestinal tract (GIT)

Faecal material contains very high numbers of bacteria; for example, Drasar (1974) presented information on bacterial populations from human faeces sampled in the UK. The mean \log_{10} counts per gram of faeces were detailed as Enterobacteria 7.9, Enterococci 5.8, Lactobacilli 6.5, Clostridia 5.7, and Bacteroides 9.8. The GIT is thus capable of sustaining considerable numbers of microorganisms and at times some of these organisms may be pathogens. Where workers have been ill with food poisoning, they will excrete the infective organism in the faeces for a period during the illness and for a time after symptoms cease. Such workers are a hazard to food safety. It is also possible for workers to carry infectious agents in their GIT without having any obvious symptoms; such persons are often termed carriers. Spread of contamination is either directly from the hands following poor toilet hygiene or indirectly as particles of faeces collect on the hairs in the anal region and are spread to clothing.

The skin

The surface of the skin is not flat; it is composed of flattened pavement cells (squames) composed mainly of keratin (Noble, 1981). There are various structures associated with the skin surface; these include hairs, sebaceous glands, apocrine and eccrine sweat glands. The skin maintains itself by depositing perspiration, oil and dead cells on the outer surface. When these materials mix with environmental substances such as dust, dirt and grease, they form an ideal environment for bacterial growth (Noble and Pitcher, 1978). The epidermis (the outer layer of the skin) also contains cracks, crevices and hollows that can provide a favourable environment for microorganisms. The level of bacteria found on the skin ranges from approximately 10^2 to 10^7 cfu/cm². Both the number and type of bacteria vary on different parts of the body and the balance of the skin flora depends upon the presence of skin disease or systemic illness.

The hands are the major source of infection from transient and resident microorganisms. Horwood and Minch (1950) found that the number of organisms recovered from the hands ranged from 1.5×10^4 to 9.5×10^7 per hand. Studies by the authors on the testing of antimicrobial soaps have typically found a range of 10^2 to 10^6 cfu/hand from finger rinses when assessing the necessary 15 subjects for these tests. The counts were similar for left and right hands, and day-to-day variation was small. Temperature and humidity are important in determining the number of microorganisms on the hands.

The surface of the skin is continually replaced by the process of desquamation, leading to the squames at the surface being sloughed off and replaced with cells from the lower layers. This constant shedding and replenishment of skin cells gives skin its characteristic function of providing a durable outer skin surface. Desquamation is the result of normal cell maturation, drying and the friction between clothes and the skin surface. The rate of loss of skin squames from the body varies according to the activity of the person, with sedentary activities resulting in the minimum loss of squames, whilst activities that cause greatest friction between the skin and clothes such as running result in a greater loss of skin squames. During undressing it has been estimated that 500 000 squames become airborne of which 5–10% may carry viable microorganisms (Noble, 1981).

Considering the skin as a whole, it is a natural reservoir of microorganisms which are released into the environment by the continuous process of desquamation, resulting in potential direct contamination of the food product. However, for healthy workers the majority of these organisms are residents and therefore not pathogenic. In addition, as skin secretions build up and the bacteria present continue to grow, the skin may become irritated. Food handlers may rub and scratch the area, thereby transferring bacteria to food from the skin in an indirect manner.

The hair

Hair is a significant potential source of contamination (Marriott, 1999) and hair density and oil secretions enhance the growth of microorganisms. Summers *et al.* (1965), cited by Woodroffe and Shaw (1974), examined the hair of hospital patients and staff. They found 30% of individuals had *Staph. aureus* in their hair, 20% *E. coli* and 10% *Streptococcus* spp. Noble (1966), cited by Woodroffe and Shaw (1974), examined the hair of individuals with no hospital contact and those with skin complaints regularly attending hospital. He found 10% of the former group and 59% of the latter to have *Staph. aureus* present on their hair. The major route of direct infection from hair is via hair loss and deposition into the product. For example, Hayes (1985) suggests that 100 hairs are lost each day. Hair can also act as an indirect transfer route, since, if hair is in poor hygienic condition and the scalp becomes itchy, microorganisms can be transferred to product via the hands after scratching.

The mouth and nose

Large numbers of bacteria are present in the mouth. Bacterial colonisation on teeth, referred to as dental plaque, contains in the order of 10^{11} organisms per gram (Gibbons *et al.*, 1964). Saliva when secreted contains few bacteria, though as it bathes the teeth it becomes contaminated as a result of bacteria dislodging from the teeth surfaces and acquires up to 10^9 cfu/ml (Gibbons and Van Houte, 1975). Brushing teeth regularly prevents the build-up of bacterial plaque and reduces the degree of contamination that might be transmitted to a food product if an employee gets saliva on the hands or sneezes.

The nose and throat have a more limited microbial population than does the mouth. However, the nasal cavity is the most important reservoir of staphylococcal infection (Polledo *et al.*, 1985). Published accounts of nasal carriage of *Staph. aureus* range from less than 10% to more than 40% in the adult population (Noble, 1981). Occasionally, microorganisms penetrate the mucous membranes overlying the surfaces within the nose, sinuses, pharynx and oesophagus and establish themselves in the throat and respiratory tract. Staphylococci, streptococci and diphtheroids are frequently found in these areas, and are highly contagious.

Direct contamination from the mouth and nose to food products is via coughs and sneezes, or spitting. Photography using high-intensity short-duration flash has shown that during coughs and sneezing, droplets and strings of mucus may be ejected from the mouth and nostrils for a considerable distance (Lidwell, 1974). Indirect contamination is via touching or wiping the mouth or nose and then touching food, either through scratching or via eating and smoking.

The ears and eyes

Various surveys have studied the microflora of the healthy ear (Singer *et al.*, 1952; Hardy *et al.*, 1954; Perry and Nichols, 1956; Moon *et al.*, 1965; Sommerville, 1966, cited by Noble, 1981), and found carriage of *Staph. aureus* of 8–22% and Streptococci of 1–16% of subjects tested. The eye itself is normally free of bacteria but mild bacterial infections may develop. Bacteria can then be found on the eyelashes and at the indentation between the nose and eye. There is no obvious direct transfer from the eyes and ears to food product, though contamination could occur following scratching or rubbing these organs.

15.2.2 Indirect routes

Indirect contamination involves people acting as a vector transferring contamination from one area or surface to another. Clothing and footwear can become contaminated with pathogens during working activities and therefore have the potential to contaminate other surfaces when the operatives move around the factory. Other examples of indirect contamination by personnel include dishcloths, chopping boards and knives which become contaminated and then are used inappropriately to contaminate other surfaces which subsequently come into contact with food. Activities relating to handling raw materials of

animal and plant origin are the most likely to result in the acquisition of pathogenic organisms.

15.3 Controlling contamination: medical screening

Effective control of contamination from personnel requires consideration of both direct and indirect modes. Control of the operatives begins with medical screening at the point of employment and is followed by daily assessment of their fitness to work. This is undertaken to ensure that employees do not work as food handlers when they are suffering from gastrointestinal and other illness that could increase their level of transmissible pathogenic organisms.

Operatives are encouraged to follow basic hygiene procedures at home prior to arriving for work, and within the workplace they have to follow documented personal hygiene procedures. Such procedures cover the control of personal habits, the wearing of make-up and jewellery and hand washing protocols. These procedures are established via thorough hygiene training as part of their induction process and reinforced by management supervision and audit. The food processor is responsible for providing a suitable range of protective clothing both to protect the operative from the processing environment and to cover the food handlers' body and so minimise the release of microorganisms from the body onto or near food operations. A laundry policy should also be in place to clean and maintain such protective clothing.

The control of indirect contamination routes is primarily concerned with recognising that operatives can become contaminated in one processing area and can transfer this contamination when moving around the workplace. Sound hygiene policies concerning the physical structure and the operative changing practices should be in place at entrances to high-risk/high-hygiene or clean-room food production areas.

Medical screening of food operatives is initially concerned with the requirement for medical certification of prospective new employees. In addition, it involves an ongoing awareness by operatives of their own health and the health of those around them (e.g. at home), from whom they themselves may become infected and thus subsequently compromise food safety. Medical certification is required in Europe for certain categories of food production, e.g. milk (Council Directive 92/46/EEC) and fish products (Council Directive 91/493/EEC). Advice on medical certification in the UK is given in the Department of Health Guideline *Food handlers: fitness to work* (Anon., 1995). The document does not recommend the use of stool testing prior to employment and suggests the use of pre-employment questionnaires, including, for example, the following questions:

1. Have you now, or have you over the last 7 days, suffered from diarrhoea or vomiting?
2. Are you at present suffering from any of the following:

- (a) Skin trouble (e.g. eczema) affecting the arms, hands or face?
 - (b) Boils, styes or septic fingers?
 - (c) Discharge from the eye, ear or gums/mouth?
3. Do you suffer from any of the following:
 - (a) Recurring skin or ear trouble?
 - (b) Recurring bowel disorder?
4. Have you ever had, or are known to be a carrier of, typhoid or paratyphoid?
5. In the last 21 days have you been in contact with anyone, at home or abroad, who may have been suffering from typhoid or paratyphoid?

If the answer to any of the questions is yes, or if gastrointestinal illness develops whilst employed, the guideline provides details of necessary requirements to be met before a food handler can start (or return to) work. Questionnaires of this nature should also be filled in by all visitors, auditors, customers, contractors, etc. who, whilst undertaking the purpose of their visit, may come into contact with the product directly or may visit food processing areas. In some countries, whilst it is not illegal to ask such questions of employees, they may not have to answer them because of legislation concerning possible infringement of personal liberties.

Food handlers suffering from gastrointestinal infection, or who have been in close contact with someone who is ill, may contaminate food. The causative agents of gastrointestinal infection include *Salmonella* spp. (non-typhoid fever), *Salmonella Typhi* and *Salmonella Paratyphi*, *Escherichia coli* O157:H7, *Campylobacter* spp., *Shigella* spp., *Vibrio* spp., *Bacillus* spp., *Yersinia* spp., *Clostridium perfringens*, *Staphylococcus aureus*, viral gastroenteritis, *Entamoeba histolytica*, *Cryptosporidium parvum* and *Giardia lamblia*.

Once employment has started, therefore, any instance of potentially infectious diseases, including vomiting, stomach disorders, diarrhoea, skin conditions and discharge from the eyes, nose or ears, must be reported to the medical department, first aider or the line supervisor. This also applies to staff returning from foreign travel where there has been a risk of infection.

If, through illness, staff are identified as being at risk to the safety of the product, they should either be sent home or moved to other work duties that do not include food handling. A record of the notification to management of the operative's illness and the subsequent action management has taken should be kept for purposes of due diligence.

15.4 Personal hygiene practices

The number of microorganisms arising from the skin and within the body of food operatives prior to commencing work, and thus the potential risk the operatives present to the food product, are controlled by high standards of personal hygiene, including the following:

- Having regular baths/showers
- Washing hair frequently

- Keeping fingernails short and clean
- Avoiding habits such as biting nails and ‘picking or scratching’ the nose and ears.

Personal hygiene policy

On arrival at their place of work, all operatives, visitors, contractors, etc., will be expected to abide by the company’s personal hygiene policy. In many companies this document is an essential part of the company’s induction training programme and operatives are often asked to sign a record to acknowledge that they have read and understood the policy and agree to abide by it.

The personal hygiene policy is usually a comprehensive document, though the sections that operatives need to be familiar with are usually more readily comprehensible, often in a number of languages and backed up by figures and posters as appropriate. The policy will include information such as the location and types of hand wash facilities, hand hygiene products used, hand hygiene procedures for employees, instructions for when to wash hands (including information on gloves), procedures for monitoring hand hygiene, procedures for the identification and control of dermatitis, training programmes and records, and details and frequency of hygiene audits.

The factory hygiene policy is often shortened to a number of key points and is posted around the factory and at reception as a quick reminder. It could typically include the following:

1. *Protective clothing, footwear and headgear* issued by the company must be worn and must be changed regularly. When considered appropriate by management, a fine hairnet must be worn in addition to the protective headgear provided. Hair clips and grips should not be worn.
2. *Protective clothing* must not be worn off the site and must be kept in good condition.
3. *Beards* must be kept short and trimmed and a protective cover worn when considered appropriate by management.
4. *Nail varnish, false nails and make-up* must not be worn in production areas. Strong aftershave or perfumes must not be worn.
5. *False eyelashes, wrist watches and jewellery* (except wedding rings, or the national equivalent, and sleeper earrings) must not be worn. Studs and earrings, if worn, should be covered in appropriate dressings.
6. *Hands* must be washed regularly and kept clean at all times.
7. *Personal items* must not be taken into production areas unless carried in inside overall pockets (handbags, shopping bags, etc., must be left in the lockers provided).
8. *Food and drink* must not be taken into or consumed in areas other than the rest areas and the staff canteen/restaurant.
9. *Sweets and chewing gum* must not be consumed in production areas.
10. *Smoking or taking snuff* is forbidden in food production, warehouse and distribution areas where ‘No Smoking’ notices are displayed.

11. *Spitting* is forbidden in all areas on the site.
12. *Superficial injuries* (e.g. cuts, grazes, boils, sores and skin infections) must be reported to the medical department or the first aider on duty via the line supervisor and clearance obtained before the operative can enter production areas.
13. *Dressings* must be waterproof, suitably coloured to differentiate them from product and contain a metal strip as approved by the medical department.
14. *Infectious diseases* (including stomach disorders, diarrhoea, skin conditions and discharge from eyes, nose or ears) must be reported to the medical department or first aider on duty via the line supervisor. This also applies to staff returning from foreign travel where there has been a risk of infection.
15. *All staff must report to the medical department when returning from both certified and uncertified sickness.*

The best personal hygiene policies are 'self policing'. In this case operatives and managers tell each other if clothing is not worn properly or someone has spotted an operative touching their face and they need to rewash their hands. Such a practice can be very effective especially when everyone is involved, including managers, visitors and engineers.

Factory clothing

The wearing of the operative's own clothing for food processing operations is generally not permitted and the company usually supplies a range of protective clothing. Protective factory clothing is worn for two reasons, and it is important that the induction training programme reflects this. Personal protective equipment (PPE), which includes gloves, safety spectacles, ear defenders, aprons, overalls and footwear with non-slip soles and metal toe caps, are worn to protect the operator from the food processing environment (cold, water, food products, etc.) and specific safety hazards as appropriate (e.g. detergents and disinfectants). The second purpose of protective clothing is to protect the food from microorganisms released from the body. Protective clothing of this type includes hair nets, hats, masks, beard snoods, overalls, coats, gloves, wrist and forearm sleeves, trousers and footwear. Consequently the type of material used and the design of protective clothing will depend upon its prime function.

Factory clothing should be hygienically designed so that it does not shed foreign bodies directly (e.g. buttons or lint) or indirectly (e.g. having outside pockets from which objects can fall out and into the product). The clothing is often of different colours to delineate either operatives working in different risk areas or specific categories of people, e.g. engineers, cleaning staff, first aiders and management.

The frequency of clothing change and the degree of decontamination during laundering are dependent upon the type of food being produced. Clothing may be laundered in-house or can be undertaken by external contractors. Clothing laundered by external contractors, however, must be laundered separately from clothing from other industries. Changing of clothing daily is the preferred option

as it is often easier to manage, preventing each operative having to make a decision as to whether his or her clothing needs changing. Traditional washing programmes are acceptable for most clothing (i.e. where visual cleanliness is the goal) but high-risk factory clothing requires greater standards of laundry sufficient to reduce the microbial load. This is usually achieved by higher laundry process temperatures such that the clothing receives a pasteurisation treatment. Some laundries now operate with similar low/high risk principles as the food industry. Dirty clothing enters the laundry in the low-risk side and passes through the process of washing and disinfection to come out at the high-risk exit for drying, steaming and packaging.

Management's responsibility

To ensure that the company's personal hygiene policy can be fully met, the company should ensure that facilities are in place to both enable and encourage operatives to fulfil its requirements. This could include the following:

- Provision should be made for the storage (e.g. a refrigerator) and re-heating (e.g. a microwave and a kettle) of staff's own food if they wish to eat their own food and/or if a canteen service is not provided.
- Suitable changing facilities for both sexes containing storage facilities for outside clothing and suitable toilet facilities, which do not open directly into food processing areas, should be provided. Factory clothing should be stored separately from outside clothing.
- Clean protective clothing should be provided daily. Following work activities, sufficient laundry bins for soiled clothing should be available.
- Hand wash facilities should be available, comprising non-hand-operated taps, liquid soap (cartridge form with antibacterial agent to prevent bacterial growth in the soap), and appropriate hand drying facilities such as warm air driers, paper towels or linen/paper towels presenting a fresh section to each user. If paper towels are specified, an appropriate receptacle for waste should also be provided.
- Wherever possible, changing facilities should be sited to allow direct access to food processing areas without operatives having to traverse external areas.
- Alcohol dispensers may be provided for personnel to apply to hands just prior to work activities.

15.5 Hand hygiene

Perhaps the most critical aspect of the reduction of the contamination risk from people is thorough hand washing. Hand washing and disinfection were reviewed by Reybrouck (1986) who defined the different terms involved and discussed the efficacy of various systems. The purpose of hand washing is to remove superficial desquamated skin squames, sweat, sebaceous secretions and associated transient bacteria as well as any organic material adhered to the

hands acquired from normal activities. The immediate (transient removal) antimicrobial effects depend upon the types and amount of washing product, the time spent washing the hands, and the mechanical pressure and friction employed. The persistent effects (resident removal) depend upon the topical and microbial product efficacy (Paulson, 1996).

Good hand hygiene encompasses the following:

- Undertaking hand hygiene at appropriate times
- Using a liquid soap (in a cartridge system) with an antibacterial agent to prevent microbial growth in the soap
- Covering all the areas of the hands following the six-point hand washing sequence as described by Ayliffe *et al.* (1978)
- Followed by thorough hand drying with paper towels or warm air hand drier
- Finishing with an alcohol rub.

Appropriate times for the washing of hands is after any activities that could contaminate the hands with pathogens and include the following:

- Visiting the toilet
- Handling raw food
- Handling waste
- Blowing the nose and /or touching body parts
- Carrying out cleaning duties
- Removing gloves
- Handling non-food-contact surfaces, e.g. machine adjustment, power switches
- Working a shift.

In addition, hands should always be washed before the following activities:

- Entering food handling areas
- Changing into high-risk clothing
- Putting on gloves.

Hand washing with both soap and water, which act as emulsifying agents to solubilise grease and oils on the hands, will remove transient bacteria. Increased friction through rubbing the hands together or by using a scrubbing brush reduces the number of both transient and resident bacteria. A cleaning compound will remove more transient bacteria, with subsequent destruction by a disinfectant. The temperature of the wash water, however, is not thought to be important in influencing microbial removal (Michaels *et al.*, 2002) and wash water should ideally be warm to encourage operatives to wash their hands frequently (too cold discourages handwashing, too hot may cause discomfort).

A suggested, comprehensive sequence for effective hand washing, modified from Marriott (1999), is described below:

1. Wet hands.
2. Apply soap.

3. Rub hands to spread soap over hands up to wrists.
4. Wash hands using the six-point hand washing sequence as described by Ayliffe *et al.* (1978). This is illustrated schematically in Fig. 15.1. All parts of the hands and wrists should be rubbed, with each step consisting of five strokes forward and backward.
5. Brush nails and other areas where dirt may be difficult to dislodge (using a clean nail brush).
6. Rinse hands.
7. Rub hands to check whether all soap lather has been removed.
8. Rinse hands again.
9. Dry.

This simple handwash has been shown to be effective at removing microorganisms from artificially contaminated hands, and log reduction values of between 2 and 3 log orders are typical in the scientific literature (Lowbury *et al.*, 1964; Mittermayer and Rotter, 1975; Ayliffe *et al.*, 1978; Paulson, 1994).

Sanitising antimicrobial agents exert a continuous antagonistic action on emerging microbes and enhance the effectiveness of ordinary hand soap at the time of application. Agents for hand disinfection must not be toxic, nor taint the food product, and should have a range of antimicrobial activity. Alcohol (70%) is the most widely used disinfectant in the food industry and is effective for

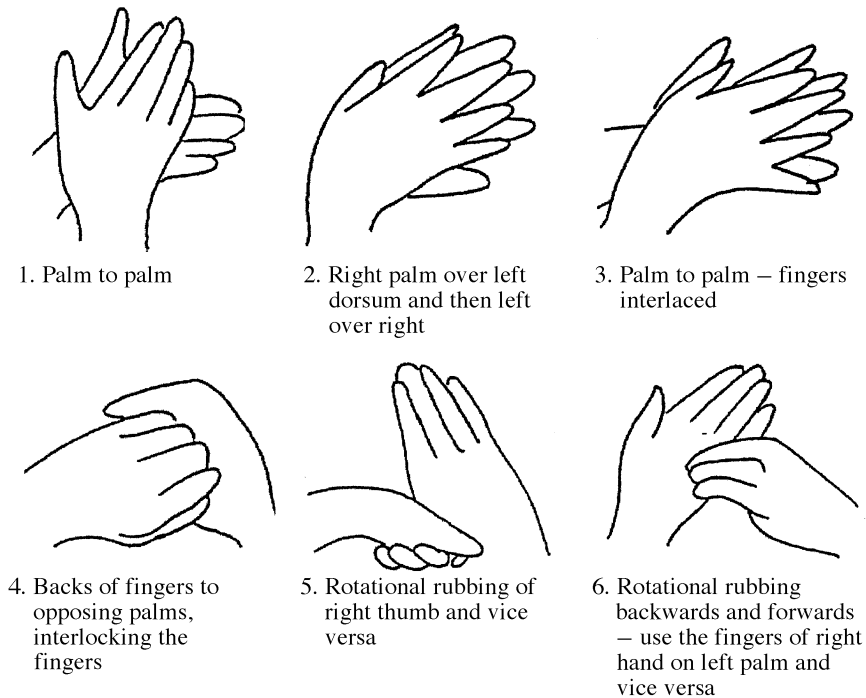


Fig. 15.1 Recommended sequence for hand washing.

rapid killing of residual transient microorganisms. Other agents such as hexachlorophane, chlorhexidine, quaternary ammonium compounds and iodophors may be used for activity against resident organisms such as *Staph. aureus*. The overall efficacy of an antimicrobial hand soap (other than alcohol-based products) depends on continuous use throughout the day. However, a compromise may have to be found between efficacy and health and safety, as the frequency of hand washing in the food industry means that dermatitis may be a problem with some of these agents.

Mechanised hand washers may be useful in ensuring that hand washing is done thoroughly and frequently. In some cases such equipment has increased the frequency of hand washing as much as threefold (Marriott, 1999). In one example, jets spray a mixture of antimicrobial cleansing solution and water on the hands, followed by a potable water rinse. The 10-second, massage-like cycle has been clinically proven to be 60% more effective at removing pathogenic bacteria from the hands than the average manual hand washing (Anon., 1997). This process can accomplish hand washing with only one-third of the amount of water used in most manual hand washing methods.

The use of alcohol wipes in the food industry has become more widespread for a number of uses, including hand hygiene. Work by Taylor *et al.* (2000) has shown that cleaning artificially contaminated hands with non-alcoholic wipes reduced the microbial level by 2.2 log orders and with alcoholic wipes by 3.1 log orders. Both these results were broadly similar to those obtained for hand washing. It may be a practical alternative, therefore, to use alcoholic wipes at a 'local' level on the production line, such that operatives needing to decontaminate their hands can use a wipe rather than having to keep returning to the hand wash basins. In addition, hand wipes can be useful for operatives in the food chain who do not currently have hand wash facilities, such as warehouse operative and vehicle drivers.

Hand drying is at least as important as hand washing in preventing the translocation of microorganisms from the hands to the food product. Work has been undertaken by the authors to demonstrate the effect of hand drying on microorganism translocation and the results are illustrated in Fig. 15.2. A volunteer with naturally contaminated hands was asked to press their hands onto 10 consecutive Petri dishes filled with agar after hand washing and hand drying for 20 seconds (poor hand drying), hand drying for 60 seconds (normal hand drying) and hand drying for 60 seconds followed by a handrub with alcohol. The data in Fig. 15.2 shows that there is considerable transfer of microorganisms to the plates with poor hand drying, with little loss in microbial numbers over the 10 plates. When normal drying was carried out, microbial transfer was much reduced and could be virtually eliminated after an additional handrub. Patrick *et al.* (1997) have also described the importance of water droplets in microorganism translocation and recommend that good hand drying is crucial in reducing translocation in clinical and public health sectors.

Drying of hands must be undertaken in a manner that ensures that hands are thoroughly dried. Warm air hand driers and single-use textile and paper towels

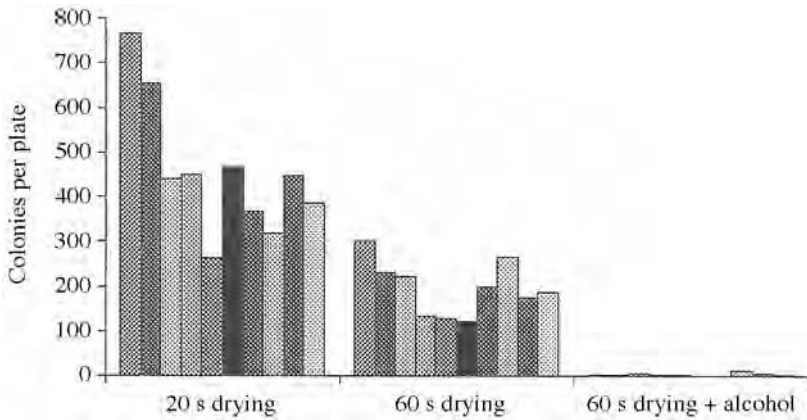


Fig. 15.2 The effect of drying times using warm air dryers, following hand washing, on the rate of translocation of naturally contaminated skin to 10 consecutive Petri dishes containing agar. Microorganism counts are expressed as the number of colonies on the plate surface transferred from the hands.

are the preferred methods of choice, although some paper/textile reels that automatically advance between dries could also be acceptable. Towels that are re-used by each operative should not be used. Warm air dryers have been shown to be as effective as paper towels with respect to the number of bacteria recovered from hands after washing and drying. In addition there is no evidence to show that warm air dryers contaminate the air; in fact it has been demonstrated that airborne microbial populations are reduced as they pass through the warm air dryer (Taylor *et al.*, 2000). The choice, therefore, between paper towels or warm air dryers is based upon circumstance. Warm air dryers take longer to dry hands and sufficient units are required for the number of personnel needing to use them at the same time, whilst paper towels present a waste disposal problem, requiring good management to ensure both towel dispenser and bins are filled and emptied effectively.

Following handwashing and drying, the benefits of wearing or not wearing gloves for food handling are not clear. Initially, gloves present a clean contact surface, and bacteria that are sequestered on and in the skin are not permitted to enter foods as long as the gloves are not torn or breached in some way. However, the skin beneath the gloves is occluded, and heavily contaminated perspiration builds up rapidly between the internal surface of the glove and skin. If this contamination contacts the food through a breach in the glove barrier, the food will receive a much higher inoculation of microorganisms than would have been transferred from the bare hand. In addition, the gloves themselves soon become contaminated and a hygiene risk unless they are frequently washed or replaced. Gloves also tend to promote complacency that is not conducive to good hygiene. If gloves are used, for example to protect the hands, or to prevent skin irritation or dermatitis from frequent washing, thorough washing of hands needs to be carried out both before and after putting on gloves. The gloves need to be

changed approximately every two hours (this usually corresponds to break times) and whenever they are damaged or holed. There are no microbiological or physical standards for gloves, and their sterility, physical integrity and chemical content (with respect to food taints) should be carefully specified to the glove manufacturer.

Monitoring hand hygiene

Thorough handwashing is clearly essential to control transient microorganisms and should be assessed as a 'critical' process. In the majority of HACCP studies handwashing is seen as a prerequisite, though for some high-risk food manufacturing operations it may be seen as a critical control point (CCP). Assessment of hand hygiene could therefore be undertaken as part of routine hygiene testing or as CCP monitoring and verification.

The microbiological assessment of handwashing, i.e. the concept that you can tell whether someone has washed their hands by swabbing their hands at random, is scientifically unfounded and is, therefore, wasteful of both time and money. This is because the levels of microorganisms on people's hands (when clean) can vary from 100 to 10 million or more, though it is thought that the loading on people is relatively stable. This means that to take a single total viable count (TVC) of a person's hands and get something meaningful from it, you must know the likely level that that person would normally have. To establish this would mean routinely swabbing all operatives and building up a picture of this 'norm', which in most food processing operations is impracticable. In addition to this, hand washing typically removes only 2–2.5 log orders of microorganisms. Therefore if one particular operative has a typical TVC count of 1000 microorganisms and on one day he had 100 000, whilst he clearly has more bugs than normal, you would not know whether he had not washed his hands. For example, before hand washing he could have touched some raw meat, contaminated his hands to a level of 10 million microorganisms and then washed his hands properly and reduced this to 100 000. Examining for the presence of Enterobacteriaceae or coliforms after hand washing may have a little more credibility, as coliforms are not part of the skin's natural flora. However, again if somebody had touched raw materials (or routinely touches raw materials) and washed their hands, their coliform count could still be high after washing.

Microbiological methods for the assessment of hand hygiene that are acceptable, include looking specifically for a pathogen, e.g. *Staph. aureus*, with the purpose of excluding carriers from working in high-risk food processing areas if the HACCP study recognises staphylococcal toxin as a risk. Such examination usually includes swabbing the hands after hand washing on three occasions and on different days. If the pathogen is routinely present on the hands, this person can be excluded from the high-risk area but is safe to work in low-risk activities. Alternatively, it is possible to assess the TVC level of the hands before hand washing and then afterwards to ensure that the operative has washed their hands sufficiently to ensure a suitable log reduction (e.g. 2 log orders) in microbiological count.

It has even been suggested that one technique would be to swab an operative's hands after they have washed them and, on leaving the processing area, to discard the swab immediately. The concept here is that whilst taking the swab may be technically pointless, the concept of going into production and 'swabbing' operatives to remind them of the necessity to wash hands is priceless!

It is also possible to assess the quality of hand drying. During the induction-training period, operatives can be asked to wash their hands with coloured water, dry them as they would normally, and then place the hands on tissue paper. Detection of any red coloration indicates poor drying. In the field, placing operatives' hands, after drying, on pre-weighed tissues can routinely monitor hand drying. These tissues are then re-weighed and the mass of water remaining calculated and compared to a target limit.

Suitable non-microbial methods of assessing handwash compliance include visual monitoring by staff or the use of CCT cameras. It is also possible to install turnstiles and interlocked door arrangements such that the turnstile or door to the food processing area will only open when a recognised handwashing trigger has been activated, e.g. the water tap has run for 10 seconds.

15.6 Training

Effective induction training and a programme of ongoing training are the best ways to educate and reinforce good personal hygiene practices. In one study of food handlers' attitudes, 62% admitted to sometimes not carrying out all food safety procedures on every occasion, with 6% admitting that they often did not (Clayton *et al.*, 2000). Lack of time was the most quoted reason for failure to implement agreed procedures. Possible factors influencing the behaviour of food handlers are summarised in Fig. 15.3 and Griffith (2002) discusses models of food handler behaviour. Management must establish appropriate procedures to ensure hygienic practices by employees. Supervisors and managers should set an example for employees by their own high levels of hygiene and good health while conveying the importance of these practices to the employees. In general, hygienic practices are more likely to be implemented if they are properly integrated into the organisation's culture. If management takes good hygiene practices seriously, provides the time and resources needed and rewards good performance, employees will take their responsibilities more seriously.

Employees should be provided with training in food handling and personal hygiene (Shapton and Shapton, 1991). Indeed, improved training has been advocated as a key way of improving hygienic practices in the food industry (Griffith *et al.*, 1995). Perhaps the most effective way to carry this out is to present all new employees with a comprehensive induction programme, then reinforce it through means of posters, clear instructions in toilet blocks, changing rooms and hand washing facilities in the plant. An induction programme should include:

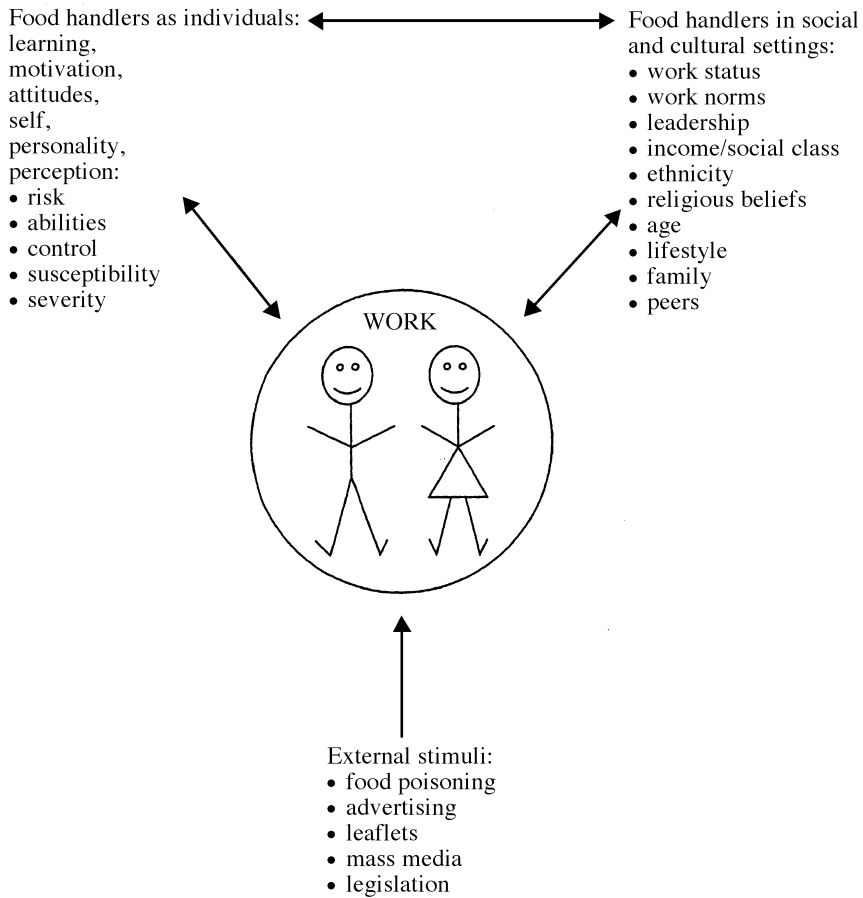


Fig. 15.3 Factors affecting food handlers' behaviour.

- Personal responsibility
- Protective clothing requirements and use
- Hand washing requirements
- Prevention of cross-contamination from raw materials to finished product areas.

Regular group sessions, which can include videos, are also helpful (Sprenger, 1983). Additionally, there must be sufficient on-going supervision of personal hygiene procedures in production departments to ensure that everyone complies with these procedures. Good hygiene practice should be part of any appraisal system of employees, supervisors and managers and violations of practices should be handled as disciplinary violations. Incentives for superior hygiene and sanitary practices should also be provided. Involving staff in developing and monitoring hygiene procedures is an effective way of winning commitment (Wallace, 2001).

15.7 Control of indirect contamination from people

Control of indirect contamination from people, where people become a vector for moving contamination from one area of the plant to an area of higher hygiene control, is a particular problem for certain sectors of the food industry such as ready-to-eat foods. This is because these types of processing operations recognise different hygiene zones, or risk areas, divisions between which are usually associated with a product heat treatment or decontamination step. Within the higher risk area, the food is often not further processed before eating and it is thus essential that this area remains free of pathogens. It is essential, therefore, that staff moving from a lower risk zone, in which pathogens may be present, into the higher risk zone, do so in such a manner that any contamination on their bodies is controlled at the point of transfer.

In this respect, the three key sources of contamination that have to be controlled are the operative's footwear, clothing and hands. Footwear, clothing and hands may become contaminated in the low-risk area by direct contact with the external environment, raw materials, food wastes, etc., whilst hands can be further contaminated in the process of removing low-risk clothing and footwear at the low-risk/high-risk barrier.

Footwear

Footwear is a potential vehicle for moving pathogens from one risk area of a factory to another and its control is simple. At the low/high-risk barrier, footwear can be either decontaminated or changed for footwear that is 'captive' to, i.e. remains in, the high-risk area. Footwear has traditionally been decontaminated by the use of either footbaths or bootwashers. Studies by Taylor *et al.* (2000) have shown that under laboratory conditions, when the footwear is soiled only with microorganisms, these techniques gave a 2–3 log reduction in viable counts of inoculated boots. Under factory conditions, however, when footwear was soiled with both food debris and microorganisms, the foot baths and bootwashers were ineffective at removing all organic soil and thus could not remove and/or decontaminate all microorganisms. In some cases, because the footbaths and bootwashers become contaminated, the level of microorganisms was greater after bootwashing than before. In addition, footwear can transport contamination significant distances, with dry contamination being transferred up to 35 m on dry floors and over 47 m on wet floors and wet contamination being transferred up to 24 m on dry and over 35 m on wet floors (Taylor *et al.*, 2000). Bootwashers also have the potential to create microbial aerosols that can transfer contamination from the footwear to the operative's clothing. In conclusion, footbaths and bootwashers should not be used at low/high-risk barriers for footwear decontamination. Bootwashers should only be used for cleaning the soles of footwear to prevent slip and trip incidences, for which they are very effective.

Footwear that is captive to high-risk is thus the method of choice for footwear control at the low/high-risk barrier. Captive boots should be cleaned in high-risk and manual cleaning and the use of an automatic washing machine have been

found to give good results, achieving a 1–3 log reduction in viable microbiological counts (Taylor *et al.*, 2000).

Clothing

The low/high-risk barrier serves as the point at which work clothing needs to be changed. High-risk factory clothing does not necessarily vary from that used in low-risk in terms of style or quality, though it may have received higher standards of laundry, especially related to a higher temperature process, sufficient to reduce microbiological levels significantly. Additional clothing may be worn in high-risk, however, to further protect the food being processed from contamination arising from the operative's body (e.g. gloves, sleeves, masks, whole-head coveralls, coats with hoods, boiler suits, etc.). All clothing and footwear used in the high-risk area is colour-coded to distinguish it from that worn in other parts of the factory and to reduce the chance that a breach in the system would escape early detection.

Hand hygiene

As in all food processing operations, control of the operative's hands is via thorough hand washing. The only difference in this case is that at the low/high-risk barrier, a specific hand washing sequence is used. The following sequence has been suggested to maximise the control of pathogens on the hands, at the earliest opportunity, whilst reducing the need for frequent hand washing which can lead to problems with dermatitis.

1. Remove low-risk/outside clothing and store in personal locker or designated storage area.
2. Remove low-risk/outside footwear and place in designated storage area.
3. Cross over low-risk/high risk barrier.
4. Wash hands using antimicrobial soap as described in Section 15.5.
5. Put on high-risk captive footwear.
6. Put on hair net, ensuring all hair is covered.
7. Put on outer clothing.
8. Pass through to high-risk area without touching door.
9. Apply alcohol to hands at entrance to high-risk work area.

To facilitate the required changing procedures at the low/high-risk area barrier, the changing facilities have to be specifically designed. The high-risk changing room provides the only entry and exit point for personnel working in or visiting the high-risk area and a basic layout should accommodate the following requirements:

- An area at the entrance to store outside clothing or low-risk clothing. Lockers should have sloping tops to minimise dust collection.
- A barrier to divide the low- and high-risk floors. This is a physical barrier such as a small wall, which allows the floors to be cleaned on either side of the barrier without contamination by splashing between the two.

- Open lockers at the barrier to store low-risk footwear.
- A stand on which high-risk footwear is stored, which also allows for the footwear to dry when it has been cleaned.
- An area with suitable drainage to carry out footwear cleaning operations
- Hand wash basins, which have automatic or knee-operated taps, with water supplied at suitable temperature (comfortable to hands) and a waste extraction system piped directly to drain.
- Suitable hand drying facilities.
- Access for clean factory clothing and storage of soiled clothing. For larger operations this may be via an adjoining laundry room with interconnecting hatches.
- Alcohol rubs placed immediately inside the high-risk production area.

15.8 References

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Hygiene and foreign bodies

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16.1 Introduction

Consumer complaints about foreign bodies are a continuing problem for the food industry. The last few years have seen an increasing emphasis on consumer rights, with frequent encouragement in the media for consumers to complain to food companies about incidents that would in the past have been viewed as trivial. There has also been greater support for complainants from government and enforcement authorities, from initiatives such as the Citizens' Charter in the UK to changes in consumer protection legislation. This has been combined with an increasing tendency towards litigation that appears to have spread to Europe from the USA.

This chapter will consider the types of foreign bodies that are reported from food and how they get into the food. The control of foreign bodies will be considered in two main ways: firstly, methods for identifying foreign bodies in order to determine what they are and how they got into the food; and secondly, the various methods for detecting and removing foreign bodies from food products during food processing. Finally, prospects for the future for each of these areas will be considered.

16.1.1 Definition

A foreign body may be defined as something that the consumer perceives as being alien to the food. The perception of the consumer is important, since not all foreign bodies are in fact alien to the food, though all have the potential to give rise to a consumer complaint. Hence foreign bodies can range from items that are demonstrably alien to the food, such as pieces of glass, metal or plastic,

through items that are related to the food, such as fragments of bone in meat products, to part of the food itself, such as crystals of sugar or salt that are mistaken for glass.

There is no doubt that over recent years consumer expectations with regard to food quality have risen dramatically, and this change in expectation has affected the view of foreign bodies as much as any other aspect of the quality of food products. Customers are therefore much less likely to accept foreign bodies than they were, say, 15 or 20 years ago. This can be attributed in part to a rise in 'consumer rights' over this period. However, the generally increasing quality of food products over the same period has resulted in the occurrence of causes for complaint, such as foreign bodies, being much rarer than hitherto. The result of this is that these occurrences stand out much more clearly in the consumer's mind. Thus there is a certain irony in the food industry being to some extent the author of its own misfortune in the increasing numbers of complaints about foreign bodies.

16.1.2 Types of foreign bodies

It follows from the definition given above that the range of possible foreign bodies is virtually limitless. One commonly made distinction is between intrinsic and extrinsic foreign bodies. Intrinsic foreign bodies are those that are related either to the raw materials used in the food product itself or to the packaging materials. Extrinsic foreign bodies are those that are not so related, and become incorporated in the product flow from an external source.

A knowledge of the raw materials used in producing a foreign body and of the processing procedures used and packaging materials employed may give an indication of the most likely types of foreign body to get incorporated with the food as an intrinsic foreign body. For example, fragments of peach or apricot stone may occur in products made with these fruits. Similarly, an understanding of the processes involved in food production can also help in identifying likely origins of extrinsic foreign bodies. An example of this might be the fact that a liquid product is filled into a jar or bottle using a narrow nozzle, such that a fragment of plastic several centimetres across could not have passed through the nozzle but must have originated elsewhere. However, it should never be forgotten that in a modern food processing operation, the occurrence of a foreign body in the final product is the exception rather than the rule. It is therefore an indication that something unusual has occurred, and hence it is often necessary to stand back from the situation and suspend disbelief, and so in the initial investigation all preconceptions as to what could or could not have happened need to be disregarded.

16.1.3 Sources of foreign bodies

Foreign bodies may get into food at any stage from initial harvesting to final processing or even preparation by the consumer. Harvesting of field crops may

result in pieces of soil, grit or stone being inadvertently collected with the crop. Weeds growing in the crop or at the edges of fields are important sources of foreign bodies, as are insects or other animals feeding on or among the crop plants. The crop itself may also be a source: for example, second-year carrots that manage to evade harvesting can give rise to the occasional woody carrot among the following year's crop. Plant material may build up on harvesting machinery and then get incorporated into the crop: this can be a particular problem with crops such as peas, where pea-shaped balls of pea leaf material may find their way into the harvested crop.

Food processing should include procedures to remove foreign bodies incorporated during harvesting of the crop, but it can also give rise to foreign bodies itself. Many foreign bodies can be traced back to pieces of food processing machinery. Apart from the more readily recognisable items such as nuts and bolts, fragments of metal or other material from worn or misaligned machinery may become incorporated into the food. Foreign material such as stones in the crop can lead to damage to processing machinery such as pumps, resulting in fragments of metal appearing in the product. Storage vessels such as tanks can lead to contamination if maintenance, modification or repair procedures are not carried out thoroughly: an example of this was fragments of weld slag found in wine after welding repairs to a storage tank had been carried out by an incompetent sub-contractor. Incorrect storage of raw materials and final products can result in infestation by food storage pests, resulting in the presence of foreign bodies such as insects or rodent droppings in the food.

Food packaging is a further potential source of foreign bodies. Offcuts of metal or plastic from packaging manufacture may sometimes get into the empty food container before filling and become mixed with the food, and the breakage of glass jars or bottles on a filling line can lead to fragments of glass getting into adjacent jars or bottles.

The possibility that foreign bodies can get into food as it is being opened, prepared or even eaten by the consumer should not be overlooked. Fragments of torn or broken packaging material from the product may become accidentally incorporated in the food during opening, especially if the pack is difficult to open. Foreign bodies may be accidentally incorporated during heating of the product, such as chips of glass from previously damaged ovenproof glassware. A foreign body found on the plate amongst several different components of a meal may also be attributed by the consumer to the wrong food product. Lastly, consumers themselves may be the source of the foreign body, as in fragments of tooth or dental filling.

16.2 Management systems for preventing foreign body hazards

16.2.1 Quality management systems

A good quality management system is vital to the effective prevention and control of foreign bodies in food manufacture. A structured preventive approach

is likely to be the most reliable basis for such a system. The traditional approach of sole reliance on finished product analysis and factory inspection is nowadays unlikely to give acceptable assurance and customer confidence that the process is under control on a continuous basis.

16.2.2 Hazard analysis

Hazard analysis is the approach which all companies, whatever their size, should use to identify the points in their manufacturing operations which critically affect product safety. Foreign body hazard analysis of a food product process starts with the identification of the sequential stages in the process from raw materials and packaging materials through to the despatch, distribution and end use of the food product. These can then be summarised in a flow diagram. Each stage of the process is then considered separately and a number of questions are considered:

- Could any foreign matter be carried forward into this stage from the previous stage?
- Could any ingredient added at this stage include foreign matter?
- Could any packaging material applied at this stage introduce foreign matter?
- Could foreign matter gain access to the product at this stage from machinery, personnel or the environment?

The answers to these questions are then listed for each production stage and preventative and/or detection and removal options considered. Actions to be taken in the event of a problem should also be listed. Considerations such as the likelihood of a problem occurring, and the practicality, effectiveness and cost of the various solutions, all then need to be considered in deciding which, if any, of the options listed should be implemented. Once the options have been decided, they should be installed, together with a means of monitoring that they are working effectively.

Smaller businesses may well be able to use the approach outlined above as part of a defence of 'Due Diligence' in UK law under the Food Safety Act 1990. The study should be carried out logically and thoroughly and carefully recorded, to give written evidence of what has been decided and why. A commitment to review the options in the event of change or unforeseen incidents is also necessary. See also Section 16.3 below. Larger businesses might reasonably be expected to use Hazard Analysis Critical Control Points (HACCP), a more sophisticated version of hazard analysis. HACCP is dealt with in considerable detail elsewhere in this volume, and this section will only address its particular application to foreign bodies.

16.2.3 HACCP

HACCP is a more sophisticated version of the hazard analysis outlined above. In a similar manner to the more basic routine, a detailed flow chart of the various

stages in the production process is drawn up and the various foreign body hazards associated with each stage are identified. Critical Control Points (CCPs) are then identified to focus resources at key points in the process. This does not remove the need for control at other points in the process, but highlights where the preventive or control measures *must* be effective. Three points are essential to any quality management system based on HACCP principles:

- Scheduled measurement or observation at a CCP that controls are working
- Monitoring procedures to detect loss of control or trends
- Detailed procedures to ensure effective implementation of controls and corrective action.

When the monitoring shows that conditions at a CCP have deviated from the specified critical limit, corrective action must be taken to dispose of the affected product (condemn, downgrade or rework, as appropriate) and avoid any recurrence.

A good quality management system should have built into it procedures for regular reviews of the way the system is operating and for consequent continual improvement. Also associated with the quality management system should be procedures for staff training and education, both before and during employment. Training needs should be identified on a formal basis and collated into an overall training programme. This training should be recorded and noted in personnel records. Schedules should be prepared for the training of new employees as part of their induction, and the need for re-training of existing employees due to change in job, or move to another job, recognised as a management responsibility. It is important that employees have a clear understanding of the company's policy and works instructions, and have the right attitude to personal and operational hygiene. However, none of this is of any use unless the company philosophy is correct and management is fully committed to quality at every level. This means instilling a quality attitude throughout the company, at all levels.

16.3 General methods for preventing the occurrence of foreign bodies

16.3.1 Design of factories and equipment and maintenance

Good design and construction of food factories and good design and deployment of the machinery within are both essential for the elimination of foreign body contamination in the food product. Other chapters in this book deal more fully with this subject, but it is important that the influence of building and equipment design on foreign body contamination is taken into consideration. Good design can prevent the entry of 'active' sources of foreign bodies such as insect, rodent and bird pests, but can also prevent 'passive' foreign bodies such as bits of machinery from becoming incorporated with the product.

The building itself can sometimes be a source of foreign bodies. Flaking paint or damage to walls or ceiling should therefore be repaired immediately. Wooden

parts such as doors or door frames need to be protected from impact damage to prevent wood splinters being produced and carried into the production area on trolley wheels or by personnel. Windows should be avoided in the production area, but where they are unavoidable they should be protected from breakage or made from a non-glass material such as polycarbonate. Polycarbonate can also be used as a glass substitute for vision panels and instrument dial covers in food production areas, and for mirrors in changing rooms. Clear plastic covers should be used to protect all light fittings. Overhead services and fittings, beams and girders will accumulate dust and debris which may be dislodged, and may harbour pests, providing runways for rodents and perches for birds. The apparently obvious solution of boxing in such fittings can also give protection to pests: a false ceiling with no crevices and which is easier to clean is often a better solution.

The design of factory equipment is also vital. Surfaces of all materials and coatings should be durable and resistant to cracking, chipping, flaking and abrasion, and the use of wood within food processing areas should be discouraged because of the risk of splinters. Fasteners such as screws, rivets, bolts, etc., should be avoided as far as possible, especially over an open product line or vessel, because of the risk of their working loose. If they are unavoidable, they should be self-locking or locked using a thread locking compound. All equipment should be self-draining or have some means of removing residual liquid. Motors, bearings and shaft entry points should not be positioned over open product lines because of the risk of contamination, especially from lubricants or metal from failing bearings. Machinery should be designed such that material from the product does not build up in corners or crevices, only to break away later and become incorporated in the product stream. Conveyor belts need to be adjusted correctly and inspected regularly for wear to prevent contamination from the belt material, fraying webbing or fibres. Wherever possible, product lines should be covered to prevent foreign bodies falling onto the product. Precautions such as the inversion of containers and/or blowing out with an air blast immediately before filling can help to remove foreign bodies from containers.

16.3.2 Prevention and control of insects, rodents and birds

All food factories are potentially subject to periodic infestation by pests. Any type of foreign body is a cause for concern, but foreign bodies originating from insects, rodents and birds often cause particular upset and revulsion to the consumer finding them. With good pest prevention and control, the actual health risk presented by pest contamination is relatively low, but the perceived health risk is extremely high. Whilst the numbers of complaints of foreign bodies such as rodent droppings is low in relation to the numbers of products sold, the potential for adverse publicity and possibly prosecution is extremely high. Effective pest control requires:

- Prevention, creating conditions in which pests find it difficult to enter buildings and/or breed within the premises
- Treatment, including regular inspection, rapid identification of the pest(s), and efficient application of appropriate control measures.

Pests enter buildings for the food, shelter, warmth and often water that they offer. Some control of pests can be achieved by preventing access to some or all of these, but they are often intrinsic to a food factory, and so pest control strategies must also include minimising the risk of entry and making conditions as inhospitable as possible for pests. The area surrounding the building should therefore be kept tidy and free from weeds, stacked pallets and boxes or redundant equipment, all of which can provide cover for rodents. A path completely surrounding the building will often achieve all of these requirements. Similarly, the accumulation of waste (edible or otherwise) in the immediate vicinity of the building should be discouraged.

Birds can be discouraged from roosting on buildings by the use of bird deterrents. To prevent the entry of rodents, building foundations should be solid and taken down to at least 600 mm below ground level to prevent rodents burrowing into the building. If it is possible for rodents to climb walls to get in, a band of 'non-friction' material applied 1 metre above the ground may be applied. Rough exterior finishes and projecting quoins, buttresses and ledges can all help to give a foothold to a climbing rodent. Ventilator grilles and air bricks can provide points of entry to rodents, birds and insects and should be sealed with wire grids. Any cracks or crevices in the external walls should be repaired immediately.

Pests often enter buildings through doorways or window openings. To prevent rodents entering, all doorways should have a working clearance of no more than 3 mm, and flexible strip curtains can be used to prevent birds passing through doorways and other permanent openings. Spaces behind skirtings, architraves and mouldings, or loose wall or ceiling tiles, can provide spaces for pest infestation. Rodents or insects can infest drains, and the use of 'back inlet gullies' will prevent rodents gaining access to buildings via the drains.

Whilst the design of the premises can do much to control pests, good housekeeping within the factory such as correct storage of incoming and outgoing stocks, stock rotation, general tidiness and removal of any food spillages are also very important.

Most food premises rely on the expertise of a pest control company or local authority to ensure that both premises and products are free from contamination. Whilst the introduction of an expert sub-contractor in this way will help to ensure that all the various aspects of pest control are covered, it does not absolve managers from the responsibility of keeping their premises free of pests. The contractor should therefore be chosen carefully and the basis of the work to be carried out should be fully understood between the parties. The contractor will be able to advise on the design of buildings and equipment, and should provide regular monitoring of pests together with immediate treatment when pests are discovered.

16.3.3 Incoming raw materials

Incoming raw materials may be a major potential source of foreign bodies. Consideration therefore needs to be given to the foreign bodies that may be present in the raw material, and what measures may be needed to remove them. It may be worth specifying that the supplier is responsible for removing any foreign bodies before delivery. This is likely to cost more, and it needs to be considered whether the supplier is technically capable of removing the foreign bodies, and whether auditing of the supplier will be needed to ensure that the work is being done to a high enough standard. The packaging of the raw materials may itself present a foreign body hazard. In the case of possible insect infestation, the question of quarantining incoming stock until it has been cleaned or can be shown to be free of contamination may have to be considered.

Packaging raw materials may also be a potential source of foreign bodies, from fragments of broken glass, through layer pads to pieces of string, staples, wire, plastic from thermoformed containers and offcuts of tinsplate from cans or caps. Again, the terms of the specification need to be agreed with the supplier, and consideration given to auditing of the supplier. Arrangements for appropriate storage of packaging materials to prevent deterioration or contamination during storage must be made, away from other materials that could contaminate or soil them. All packing must obviously be clean at the point of use. All external wrapping materials such as layer pads should be removed carefully and disposed of properly. Packaging materials and containers should only be used for the purpose for which they were intended; a can 'borrowed' to contain a few screws by a repair technician may inadvertently be returned to the production line, together with some of the screws! Great care needs to be taken if packaging materials are recycled or re-used that they are properly cleaned and free of foreign bodies before re-use.

16.3.4 Personnel factors

Personnel are a major potential source of foreign bodies in food premises of all kinds. Jewellery, hairs, pens and tools from personnel can all readily contaminate foodstuffs, but good recruitment, training, clothing and operating procedures can do much to mitigate the risk. It is important, therefore, that management understands this potential source and takes active measures to manage it. Recruitment of staff with appropriate attitudes and correct training at the start of employment and periodically thereafter are clearly essential. Provision of appropriate authorised clothing, including hairnets and beard snoods, for both staff and visitors, and rules regarding the wearing of jewellery can prevent many obvious foreign body problems. Standard operating procedures, such as pre-production hygiene check and a ban on all loose items within the production area unless required for the work, will also reduce the risks. Provision needs to be given for designated eating, drinking and smoking areas, and changing, hand washing and toilet facilities. Clear rules are required to regulate who has access to production areas within the factory. The success of

any factory procedure depends upon the commitment of senior management to its application and use. The performance of all personnel in observing the factory hygiene regulations should be monitored so that appropriate action can be taken to ensure that the regulations are adhered to and foreign body contamination prevented.

16.3.5 Distribution

Foreign bodies may also enter food products during distribution to wholesalers and retailers. This can be controlled by ensuring packs are properly sealed during production, that they are not mechanically damaged during distribution, and that pests cannot gain access to the product through the packaging. Food spillage on the packed product must be avoided to minimise pest activity. Storage areas and means of transport must be kept clean and free of pests. A tamper-evident pack design may be appropriate in some cases. Storage facilities must be appropriate to the product, and advice to wholesalers and retailers may be necessary, as well as storage guidelines on the pack for the eventual consumer.

16.3.6 Catering

There are particular foreign body hazards associated with catering establishments, combining as they do elements of the food production process with the hazards associated with the presence of consumers and with the serving and consuming of food. Where food is kept on open display, care needs to be taken to provide adequate protection of the food against foreign bodies being dropped on it, either by catering staff or, in the case of self-service establishments, by consumers. Whilst catering staff may be subject to operating procedures regarding the wearing of jewellery, protective clothing and blue plasters, ordinary consumers will not, and moreover will probably not have been trained in safe food handling techniques. Objects may also get into the food in the servery as a result of food preparation, e.g., from chopping, machine mixing, crockery or glass breakages or cross-contamination between separate dishes from lack of separate utensils. A common source of glass complaints in such establishments is chipping of glass display cabinets.

16.3.7 Commercial factors relating to prevention of foreign body incidents

The control of foreign bodies in food products has to be seen within the commercial environment within which it takes place. The criterion must therefore be to choose an approach to foreign body control in relation to the risks and costs involved. The choice of method will be influenced both by the size of the enterprise and by the impact the cost will have on the commercial viability of the enterprise. For example, a low-cost manual system may be the correct solution for a small operation, where a larger enterprise would perhaps install a

machine. A low-cost manual system may be the appropriate solution when the problem is short term. The choice of equipment will depend on the technical problem to be solved, the cost of the equipment, the particular foreign body hazard and the risk involved. Assessment of the risk will involve not only the legal position but also the publicity risk to the business of a foreign body incident.

16.3.8 Investigation of foreign body incidents

The investigation of a foreign body incident involves a number of clear stages. The first essential step is to determine all the known facts in the case. Unfortunately, when a foreign body complaint is made, the complainant is often in an emotional state, and this, coupled with often poor procedures for collecting information on complaints, results in a very incomplete set of information as to the circumstances of the incident. This is unfortunate for all concerned. The complainant may leave the store after making a complaint feeling dissatisfied, whilst the store has incomplete information and an unhappy consumer as well. It is therefore essential that stores and food manufacturers receiving consumer complaints do so in an organised and professional manner. Quite apart from the technical aspects, it is simply good customer relations, and may often defuse a situation which could rapidly get out of hand, whether the complaint is justified or not.

It is important that precise details of the circumstances under which the foreign body was discovered are recorded. In particular, it is essential to know whether the foreign body was found when the pack was opened, during food preparation or whilst eating the product, and whether or not the foreign body could have been heated during preparation or mixed with other food products. Any batch codes or dates on the food package should also be recorded, and if possible the packaging should be available for examination in case it shows evidence of how the foreign body got into the product. All data should be entered on a database of all consumer complaints. Such a database can be extremely helpful in identifying known patterns of complaints due to seasonal, raw material or other product factors, or in associating particular types of complaints with other variables such as the type of packaging used. It can also be helpful in identifying persistent complainants. When an individual consumer complaint is seen against the overall pattern of complaints, it is much easier to identify a new kind of problem or one that requires particularly prompt action.

The identity of the foreign body should be determined as precisely as possible by laboratory examination. It may be possible as a result of these tests to determine whether or not the foreign body has been subjected to food processing or whether it has been in contact with the food. It may also be possible to deduce whether it is likely to have originated with raw materials, in the production, distribution or retail processes, or even from the consumer. The identity of the foreign body may give some indication as to whether this is an isolated incident, part of a pattern, or something that is likely to recur.

It may be important to determine the extent of possible contamination: this will depend on the type of foreign body involved and whether or not other, similar complaints have been received. If it is judged that there is a significant risk that other stock may be affected, decisions then need to be taken as to whether the situation can be controlled simply by isolating affected stock and preventing any more being sold, or whether a public recall will be necessary. Companies should have in place a recall procedure that can be immediately instituted if this is deemed necessary. Consultation with local enforcement authorities is recommended. In certain cases it may be worthwhile to check isolated or recalled stock using methods such as metal detection or X-ray scanning to identify the contaminated packs, after which it may be possible to redistribute stock that is now known to be unaffected. Some manufacturers of suitable equipment are able to offer such a service. Finally, measures may be taken to prevent a recurrence of the incident, if appropriate.

16.3.9 The law

In the United Kingdom, the presence of a foreign body in a food product can constitute an offence under the Food Safety Act 1990 in that it renders the product to be 'not of the nature or substance or quality demanded' (Section 14). In addition, it may render the food 'unfit for human consumption, or it is so contaminated (whether by extraneous matter or otherwise) that it would not be reasonable to expect it to be used for human consumption in that state' (Section 8). However, the same Act also provides that it shall be a defence for a company to show that it 'took all reasonable precautions and exercised all due diligence to avoid the commission of the offence' (Section 21). What constitutes a Due Diligence Defence is a matter for the Courts, and no absolute guidance can be given. However, larger companies may be required to prove that they use more sophisticated and up-to-date systems than smaller ones, and may need to produce more detailed records. Nevertheless, a smaller company must still be able to demonstrate its diligence in taking measures to avoid the presence of foreign bodies in its products, even if the methods used are more basic and the checks more straightforward. As a minimum, it is likely that for a Due Diligence Defence to be successful, a company must be able to demonstrate that it has:

- considered what foreign body hazards might arise
- judged the likelihood of the occurrence, the risk, the concern and the potential danger to the consumer
- selected and installed controls which are demonstrably effective
- integrated the controls into a whole plan
- set up a review system for continuous improvement
- maintained a full record of the above.

16.4 Detection systems for foreign bodies

16.4.1 Detection and removal versus separation

Approaches to the technical methods of combating foreign bodies on the food production line fall into two main categories:

- Detection and removal systems
- Separation systems.

Separation systems are mechanical methods such as sieving and flotation that aim to separate foreign bodies from the food as a result of basic physical differences. In many cases these methods are intrinsic to the production system itself. Possibly the most ancient is the process of winnowing to separate wheat from chaff, but more recent technologies have become much more complex.

Detection and removal systems, in contrast, are systems designed specifically to detect the presence of a foreign body in the food and remove it as a consequence of having discovered it. The oldest of these methods is manual sorting, whilst the newest such methods use extremely sophisticated electronic technology.

16.4.2 Metal detection systems

The first industrial metal detector was produced in the UK in 1948 by Bruce Kerr to salvage a large quantity of contaminated confectionery. Since then the demand for metal detectors has grown, particularly in the UK.

Metal detectors are of two main types. The most widely used is that based on the Balanced Coil System (Fig. 16.1), in which the food product being tested passes through an aperture surrounded by two receiver coils with a transmitter coil arranged between them. The transmitter coil generates a field similar to that generated by a radio transmitter. A metal particle travelling through the field disturbs it, and this change is detected by the two receiver coils.

The second type of metal detector is that based on the Magnetic Field System (Fig. 16.2), in which the food product being tested passes through a tunnel or passage subjected to a strong magnetic field, which has the effect of magnetising any magnetic metal particle which passes through it. When the magnetised particle passes under coils incorporated in the tunnel, a current is generated in the coils, which is amplified by the electronics of the metal detector and used to generate a detection signal output. Only magnetic metal materials will be detected by this system, and so it will not detect non-ferrous metals and most (but not all) stainless steels. As a result of this, the major application of this type of detector is in food products packed in aluminium foil.

Metal detectors have a number of limitations. They will not detect metal particles below a certain size. Many food products are electrically conductive or

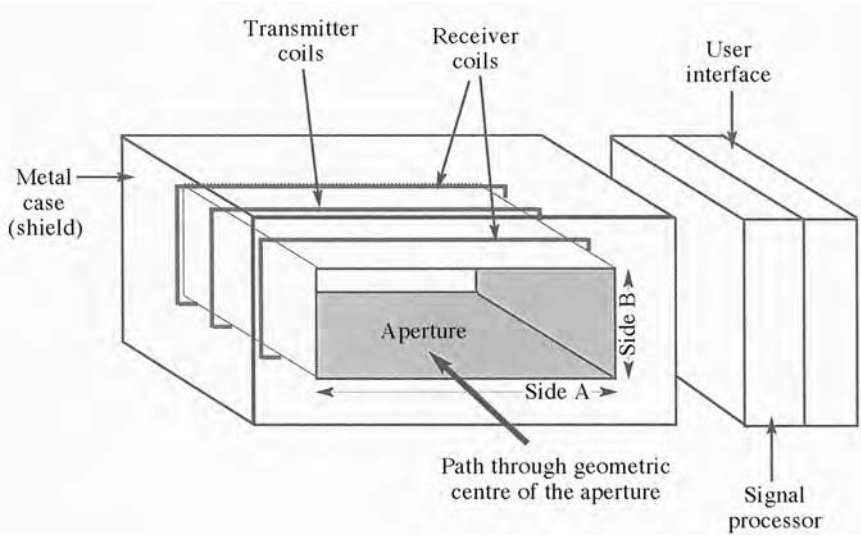


Fig. 16.1 Schematic diagram of a balanced coil metal detector (from Campbell, 1995).

have magnetic properties, reducing the sensitivity of the detector to metal fragments. Some metals are more readily detected than others, and the ease of detection of a metal fragment other than a perfect sphere will depend upon its orientation as it passes through the detector.

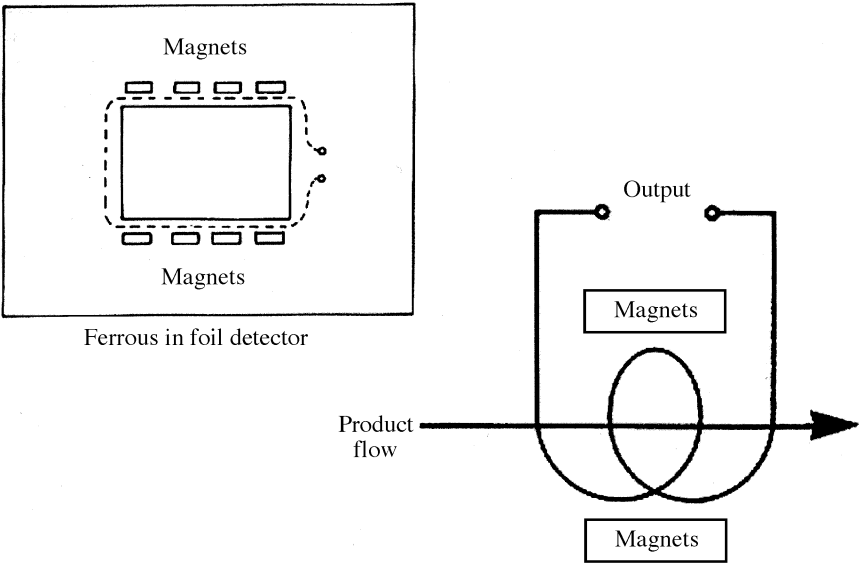


Fig. 16.2 Operation of a magnetic field metal detector (from Campbell, 1995).

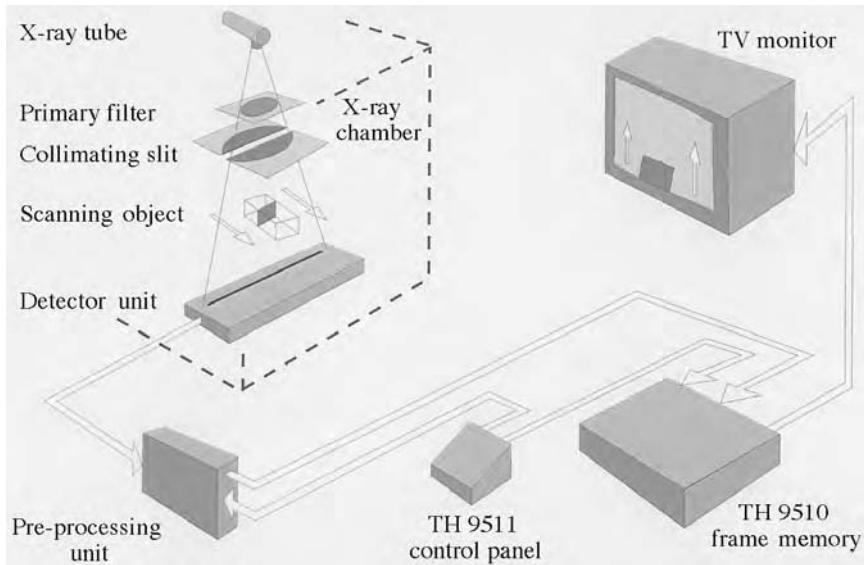


Fig. 16.3 X-ray linear detector-based system with TV image display (from Campbell, 1995).

16.4.3 X-ray detection systems

All X-ray detection systems have the same basic components, illustrated in Fig. 16.3. All systems rely on the X-ray beam either being partially absorbed by the material through which it travels, in proportion to the density of the material, or inducing fluorescence in the material through which it passes. Three main systems are available, the first two being more suitable for food.

- Image intensifiers (Fig. 16.4). The differential absorption of the X-rays by different parts of the object under investigation is intensified to produce an image viewed by a TV camera and supplied either to an image processor or to a monitor for the operator.
- Line scan systems (Fig. 16.5). A linear sensor is used instead of a screen, located under the X-ray beam restricted to a narrow fan shape at right angles to the direction of flow of the product. Each of the discrete units of the sensor array converts the energy of the X-ray beam falling on it to an electrical signal. The processor examines each scan line and outputs a signal when an abnormal value is detected.
- Fluoroscopy. This type of equipment is mainly used at present for security applications, but is not suitable for use with food applications because of its low definition on the screen.

X-ray systems can be a relatively expensive option for foreign body detection, but can be tailored to detect a range of foreign body types that cannot

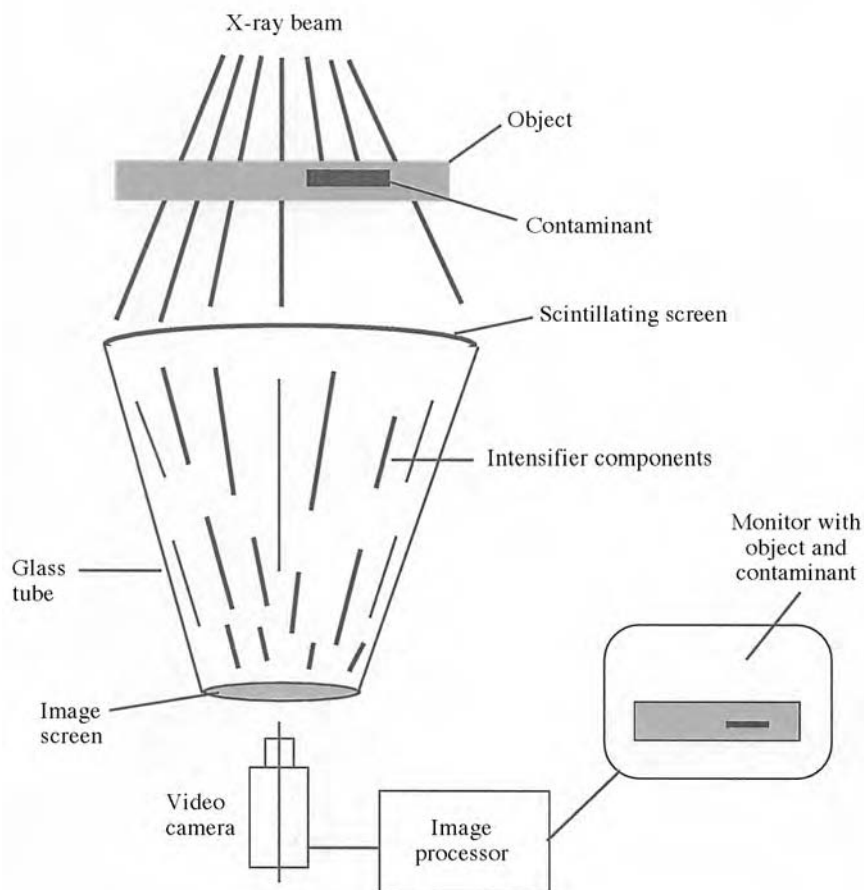


Fig. 16.4 Schematic diagram of an image intensifier X-ray detector (from Campbell, 1995).

be readily detected by any other method. Thus ferrous and non-ferrous metals, stone, glass and bone are usually readily detectable, but dust, debris, insects, low-density rubber and plastic, plastic films, wood, paper, oil, fabrics and extraneous vegetable matter are not usually detectable. The major technical limitation is the requirement for a significant difference in density to X-rays of the food product and the foreign body being detected. For many years the major barrier to development of this technology was the computer power needed to achieve the necessary speed of image analysis for realistic line speeds in a food industry environment. In recent years these problems have been solved, and the cost of this equipment has reduced substantially.

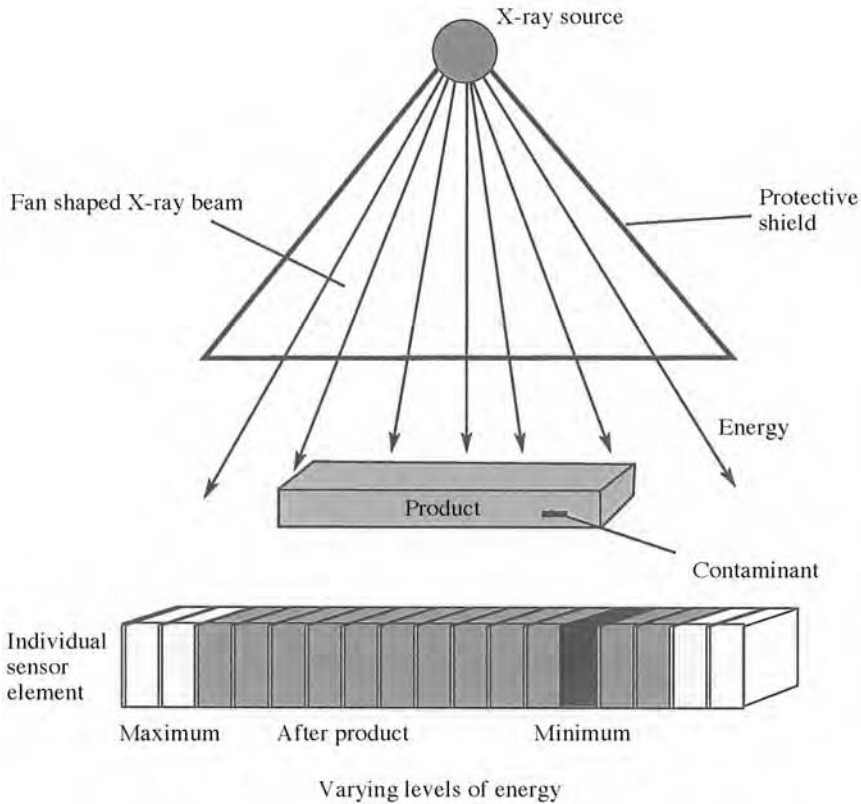


Fig. 16.5 Schematic diagram of a line scan X-ray detector (from Campbell, 1995).

16.4.4 Optical systems

Optical inspection systems (Fig. 16.6) for food use take a number of forms, ranging from simple colour sorters to complex image recognition systems able to sort by shape. The product is fed towards the illuminator by a feed system in an appropriate fashion, for example aligning elongated products such as chips (french fries) so that they are orientated in a consistent manner. The illumination system will be tailored to the specific application, and may include one, two or three different coloured light sources. Monochromatic units are capable of sorting only dark and light coloured objects, whilst the introduction of two or more colours allows more sophisticated functions. The product is detected by a detection system, which can vary from a simple diode to detect light or dark to an array of charge-coupled devices capable of creating an image. The signal from the detector is fed to the signal processing system, which again varies from a simple system able only to distinguish light and dark objects, to complex image-processing systems. Separation systems also vary widely, depending on the type of product being checked. Although no optical system is perfect, they

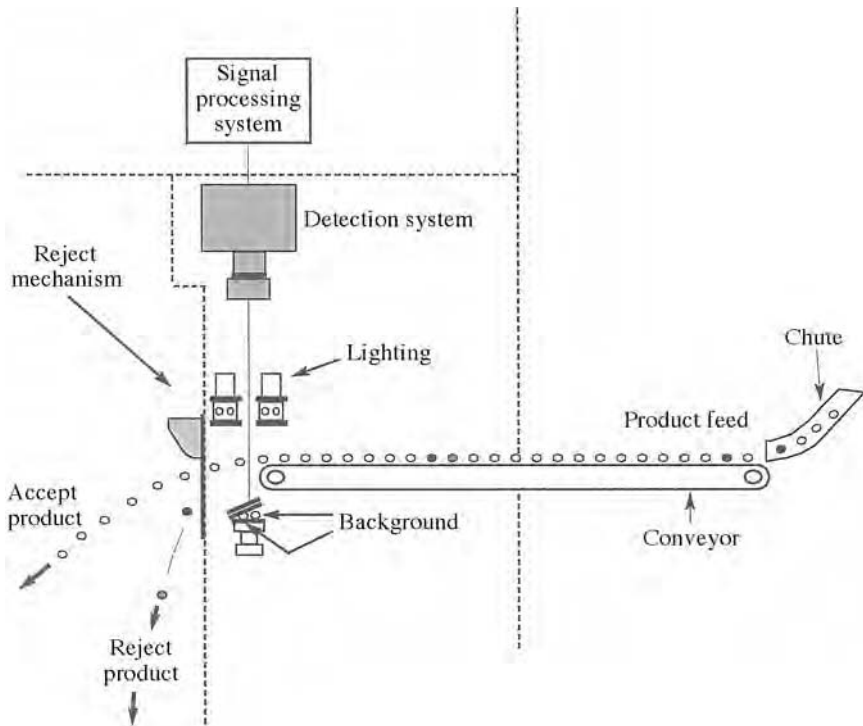


Fig. 16.6 Schematic diagram of an optical sorting system (from Campbell, 1995).

can offer efficiencies from 85% to over 99% in some cases, and have a consistent level of effectiveness over a long period.

16.4.5 Manual systems

In general, humans are far more versatile and adaptable than machines, using up to five different senses and having the dexterity to manipulate the sample, coupled with the ability to judge. For short spells, therefore, humans can carry out inspection work to detect foreign bodies with great skill, care and sensitivity, and can readily adapt to new or previously unthought-of foreign body types. However, human inspectors cannot continue to work uninterrupted for long periods of time without a decrease in their efficiency. The efficiency of human inspection can be greatly increased by providing suitable working conditions, with factors such as good lighting, working height, belt width, colour and speed, and the density and depth of product that is presented for inspection. Inspectors should work for short periods of time, say 30–40 minutes maximum, to maintain inspection standards. Maximum efficiency levels between 80% and 90% can be expected.

16.4.6 Rejection systems

All of the automatic systems outlined above require some form of rejection system to remove the product containing the contaminant from the production line. A range of methods are available, each of which has different applications and limitations. Some rely on some form of alarm, requiring an operator to respond to remove the offending package. Others use flaps, pushers or air blasts to remove the contaminated package from the line. Having removed the package from the line, it is essential that it is held in a reject bin until it can be examined, investigated and disposed of by an authorised person.

16.5 Equipment for separation of foreign bodies

16.5.1 Air separation systems

Air separation systems are dry cleaning methods that are rarely used in isolation, normally being combined with other removal systems. Air separation methods are relatively cheap and convenient, but care must be taken that they do not generate excessive levels of dust that might cause a fire or explosion. They are of two main types:

- Aspirators (Fig. 16.7) usually have specific applications for the separation of materials of different weights or densities such as the separation of chaff from wheat or shell fragments from nuts. A strong current of air passing through the product carries lighter material off, separating it from the heavier material. Specific gravity methods differentiate by density or weight when the impurities are of equal size and weight to the product. In contrast, air resistance used in selective aspiration draws a strong current of air through a thin stream of the material to be cleaned, carrying lighter particulates away.

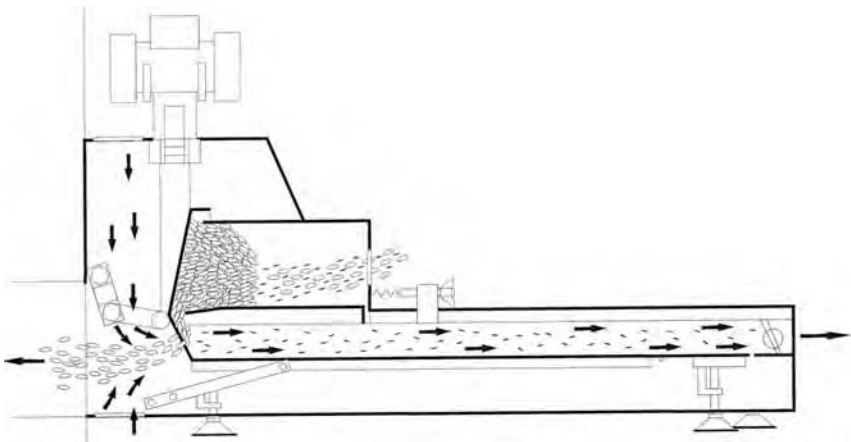


Fig. 16.7 Air separation by aspiration (from Campbell, 1995).

- Abraders and graders are useful for removing surface contaminants of food material such as soil or husk. Dry scouring by friction or impaction using tumblers, vibrators, abrasive discs and rotating brushes are all variants of this general type. They are usually used in conjunction with aspirators to remove the loosened material.

16.5.2 Liquid separation systems

Liquid separation systems involve a wide range of wet cleaning methods, which are usually used in conjunction with other separation techniques. The washing of food is frequently one of the first stages of processing, particularly on agricultural crops. Common methods include:

- Washers and sprayers (Fig. 16.8), in which the product is carried in or through clean water to remove light or surface contamination. Batch systems may involve tipping the product into a vessel and adding water before agitating and pouring off the dirty water, whilst continuous systems may involve spraying water onto the food as it passes along on a mesh, contaminants falling through the mesh with the water.
- Settlers and flumes are used to remove either light or heavy contamination. The density difference between food and water allows food to float off, whilst heavier contaminants sink to the bottom of the water. Foodstuffs may be carried along in a water flume, or may be left to soak in a settling tank. Settling tanks may be fitted with sparge pipes to produce air bubbles, which help to lift product to the top of the tank whilst soil drops to the bottom.
- Ultrasonic cleaning works by causing agitation of particles in a fluid, so loosening contaminants, which can then be removed by conventional separation techniques. However, this approach has limited use in the food industry.
- Centrifuges work by separating food material with different phases and different densities by centrifugal force. Perhaps the most well-known food

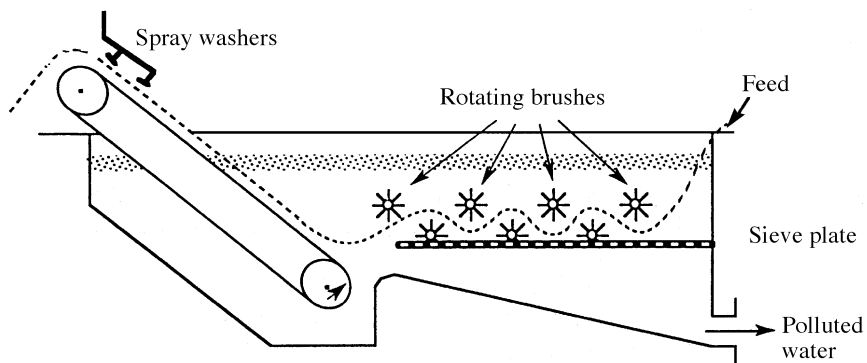


Fig. 16.8 Water separation (from Campbell, 1995).

application is not in foreign body removal, but the separation of cream from milk. The two principal systems used for foreign body removal are clarifiers, where the contents rotate in a rotating drum, and hydrocyclones, in which the rotation is achieved by a tangential supply to the stationary apparatus. In either case, the operating conditions have to be chosen very carefully to optimise separation of the phases from each other.

All liquid separation systems are limited by the damage that immersion in water can do to many food products.

16.5.3 Sieves and filters

Sieves and filters remove foreign and extraneous matter on the basis of size, and are equally applicable to both wet and dry systems, to the full spectrum of food materials, and to all levels of manufacturing output. They range from simple mobile hand-operated systems to integrated dedicated in-line installations. The simplest sieves are static grids, with meshes of any size, depending on the separation required. Other systems include perforated plates with square or round holes, which can be made from materials such as woven steel, copper or bronze wire. More complex systems can be built up, consisting of a series of meshes arranged vertically, horizontally or inclined. The sieving efficiency can be assisted by any combination of brushes, hammers, bouncing balls, aeration, or vibratory or rotary movement.

Sieves should normally be employed early in the process when used as a primary cleaner, because they are capable of removing a wide range of contaminants. However, they can be used at any stage throughout a process, depending on where foreign bodies are likely to occur. They cannot, of course, remove particles of similar size to the material being cleaned. Sieves are susceptible to mechanical damage, and also to blinding or blocking. Wet sieving can give rise to bacteriological and/or corrosion problems, whilst dry sieving can present a fire and explosion hazard.

16.5.4 Magnetic grids and permanent magnets

Magnetic separators used in the food industry are normally powered by permanent magnets. Low intensity magnetic fields from ceramic magnets (either barium or strontium ferrite) are used to attract larger ferrous particles such as nuts and bolts, whilst higher intensity magnetic fields from rare earth magnets are required for attracting small or weakly magnetic particles, including rust scale and some stainless steels. There are four basic types of magnetic separator (Fig. 16.9):

- Plate magnets are usually enclosed in a box, one surface of which acts as a magnetised plate. They are usually installed above conveyors or in the base of chutes, ducts, etc.
- Rod magnets are cylindrical permanent magnets placed in the product flow, either singly or in multiples, or built into grids through which the food

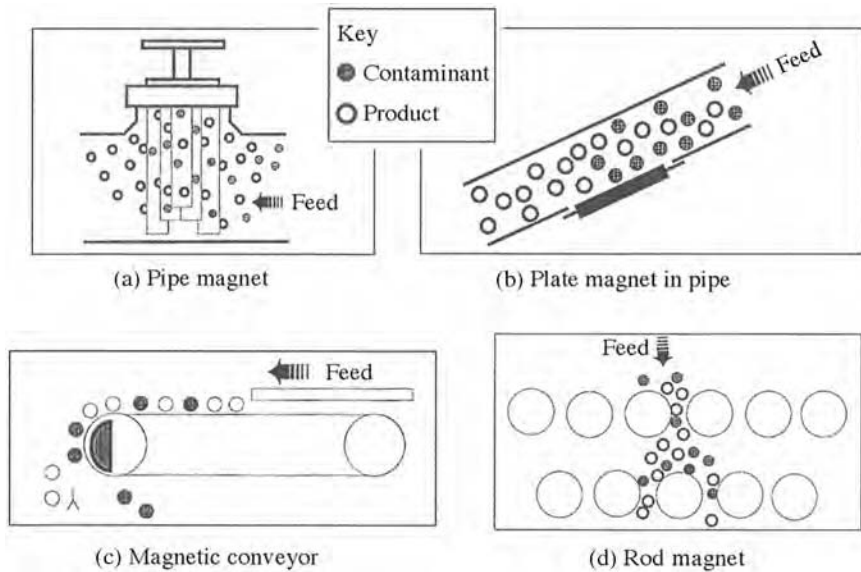


Fig. 16.9 Four different types of magnetic separator.

material flows. The grids may be built into drawer-type assemblies for easy removal and cleaning. They are suitable for either dry or wet materials, but for powders with poor flow characteristics the rods must be vibrated to prevent bridging.

- Pipeline traps are used for liquids transported in pipelines, and are arranged as groups of magnets through which the food must flow. Rod magnets may be used for liquids such as juices or soups, but plate magnets that do not impede the flow should be used for thicker liquids such as soups and stews.
- Magnetic drum separators consist of a non-magnetic rotating drum that contains a magnetic unit extending approximately 180° around the periphery. Typically this may form the end of a conveyor belt. Food material is fed to the top of the drum and non-magnetic material drops straight off whilst magnetic material is attracted to the magnet and held to it to the point where the magnetic field ends, at which point it is thrown off by centrifugal force. Separators of this type are used to extract contaminants from free-flowing materials such as grain, rice, tea and sugar.

Magnetic systems will not extract non-magnetic metals. Metallic materials arranged in descending order of relative magnetic susceptibility are mild steel, magnetic stainless steel, rust scale, and abraded non-magnetic stainless steel.

Unless the system is self-cleaning, the magnets in all systems will need to be removed from the line periodically and cleaned. Depending on the application, it may be desirable to keep records of the material removed from the magnet at each cleaning.

16.6 Future trends

16.6.1 Future trends in foreign body types and complaints

Great strides have already been made by the food industry in developed countries in reducing the numbers of foreign bodies occurring in food products. The types of foreign bodies that will be reported from food products in the future will be governed by the materials with which the food comes into contact, and by developing technologies to prevent their introduction and aid their detection and removal. The materials with which the food comes into contact will be influenced by changes in the materials involved in everyday life, particularly those used in the construction of food harvesting and processing machinery, and in food packaging. An example of such a change in the past is the reduction in numbers of glass fragments occurring in food as a result of the breakage of jars and bottles on filling lines. This followed the introduction and enforcement of more stringent factory procedures after breakages to remove adjacent jars or bottles. Another example is the increasing numbers of complaints regarding plastic fragments as the use of plastics in food packaging and food machinery rises.

Since some consumer complaints undoubtedly arise from contamination in the consumer's home, whether accidental or deliberate, trends in the domestic use of various materials will also influence the level and type of complaints. This is almost certainly the cause of the continuing complaints of glass fragments in food, despite the precautions taken against glass contamination during food processing and packing.

16.6.2 Future trends in foreign body detection, removal and separation systems

There are a number of possible techniques which may have application for foreign body detection and removal in the future. These include Nuclear Magnetic Resonance Imaging (NMRI) (Edwards, 2004). This system has been shown to be capable of imaging some foreign bodies within food. Any ferrous metals present in the product or packaging can distort the image, but aluminium foil can prevent images being obtained, particularly from within sealed containers. Plastics, paper or glass do not interfere with the image, but are difficult to detect. The images currently obtainable are not as clear as those from some other imaging techniques, but may offer potential for improvement.

The application of ultrasound to foreign body detection is probably limited to situations where the detector can be placed in physical contact with a filled container, to produce an image which is then analysed to detect abnormalities such as foreign bodies. Microwave absorption, in which a thermal imaging camera measures the amount of energy absorbed by the product after microwave heating, may have applications in detecting foreign bodies within filled sealed containers.

The dielectric constant of the sample presents another possible technique. The sample is passed between the two plates of a parallel plate capacitor, and the presence of glass or plastic can be detected. This approach probably has more potential for development to the fast line speeds required by the food industry than most of the other possible methods. Current X-ray systems use a single X-ray beam to produce a two-dimensional image for analysis. Some research has been carried out to develop a two-beam system capable of producing a three-dimensional image, which should enable small, thin particles to be more readily detected. Such a technique is likely to require huge computing resources to run at realistic line speeds for food industry use.

16.6.3 Future trends in foreign body identification

The laboratory identification of foreign bodies reported from food will continue to be an essential part of the process of investigating foreign body incidents with a view to preventing recurrences. Increasing demands from consumers and enforcement authorities, together with the threat of adverse publicity and/or prosecution, are likely to increase the pressures for more detailed and accurate identification. This is likely to force food companies to make greater investments in the investigation of individual foreign body complaints, something that some companies have been reluctant to do in the past, believing that the costs of investigating individual complaints cannot be justified on commercial grounds. It will also lead to a greater emphasis on quality control procedures in foreign body identification, so that the results of such work can be relied upon and will stand up in court. Initiatives such as the CCFRA Foreign Body Identification Scheme (FOBS) will enable laboratories to demonstrate their competence in this work.

The methods used in foreign body identification have always come from a very wide variety of different academic disciplines, and therefore the methods used in the future will depend on developments in those disciplines. A particular area that has always provided methods for foreign body identification is forensic science, and forensic methods in the investigation of crime are becoming ever more sophisticated.

Those charged with the laboratory identification of foreign bodies will be aided by developments in microscopy techniques such as X-ray microscopy. However, probably the most important developments in the next few years are likely to be improvements in DNA analysis techniques, coupled with reductions in the present rather high costs of such work as more kits and reference material become available. This will enable much more precise identification of foreign bodies of biological origin, and it will also become possible to obtain useful data from much smaller samples than hitherto, as DNA amplification methods become more widely available.

16.7 Sources of further information and advice

There are many sources of further information on hygienic design to control the presence of foreign bodies in foods. Some good general guidelines are given in Campbell (1995). CCFRA Technical Manual No. 7 gives more details of the hygienic design of food processing equipment, whilst Technical Manual No. 40 details the hygienic design of floors and Technical Manual No. 44 covers the hygienic design of walls, ceilings and services for food production areas. Manufacturers of surface finishes such as tiles may also be able to offer advice, and local environmental health departments should also be consulted. Campbell (1995) gives much detail on the various methods of detection and removal of foreign bodies. Manufacturers of foreign body detection and removal equipment can also offer advice on the capabilities, advantages and drawbacks of the equipment they supply.

Advice on Quality Management Systems is also available from a wide range of sources, and many consultants operate in this subject area. CCFRA Technical Manual No. 38 gives a general introduction and guide to HACCP in the food industry. Edwards and Redpath (1995) give details of a wide range of methods for the laboratory identification of foreign bodies reported from foods. Advice on product recall is given in a report published jointly by the CBI, DTI and BRC in 1999. This is a good practice guide, helping businesses to take corrective action to safeguard consumers from unsafe products.

16.8 Conclusion

While the available technology may not eliminate all foreign bodies from food, the correct application of technology will assist in removing many of them. The ability of the food manufacturer to prevent foreign body contamination once the product leaves the factory is limited, but even here, careful packaging design and attention to distribution conditions can do much to control the problem, as can careful wording of instructions to the consumer on the food pack. After removal and identification of the foreign body, the source can be traced more easily. Following identification of the source of the foreign body, control measures can be implemented, on the basis of an HACCP plan, which will assist in preventing a recurrence of the incident.

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Pest control: insects and mites

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17.1 Introduction

Insects occur at every point along the chain of food production from the open field or greenhouse environment to larders and pantries in domestic premises. Their presence causes concern not only because of their appearance and the direct spoilage they cause to food products, but also because of the microbiological contaminants and pathogens they may carry, and because of possible allergenic reactions that their exuviae and frass may generate. Infestation of a single species of bruchid (*Callosobruchus maculatus* (F.)) has been estimated to cause losses of 4% of the stored cowpea crop in Nigeria each year (Lale and Mustapha, 2000), while weight losses caused by stored product pests of over 20% have been reported for maize stored in several localities (Schulten, 1975; Krall, 1987; Giga *et al.*, 1991). Clearly direct losses are highest in tropical climates where conditions are optimal for rapid population increase, but even in the cooler climates of Western developed nations very low tolerances for arthropod presence result in high losses during trading of food commodities. The cost of transport and treatment of bulk produce arriving by road or rail can be 10–20% of the load value (Hagstrum and Subramanyam, 2000).

The association of insect pests with diseases and contaminants is a field that has received less attention over the years, although the health implications of insect infestation have long been realised (Busvine, 1964). Besides the risk of insects acting as vectors for pathogens, links between allergies and stored product infestations have been documented in a number of situations (Herling *et al.*, 1995; Armentia *et al.*, 1997). Mites in particular have been associated with various skin allergies, asthma and systemic anaphylaxis (Dekker, 1928; Sporik

et al., 1990; Matsumoto *et al.*, 1996; Chambers *et al.*, 1999). Although mites occur widely in domestic premises, it is only recently that firm evidence has been obtained for their physical presence in food (Chambers *et al.*, 1999 and references therein). Although the proportion of occasions on which the ingestion of storage mites or their faeces affects human health may be small, the presence of mites is clearly not consistent with increasing demands from customers for food of high quality, free from health risks. However, there has been increasing difficulty in achieving effective control of these mites with conventional pesticides, and effective alternative approaches are needed urgently.

The occurrence of insects and mites in the food industry is a major problem and their presence in food products quite unacceptable on several fronts. In many countries food processors and distributors are under legal obligation to combat infestation to the point where no insects can be detected towards the end of the food chain. A wide range of control methods in use or at an advanced stage of investigation are described below.

17.2 The spread of pests

The association of insects with human attempts to store food reaches back into early history. Evidence of several species currently associated with grain and meals has been found in the remains of offerings left in the tombs of ancient Egypt to accompany the departed on his or her journey, and stored product beetle remains date back to Roman times in Britain (Howe, 1991). Most species that have risen to significant pest status have been traced to natural habitats such as bird and animal nests, forest litter, dried vegetable matter and dried animal carcasses. Over the years well over 100 species have been associated with stored food and Table 17.1 lists a selection of the more commonly encountered pests and the foods they prefer.

With the advent of increased storage of food for longer periods and the establishment of international trade, many species of tropical origin have become established in food handling premises in temperate zones. Here storage conditions can be and are changed by mould and insect activity to simulate those in the tropics. Hence many species have become truly cosmopolitan in distribution. A tropical origin is reflected in their high-temperature optima for development, but in addition many species possess a cold-tolerant stage, usually the adult. This is an important ingredient for survival in the temperate environment when the environmental buffering effect of the stored commodity is lost because of the periodic emptying of the store. Native species normally have life cycles linked to the seasonal cycle and pass the winter in a state of diapause, the insect equivalent of hibernation. The occurrence of cold tolerance in tropical species may seem surprising at first but in fact cold tolerance is often linked to a tolerance of high temperatures also. An ability to survive short periods at high temperatures is a necessary survival mechanism for beetles living in the tropics where midday temperatures often exceed 40°C. Conversely,

Table 17.1 Arthropod pests and their occurrence on foods

Species	Common name	Food products attacked
Acarina (mites)		
<i>A. siro</i> (L.)	Flour mite	Flour, grain, meals
<i>Acarus farris</i> (Oedemans)	–	Cereals
<i>Carpoglyphus lactis</i> (L.)	Dried fruit mite	Dried fruit, jams
<i>Lepidoglyphus destructor</i> (Schrank)	Cosmopolitan food mite	Cereals, flour, oilseeds
<i>Tyrophagus longior</i> (Gervais)	Grainstack mite	Grain, brans
<i>T. putrescentiae</i> (Schrank)	Mould or cheese mite	Herbs, seeds, meals, dairy products, oilseeds
Dictyoptera (cockroaches)		
<i>Blatta orientalis</i> L.	Oriental cockroach	Food residues in kitchens, food processing facilities
<i>Blattella germanica</i> (L.)	German cockroach	
<i>Periplaneta americana</i> (L.)	American cockroach	
<i>P. australasiae</i> (F.)	Australian cockroach	
Psocoptera (book lice, psocids)		
<i>Lepinotus patruelis</i> Pearman	Black domestic psocid	Opened packets in larders
<i>Liposcelis bostrychophila</i> Badonnel	Stored product psocid	Larders, pantries, grain
Coleoptera: Anobiidae		
<i>Lasioderma serricorne</i> (F.)	Cigarette beetle	Herbs, cocoa, soya, cereals
<i>Stegobium paniceum</i> (L.)	Drug store, bread or biscuit beetle	Flours, meals, powders
Coleoptera: Anthribidae		
<i>Araecerus fasciculatus</i> (DeGeer)	Coffee bean weevil	Coffee and cocoa beans
Coleoptera: Bostrichidae		
<i>Prostephanus truncatus</i> (Horn)	Larger grain borer	Maize
<i>Rhyzopertha dominica</i> (F.)	Lesser grain borer	Cereal grains

Table 17.1 Continued

Species	Common name	Food products attacked
Coleoptera: Bruchidae		
<i>Acanthoscelides obtectus</i> (Say)	American seed beetle	Beans
<i>Bruchidius atrolineatus</i> (Pic)	–	Cowpeas
<i>Bruchus ervi</i> Froelich	Mediterranean pulse beetle	Lentils, pulses
<i>B. lentis</i> Froelich	Pulse beetle	Beans, pulses, lentils
<i>B. pisorum</i> (L.)	Pea weevil	Peas, beans
<i>B. rufimanus</i> Boheman	Bean beetle	Beans
<i>Callosobruchus chinensis</i> (L.)	Adzuki bean weevil	Various beans and peas
<i>C. maculatus</i> (F.)	Cowpea weevil	Cowpea, beans, groundnuts
<i>Caryeden serratus</i> (Olivier)	Groundnut seed weevil	Pods, pulses, groundnuts
<i>Zabrotes subfasciatus</i> (Boheman)	Mexican bean weevil	Beans, tropical legumes
Coleoptera: Cleridae		
<i>Necrobia ruficollis</i> (F.)	Red-shouldered ham beetle	Dried fish, meat and dairy products, copra,
<i>N. rufipes</i> (Degeer)	Copra beetle, red-legged ham beetle	cassava, dried fruit, cocoa
Coleoptera: Cucujidae		
<i>Cryptolestes ferrugineus</i> (Stephens)	Rusty grain beetle	Cereals, dried fruit, cocoa
<i>C. pusillus</i> (Schoenherr)	Flat grain beetle	Cereals, various meals
<i>C. turcicus</i> (Grouvelle)	Turkish grain beetle	Cereal products, flour
Coleoptera: Curculionidae		
<i>Sitophilus granarius</i> (L.)	Granary or grain weevil	Wheat, barley
<i>S. oryzae</i> (L.)	Rice weevil	Cereal grains
<i>S. zeamais</i> Motschulsky	Maize weevil	Cereal grains

Coleoptera: Dermestidae

Attagenus unicolor (Brahm)
Dermestes haemorrhoidalis Kuster
D. lardarius L.
D. maculatus Degeer
Trogoderma glabrum Herbst
T. granarium Everts
T. variabile Ballion

Black carpet beetle
Black larder beetle
Larder beetle
Hide beetle
–
Khapra beetle
–

Cereal products, fish meal
Bacon, sausage, dried fish, ham, cheese, cocoa,
bone meal, dog biscuits, etc.
Cereal products, pet food
Grain and cereal products
Grain

Coleoptera: Nitidulidae

Carpophilus dimidiatus F.
C. hemipterus (L.)

Corn sap beetle
Dried fruit beetle

Dried fruit, cocoa, copra
Dried fruit and related products

Coleoptera: Ptinidae

Ptinus fur (L.)
P. tectus Boieldieu

White-marked spider beetle
Australian spider beetle

Cereal residues
Cereal residues

Coleoptera: Sylvanidae

Ahasverus adveni (Waltl)
Cathartus quadricollis Guer
Oryzaephilus mercator (Fauvel)
O. surinamensis (L.)

Foreign grain beetle
Square-necked grain beetle
Merchant grain beetle
Saw-toothed grain beetle

Grain, copra, oilseeds
Cereals, dried fruit, cocoa
Oilseeds, dried fruit, cocoa
Cereals, dried fruit, nuts, oilseeds

Coleoptera: Tenebrionidae

Cynaues angustus (LeConte)
Gnatocerus cornutus (F.)
G. maxillosus (F.)
Latheticus oryzae Waterhouse
Tenebrio molitor L.
T. obscurus F.
Tribolium castaneum (Herbst)
T. confusum J. du Val

Larger black flour beetle
Broad-horned flour beetle
Slender-horned flour beetle
Long-headed flour beetle
Yellow mealworm
Dark mealworm
Rust-red flour beetle
Confused flour beetle

Grain, meals
Flour, cereal products
Flour, pulses
Grains, groundnuts, cassava
Cereal and other residues
Cereal residues, etc.
Cereal products, oilseeds,
cocoa, nuts, dried fruit,
most stored products

Table 17.1 Continued

Species	Common name	Food products attacked
Coleoptera: Trogossitidae <i>Tenebroides mauritanicus</i> (L.)	Cadelle	Cereals, seeds, nuts, dried fruit
Lepidoptera: Gelechiidae <i>Sitotroga cerealella</i> (Olivier)	Angoumois grain moth	Cereal grains
Lepidoptera: Oecophoridae <i>Hofmannophila pseudospretella</i> (Stainton)	Brown house moth	Opened packets and food residues in kitchens
Lepidoptera: Pyralidae <i>Corcyra cephalonica</i> (Stainton)	Rice moth	Cereals, dried fruit, cocoa
<i>Ephestia cautella</i> (Walker)	Tropical warehouse moth	Cereals, dried fruit, nuts, etc.
<i>E. elutella</i> (Huebner)	Warehouse moth	Cereals, cocoa
<i>E. figulilella</i> Gregson	Raisin or fig moth	Dried fruit
<i>E. kuehniella</i> Zeller	Mediterranean flour moth	Cereals, flour
<i>Paralipsa gularis</i> (Zeller)	Stored nut moth	Nuts, cocoa, dried fruit
<i>Plodia interpunctella</i> (Huebner)	Indian meal moth	Nuts, dried fruit, cereals, oilseeds, cocoa, meals, etc.

tolerance to short heat exposures is often found in cold-tolerant stages such as the overwintering larvae of warehouse moths (Bell, 1983).

The spread of stored product pests is continuing today. Until the 1970s, the greater grain borer *Prostephanus truncatus* was a species more or less confined to Central America. In the 1980s it suddenly became a major pest in Africa, spreading across the continent and causing heavy losses to maize crops. On another front Howe (1991) tracks the arrival of a succession of ptinid beetle pests of flour mills from 1830 to 1939 in parallel with the growth of international trade. The same period has seen the worldwide establishment of the Mediterranean flour moth *Ephesia kuehniella* in flour mills and subsequently we have seen the replacement of the granary weevil *Sitophilus granarius* by the saw-toothed grain beetle *Oryzaephilus surinamensis* as the principal pest of stored grain in western Europe. Undoubtedly, the ability of beetles from warm climates to overwinter at higher latitudes in refuges in the fabric of stores has been a major ingredient in their becoming established as major pests throughout the world's food supplies.

17.3 Physical control of pests

Logically, the use of physical control methods is the primary route to follow to avoid and combat pest control problems. Currently physical control is the most actively researched field in the quest to devise new pest control strategies.

17.3.1 Aeration

Aeration is a technique used widely in temperate climates for the cooling of bulk commodities such as grain. It is engineered by a fan fitted to a purpose-designed ducting system. This supplies an air flow to the base of a silo or to evenly spaced channels under the floor of a grain store which are covered by fine mesh metal panels to prevent ingress of grain. In the absence of a ventilated floor, reinforced perforated ducts can be laid on the floor prior to the arrival of the grain and manifolded to a fan-driven air flow. It is often considered that a secondary use for aeration is for grain drying or conditioning. However, the aeration flow rates to achieve any significant change in grain moisture content need to be at least an order of magnitude greater than for cooling, and usually the fans installed in grain stores are unable to generate this volume of air movement. For any effective result the air passing through the system needs to be cooler and drier than the commodity and so some kind of fan control needs to be employed to shut down air flows in warm or very wet weather.

Aeration can readily be practised in warmer climates or in the summer by utilising the time of day when cool temperatures prevail (Armitage, 1987; Lasseran and Fleurat-Lessard, 1991; Berhaut and Lasseran, 1986). Aeration is a part of many grain pest management programmes and plays a most important role in preventive control measures at a cost highly competitive with other

disinfestation processes (Armitage *et al.*, 1991). The use of aeration to provide moderately low temperatures to control infestations by storage pests has long been recommended (Burgess and Burrell, 1964). Insect pest development is brought to a halt between 10°C and 20°C, depending on the species, although mite species are known to continue development down to 5°C. Most of the immature stages of stored product pests die off if grain is held at less than 5°C for several months, though adults may survive.

17.3.2 Cold

Apart from the use of aeration systems for bulk commodities described above, cold treatments are widely used as part of integrated pest management systems for stored products (including grains, cereals, oilseeds and seeds), especially in countries with low ambient temperatures after harvest, for example in Canada, but cold treatment is also used in the dried fruit industry where cold storage warehouses are part of a storage system. Cold storage is also used for fresh fruit and other perishable commodities.

Most insects require only a few days' exposure at very low temperatures (−15°C or below) to ensure control (Chauvin and Vannier, 1991; Fields, 1992). The stage of development of the pest is a factor in its cold resistance: eggs are more sensitive, and adults or larvae are the most cold tolerant (Banks and Fields, 1995). Furthermore, some species of insects have the ability to acclimatise to cold and may become tolerant to otherwise lethal cold temperatures. For this reason, rapid cooling from harvest temperatures to cold temperatures should be part of any storage strategy to prevent cold acclimatisation and improve insect control.

The periods of intense winter cold have long been used by millers and warehouse keepers in Canada and the northern USA for a 'freeze out' of pests (Worden, 1987) and there is seldom a need for chemical control methods in the first few months after treatment. Cold can also be used as a spot treatment by the injection of liquid nitrogen into confined spaces such as wall voids (UNEP, 1998). Insulation in walls can affect cold distribution, causing warm spots in walls. Interior surfaces can be stained and warping of wooden structural components is possible.

Cold storage is widely used for post-harvest treatments of perishable commodities. Sub-zero temperatures have a rapid effect on insects but it is not necessary for temperatures to be this low to be of use for pest control. Insects may be lethally injured by cold shock even though their body fluids do not freeze (Lee, 1991). Quick freezing at temperatures below −10°C are really only suitable for fruit pulp or slices on route for processing into juice, as extensive damage occurs to the unprocessed treated commodity (Gould, 1994). Usually the exposure to cold is for a limited period, as for example the holding of fruit for 10–22 days at −1°C to +2°C to kill tephritid fruit flies on citrus fruit, apples, pears, grapes, stone fruit, carambola, lychees, loquats and kiwifruit (Gould, 1994). Potential quarantine treatments based on cold exposure have also been

studied for codling moth *Cydia pomonella* (L.) (Moffitt and Burditt, 1989) and oriental fruit moth *Grapholitha molesta* (Busck) (Dustan, 1963; Yokoyama and Miller, 1989).

For commercial treatment of perishable commodities, cold treatment is carried out in transit in export containers or by using land-based facilities, and precise records of the temperature and duration of exposure are required to show compliance with phytosanitary treatment specifications in order for the disinfestation treatment to be acceptable to the receiver. Exposure times and temperatures are linked to the pest but need to be chosen after evaluation of effects on the fruit being treated. Many tropical and subtropical fruits are susceptible to cold, but chilling injury can be reduced if the commodity is conditioned at moderate temperatures prior to exposure to cold (Houck *et al.*, 1990), or if there are interruptions during the low temperature exposure (Paull and McDonald, 1994) though treatment efficacy may be affected. Details of cold exposures required for effective control of fruit fly species are given in Table 17.2, based on information collected for the USDA-APHIS-PPQ Treatment Manual (Gould, 1994).

The effects of cold on insect and mite pests of durable products is reviewed by Fields (1992). Fields and White (1997) equate the rate of population development, rather than just the ability to survive cold temperatures, with the pest status of stored-product insects in Canada. Below about 10°C insect reproduction ceases and population levels of most pests slowly decline. At 4°C adults of most species can survive for many months. Immature stages of species

Table 17.2 USDA-APHIS-PPQ cold treatment times for different species of fruit fly (after Gould, 1994)

Species/group	Cold treatment
<i>Ceratitis capitata</i> (Wiedemann)	10 days at 0°C or below 11 days at 0.55°C or below 12 days at 1.11°C or below 14 days at 1.66°C or below 16 days at 2.22°C or below
<i>Anastrepha ludens</i> (Loew)	18 days at 0.55°C or below 20 days at 1.11°C or below 22 days at 1.66°C or below
Other species of <i>Anastrepha</i>	11 days at 0°C or below 13 days at 0.55°C or below 15 days at 1.11°C or below 17 days at 1.66°C or below
<i>Bactrocera tryoni</i> (Froggatt)	13 days at 0°C or below 14 days at 0.55°C or below 18 days at 1.11°C or below 20 days at 1.66°C or below 22 days at 2.22°C or below

of tropical origin, such as *Sitophilus oryzae*, *S. zeamais*, *Tenebroides mauritanicus* and *Lasioderma serricorne*, tend to be cold sensitive, although some important pests including *S. granarius*, *Cryptolestes* spp., bruchids, mites and some Lepidoptera are quite tolerant (Armitage, 1987; Lasseran and Fleurat-Lessard, 1991; Fields, 1992). In consequence, cooling typically requires very long holding times to be effective.

Cold treatments are used as part of IPM systems and for disinfestation or management, of grain pests in stored grain or grain storage structures (Fields and Muir, 1995; Banks and Fields, 1995). Besides aeration (see Section 17.3.1 above), cooling can be achieved by turning the grain through a conveyor, transferring grain from one bin to another in cold weather, and leaving it outside if possible for a few days before returning it to storage (Marcotte, 1995). Where ambient conditions are unfavourable for normal aeration, i.e. high temperature or humidity, air dehumidified and chilled using a refrigeration unit may be used for the aeration. Many grain silos in the Mediterranean and subtropical regions use this process (Brunner, 1987). The strategy is to reduce the temperature of the grain within a few days after harvest to below the development temperature threshold of the main insect pests. A single refrigeration unit is used for several bins in a silo system, each bin being refrigerated in turn for a few days. The equipment is, however, energy consuming and can be expensive.

Cold storage has been extensively used in the dried fruit industry, though very low temperatures are unsuitable for storage of dried vine fruit because of the resulting crystallisation of sugars. It is used for prunes, dates and dried pears, and is appropriate for nuts and beverage crops. Cooling to very low temperatures (-10 to -18°C) is an established system of disinfestation of dates, a 10.5-hour exposure to -10°C , or a 2.25-hour exposure to -18°C , killing all stages of the relevant insect pests (Donahaye *et al.*, 1991). It is most effective when combined with a brief exposure to low pressure or 2.8% oxygen, which causes insects to leave the centre of the fruit (Donahaye *et al.*, 1992), making them vulnerable to the cold treatment.

All common stored product insect pests can be controlled in food media exposed for two weeks to temperatures lower than -18°C , i.e. in an efficient freezer. This type of treatment is used preventatively for the disinfestation of high-value products, such as special seed stocks, and organically grown rice, in some developed countries. This technique is efficient but only practicable for small quantities in batches. It is important to note that the temperature to control the pests must be reached throughout the product to be protected and that many commodities are poor thermal conductors and provide some protection against the cold. It cannot be assumed that ambient temperature and commodity temperature are the same and accurate temperature monitoring systems are required.

17.3.3 Controlled atmospheres

Treatment with controlled atmospheres (CA) based on replacement of air with carbon dioxide (CO_2) or nitrogen offers an alternative to fumigation for insect

and mite control in all durable commodities. CAs have also long been in use on fresh fruit and vegetables but mainly for the purpose of delaying ripening and ageing, which involve much higher oxygen levels and much lower CO₂ levels than for insect control. For effective control of most insects, atmospheres need to contain less than 1% oxygen or a minimum of 40–60% CO₂ while for mites a slightly higher oxygen level of 2% retains efficacy. CAs with high levels of CO₂ or less than 1% oxygen are able to halt the growth of fungal pests but are unable to destroy them. Work on the effect of CAs on different insect pests of perishable commodities was recently reviewed by Carpenter and Potter (1994). These authors also carried out the first commercial CA quarantine treatment in the export of asparagus from the US to Japan, featuring a 4.5-day exposure to 60% CO₂ followed by transport at 0–1°C.

CAs require a long time (weeks rather than days) for effective action and are unlikely to be used for disinfestation where fast turnaround is necessary, unless combined with other factors such as high pressure or raised temperature. The technology may require registration or other regulatory approval in some countries. The times required for control of various storage pests are listed in Table 17.3.

Low-oxygen atmospheres can be generated by the physical separation of oxygen and nitrogen from air, by burning a hydrocarbon fuel such as propane, or by obtaining nitrogen gas from cryogenic tanks or pressurised gas cylinders. The use of bulk gas supplies is the most expensive option and is little used. Two

Table 17.3 Exposures (days) required for kill of storage insects under two controlled atmospheres (after Bell, 1996)

Species and stages	60–95% CO ₂		<1% O ₂		
	15–20°C	25–30°C	15–20°C	25–30°C	35–40°C
<i>Acarus siro</i> , all stages	6–14	–	7	–	1
<i>Cryptolestes ferrugineus</i> , adults	7	4	6–10	2	–
<i>Ephestia cautella</i> , eggs and larvae	7	5	5–6	2	–
<i>E. elutella</i> , larvae	14	–	>28	–	–
<i>Lasioderma serricornis</i> , all stages	–	6	9	6	1
<i>Liposcelis bostrychophila</i> , all stages	8–14	–	–	2	1
<i>Oryzaephilus surinamensis</i> , adults	5	3	4–10	–	–
<i>Rhyzopertha dominica</i> , all stages	28	–	>28	–	–
<i>Sitophilus oryzae</i> , all stages	28	>18	>28	>18	–
<i>S. granarius</i> , all stages	42–56	>9	>49	>14	–
<i>Tribolium castaneum</i> , adults	6	3	4–7	2	1
<i>Trogoderma granarium</i> , larvae in diapause	>18	>17	–	>14	–
<i>Tyrophagus longior</i> (Gervais), all stages	14	–	14	–	–

systems exist for the separation of nitrogen from air: pressure swing adsorption (PSA) and membrane filtration. PSA operates by passing compressed air through two beds of molecular-sieve coke. The nitrogen and oxygen are separated due to their different rates of adsorption with the nitrogen passing through the bed and into a holding tank. The two beds work alternately with one pressurised with incoming air while the other is returned to atmospheric pressure, releasing the more strongly sorbed oxygen and other gases to waste. The second system is based on filtration of compressed air through a vessel containing thousands of semipermeable membrane tubes which differentiate between oxygen and nitrogen, oxygen permeating through the membrane to the space between the tubes while nitrogen is retained.

Carbon dioxide atmospheres typically are applied at about 60% CO₂ in air, using supplies of liquid CO₂ and a vaporiser. At this level there is about 8% oxygen present, normally enough to support most stored product pests indefinitely. CO₂ thus is regarded as having a toxic effect on insect pests (Jay, 1971; Bell *et al.*, 1980) and not to act just as an inert gas that reduces the oxygen level to below that supporting life. Data on exposure times for control are available for many species and stages of stored product pests under particular sets of conditions (Annis, 1987; Bell, 1996). Most species are completely controlled by exposures of 2–3 weeks at 25–30°C. As an extreme case, larvae of *T. granarium* in diapause require exposures longer than 17 days at 30°C or less, with CO₂ levels at or above 60% in air (Spratt *et al.*, 1985).

Structures for use with CAs must be well sealed to achieve and maintain effective gas levels and keep gas usage to within economically acceptable bounds (Mann *et al.*, 1997). Silo bins sealed to a standard suitable for recirculatory fumigation with methyl bromide are typically suitable for CA use. The use of a continuous flow of CA, such as that provided by combustion of propane, can allow somewhat less gastight enclosures to be treated successfully (Bell *et al.*, 1993a, 1997). Application of CA may be constrained by the cost of the CO₂ or nitrogen required, particularly in developing countries. However, the technology of generating nitrogen from air on site is progressing rapidly, and cheap, efficient systems are becoming available. Propane or LPG currently offers the most economically competitive method of continuously generating a low-oxygen atmosphere on site as established by tests in the USA, France and the UK. Loaded grain bins of over 1000 tonnes capacity have been held under a less than 1% oxygen atmosphere for treatment periods long enough to kill all pests (Fleurat-Lessard and Le Torc'h, 1987; Bell *et al.*, 1997).

The effective use of CO₂ for grain storage was developed principally in Australia and the USA, although Australia, for preference, currently uses the fumigant phosphine to treat bulk grain. However, CO₂ is being used for stored rice and other bagged commodities in some south-east Asian countries where bagged grain is stored in warehouses long term. CO₂-based CA systems are used on a large scale in Indonesia for long-term storage of bagged milled rice stocks (Nataredja and Hodges, 1990; Sukprakarn *et al.*, 1990). Until recently, use of CO₂-based atmospheres was preferred over nitrogen-based ones for bulk grain

for various technical reasons. Recent developments in the on-site generation of nitrogen-based atmospheres have altered this situation. Nitrogen-based controlled atmospheres are in commercial use in Australia at an export grain terminal in bins originally designed and equipped for methyl bromide treatments (Cassells *et al.*, 1994).

In the dried fruit and nut industry the improved quality retention of many products held under CA makes the technique an attractive proposition for pest control. Treatment of almonds in silos with CA has been successfully demonstrated under full-scale commercial conditions (Soderstrom *et al.*, 1984). Use of CO₂ as a control procedure has also been successfully tested for sultanias in cartons in stacks (Tarr *et al.*, 1994) and in export freight containers (Banks *et al.*, 1993b). Improvements in on-site generation of nitrogen (Navarro and Donahaye, 1990; Banks *et al.*, 1993b; Bell *et al.*, 1993a, 1997; Banks and Annis, 1997) should encourage further studies on the use of low-oxygen atmospheres for these commodities.

High pressure CO₂ (above 20 bar) can potentially provide a rapid disinfestation system (a few hours or less) of commodities (Le Torc'h and Fleurat-Lessard, 1991; Nakakita and Kawashima, 1994; Ulrichs, 1994). Carbon dioxide at about 25 bar pressure is in limited use in Germany to treat beverages, nuts and spices (Gerard *et al.*, 1988; Prozell and Reichmuth, 1991; Prozell *et al.*, 1997), controlling all stages and species of pest insects in less than three hours. The high construction and operating costs of pressure chambers require investment capital to be available but several industries are bringing the technique into use. The rate at which the pressure can be released affects the efficacy of action (Nakakita and Kawashima, 1994; Ulrichs, 1994), but in practice there are physical constraints on the rate at which pressures can be manipulated.

17.3.4 Exclusion and packaging

Packaging of finished food products is a vital aspect of infestation prevention. The package should be designed to protect the product from the point of manufacture to the time it is consumed, an interval which can be as long as several years (Mullen and Pederson, 2000). Insect pests with a known ability to penetrate paper and polythene packaging include the beetles *Rhyzopertha dominica* and *Lasioderma serricorne*, and larvae of the moths *Plodia interpunctella* and *Corcyra cephalonica*. Many other stored product pests are opportunistic in entering packages through tiny gaps and imperfections in the seal. Packaging needs to be designed to avoid folds as far as possible, and glue seals need to avoid channels and over-wraps. Use of materials acting as a barrier to the escape of food volatiles or odours is helping in minimising pest attraction. Alternatively the use of a repellent such as methyl salicylate can be incorporated in the packaging. Another option is packaging under modified atmospheres. The packaging of fresh fruit and vegetables using polyfilms or coatings made from wax- or cellulose-based compounds that are impermeable to atmospheric gases

offers the option of self-modification of the atmosphere immediately surrounding the commodity to levels preventing pest development (Hallman *et al.*, 1994). Shrink wrapping enhances the ability for such an atmosphere to develop. This approach closely resembles the principle of hermetic storage used for storage of other crops, an area which, together with use of vacuum, has recently had renewed focus as a research topic (Sabio *et al.*, 2000; Navarro *et al.*, 2001).

17.3.5 Heat

Heat treatment technologies provide for crops and stored products the prospect of rapid elimination of pests, a facility offered by only a few other techniques such as fumigation with methyl bromide or other fast-acting fumigants (Banks, 1998). Commodities need to be heated to temperatures of 43–70°C and then rapidly cooled to avoid damage to heat-sensitive products. On perishable crops two types of heated air treatments are practised, vapour heat and forced hot air. Vapour heat was the first to be used and applied hot air saturated with water to the fruit, transferring heat by condensation (Armstrong, 1994). Vapour heat treatments feature a rapid heating phase from ambient followed by a more gradual increase to the critical end point temperatures of 43–57°C, depending on commodity and pest sensitivity. More recently, forced hot air at relative humidity less than 90% (usually less than 60%) has been introduced to avoid heat transfer by water condensation, which causes damage in certain fruit.

For durable stored products target temperatures can be much higher (up to 70°C), and humidity needs to be carefully controlled to prevent moisture content changes during both heating and cooling operations. The treatment time required is strongly dependent on the temperature reached and experienced by the target pest. If the buffering effect of the food commodity is removed, insects are killed within a few minutes above 55°C (Table 17.4).

For fresh fruit and vegetables, hot water dipping is another heat application method. Hot water is an excellent medium for heat transfer and has long been used to reduce pathogens on fruit (Armstrong, 1994). The adverse effects on fruit may be improved by hydrocooling fruit after dipping, but the consequence

Table 17.4 Response of insect pests to high temperatures experienced by developmental stages (modified after Banks and Fields, 1995, and Burks *et al.*, 2000)

Temperature range (°C)	Effect on insects
25–32	Optimum for development
30–36	Maximum temperature for reproduction of most species
36–42	Populations die out, mobile insects seek cooler zones
42–50	Death within a day
50–60	Death within an hour
Above 60	Death within a minute

of effectively shortening the treatment exposure to high temperature on subsequent insect mortality needs further investigation now that hot water is being used alone rather than in combination with chemicals (Sharp, 1994).

Stored product pest insects (all stages) can be eradicated in approximately one minute if they are exposed within the commodity to a temperature of 65°C. This high speed of action allows design of high-throughput plants, such as those based on spouted or fluid beds (Claflin *et al.*, 1984, 1986; Thorpe *et al.*, 1984; Fleurat-Lessard, 1984). Pilot and laboratory studies, reviewed by Sutherland *et al.* (1987) and Banks and Fields (1995), have typically used heated air at 90°C, or greater, as a heat transfer medium into the grain with the objective of heating the grain briefly to above 65°C. Such exposures cause no detrimental effect on the end use qualities of treated cereals at levels of heating required to eliminate insect pests. These include breadmaking quality of wheat, rice quality and malting quality of barley (Fleurat-Lessard, 1985; Sutherland *et al.*, 1987). However, the margin of error is small and only slightly excessive treatment can cause some adverse effects (Fleurat-Lessard and Fuzeau, 1991). Fluid-bed heating systems for bulk grain have been developed to a commercial prototype stage, with treatment rates of up to 150 t/h (Evans *et al.*, 1983; Thorpe *et al.*, 1984; Fleurat-Lessard, 1985; Sutherland *et al.*, 1987), but installation of large-scale heat treatment facilities is likely to be capital intensive. There are currently no installations which meet the typical handling speeds of large modern grain terminals, often 500 t/h or more on one belt.

Pilot studies have been carried out on the use of rapid heating of grain by microwaves, radio frequency radiation or infrared radiation (Boulanger *et al.*, 1969; Nelson, 1972; Fleurat-Lessard, 1987; Ingemanson, 1997). Recent tests indicate that selective heating of the infesting insects in stored grain increases non-linearly at frequencies above 10.6 GHz and that a frequency of 28 GHz is close to the optimum for enhanced selective heating of maize weevils inside grains (Halverson *et al.*, 1997). Halverson *et al.* (1997) report studies of both static (batch process) and dynamic (continuous process) applications used to modify prototype equipment to permit dynamic processing at a rate of 24 t/h (Halverson *et al.*, 2000). Much further development is needed to increase throughput rates to those at export terminals.

Heating above 50°C (122°F) for 20–30 h has been used to control insects in flour mills for almost 100 years. It is increasingly used by a number of major food processors as an important part of their pest control programme (Heaps and Black, 1994). Food plants that can be successfully heat treated rarely require fumigation. Brief heat treatments also have potential to disinfest cocoa, coffee and specific dried fruit and nuts. Techniques will need to be researched carefully before adoption to determine effects on quality of the treated product. It is already known that high temperature storage or treatment of many dried fruit and nuts can lead to detrimental colour change or rancidity.

Heating can provide an alternative treatment method to using chemicals but also can synergise other treatments. For fumigants and controlled atmospheres it does this in three ways: by increasing the diffusion and distribution of gases and

hence their powers of penetration, by reducing physical sorption and by increasing the toxicity or level of stress to target pests. Heat is particularly effective in increasing the efficacy of control using CO₂.

17.3.6 Impaction

Many situations in which agricultural products are mechanically conveyed during food processing offer the opportunity for control of insects by shock, abrasion and impaction. The principle was developed over 60 years ago for use in the flour milling industry (Cotton and Frankenfeld, 1942) and machines such as the Entoleter became a routine fixture in flour mills. In the Entoleter, flour falls between two rapidly spinning discs. Centrifugal force pushes the flour to the edges of the discs where it impacts a row of steel pegs mounted on the rims, and is thrown against the outer steel casing before falling into the basal receiving hopper. The material passing through the Entoleter thus encounters two major impactions and this is responsible for the control of all free-living insect stages (Bailey, 1962).

Working with moving grain, Loschiavo (1978) found that dropping of adult insects into free-flowing grain caused substantial mortality, while Bahr (1991) found that with a range of stored grain insects, passing through a pneumatic conveyor caused between 48% and 95% mortality of adult beetles, while four passes through a vacuum cleaning system caused between 72% and 100% kill, depending on the species, of all developmental stages. Moving grain by screw auger has also been shown to reduce the number of free-living stored product insects and mites (White *et al.*, 1997).

Free-living insects prove easier to control than those developing inside the grain. Subjection of grain to impaction machinery could not eliminate internal grain feeders below levels causing damage to the grain (Bailey, 1962; Stratil *et al.*, 1987). In studies on bruchid infestation of beans, Quentin *et al.* (1991) found that gentle tumbling of beans every 8 hours over a two-week period reduced population growth by 97%. The effect was explained by prevention of first instar larvae from entering the seed after egg hatch. The use of disturbance and impaction techniques merit further experimentation and development in the field of insect control.

17.3.7 Inert dusts

Inert dusts may be clays, sands, ashes or earths; diatomaceous earths (fossilised remains of diatoms consisting mainly of silica with small amounts of other minerals); silica aerogels (very light, non-hygroscopic powders that are effective at lower dosages than diatomaceous earth formulations); and non-silica dusts, such as phosphate and lime. Inert dusts have a long history of use for grain protection (Ebeling, 1971; Golob and Webley, 1980; Quarles, 1992a, 1992b) and more recently have been evaluated as protectants for legumes (Giga and Chinwada, 1994). Inert dusts are rapid in their lethal action under favourable

conditions for most pests. *Trogoderma* species do not appear to be effectively controlled. Available data on responses of immature stages of grain pests is limited, although the success of inert dusts in suppressing population growth suggests that they have a strong effect on free-living immature stages, and recent tests have demonstrated their efficacy against mites (Cook and Armitage, 1999).

Several inert dusts are registered in some countries for treatment of grain and pulses against insect pests. They are particularly useful in dry conditions to control pests in storage structures (Fam *et al.*, 1974). They can form a useful part of IPM strategies as sprays applied to the fabric of the building to minimise residual infestation and migration of pests. Inert dusts have also long been used as carriers for insecticides, but current initiatives seek to improve formulations for use alone. These new formulations, based on diatomaceous earth (DE), are being designed to minimise their abrasive properties (to protect conveying machinery) and enhance their insecticidal action as desiccants by promoting their capacity to selectively absorb insect cuticular waxes. They provide a direct alternative to chemical protectants for effective pest control in dry grain (Desmarchelier and Dines, 1987), but lose effectiveness at humidities above about 75% RH (Le Patourel, 1986). Dryacide, an activated DE, is in widespread use in Australia in the grain handling industry, and Protect-ItTM, an enhanced DE formulation, has been tested successfully in Canada (Fields *et al.*, 1997). Some formulations are accepted as suitable for use on foods certified as 'organic' in some countries. DEs are widely used as food and processing additives.

Inert dusts do not require capital equipment, are relatively non-toxic, provide continued protection, and do not affect baking quality (Desmarchelier and Dines, 1987; Aldryhim, 1990). Their disadvantages are decreased flowability of grain, visible residues that can affect grading, and decrease in the bulk density of grain. Marine silicates may give rise to dust problems in the workspace, with some risk of carcinogenicity, a problem not encountered with DEs of freshwater origin. Korunic *et al.* (1996) summarise the uses and properties of new DE formulations that overcome many of the problems associated with this technology. Research is on-going in relation to new methods of application (Fields *et al.*, 1997).

17.3.8 Irradiation

The process of irradiation involves the use of gamma energy, accelerated electrons or X-rays to penetrate the commodity. The most common radiation source is cobalt-60, which provides a constant field of ionising energy. The effectiveness of treatment for insect control and effect on food quality is related to the energy delivered. While operating costs are low, the capital investment for irradiation facilities is high, and the infrastructure must be present to support a commercial radiation facility.

Disinfestation by irradiation has been under investigation since 1912. More recently Brower and Tilton (1985) and Tilton and Brower (1987) summarised

the radio-sensitivity data on 40 stored-product pest species to identify options for quarantine uses and disinfestation of grain and grain products. These data showed that pests vary in their sensitivity to radiation. Generally, the developmental stages are more sensitive than adults, females are more sensitive than males, and adults are more easily sterilised than killed. Comparing groups, beetles and mites are more sensitive than moths, and fruit flies are more sensitive than beetles. The use of irradiation for quarantine is hampered by the fact that the insects are usually damaged and incapable of completing development or sterilised and incapable of reproduction, but may remain alive in the commodity for weeks afterwards.

Selection of the type of irradiation equipment to be used depends on whether the commodity is to be irradiated in packages or in bulk, the quantity of product to be treated and other factors. Accelerated electrons are slightly less effective than gamma rays in insect control, lacking the penetrative power of the latter (Adem *et al.*, 1978). However, they are inherently easier to work with as they can be switched on and off. Gamma irradiators can treat packaged or bulk products, and accelerators can more effectively treat bulk products in thin layers (2–5 cm thickness). Irradiation is effective at all temperatures with either bulk or bagged commodities. The dosage of irradiation which can be used is limited by effects on the quality of the commodity. Irradiation at some doses may stop germination of grains and seeds; for instance, it is not suitable for use on malting barley. Like fumigation, irradiation does not confer residual protection against pests, so packaging materials or post-treatment storage controls should be employed to prevent reinfestation.

In Indonesia, about 300 tonnes of bagged rice per week have been irradiated as part of government rice storage practice since 1994 (UNEP, 1998). It is an effective treatment against *Sitophilus oryzae* (rice weevil) at a minimum dose of 0.40 kGy. The packaging materials are polyethylene liners plus polypropylene outer bags sewn shut with polyester thread. A full-scale commercial electron beam accelerator was formerly in use at Odessa, Ukraine, for the treatment of imported grain (Zakladnoi *et al.*, 1982), but is no longer operating.

Concerns hampering public acceptance of irradiated foods appear to be diminishing, especially in the light of increased public awareness of irradiation as a means of combating microbial contamination, but there is still some opposition. However, there are few agreements enabling the movement of irradiated products in international trade. Irradiation is approved for at least one food use by 41 countries, although in just over half of these the treatment is primarily for disinfestation purposes (Anon., 1998).

17.3.9 Screening, sorting and sanitation

The screening and sorting of many harvested crops is an effective method of preventing infested produce from entering the food chain in developed countries and in classifying produce according to suitability for animal or human feed in developing countries. For example, Compton and Sherington (1999) describe a

simple technique for classifying maize cobs into categories based on the level of damage by visual comparison with standard pictures, which is suitable for use by subsistence farmers. Screening and sorting measures are designed to remove pests or prevent their access to the product or commodity. Systems have been designed to separate out infested grains by projection through air or by aspiration technology. In flour mills screens and sifters remove insect stages and fragments from the production line.

Good sanitation practice is a vital component in the control of food pests, regardless of any other practices carried out. It reduces pest food and harbourages within and without a structure by regularly removing waste and debris during vacuum cleaning, sweeping and washing. Construction and maintenance also play major roles in reducing pest harbourages and denying pest access to structures. New machinery and facility construction should include pest preventative design as a priority. For existing facilities, problems may only be solved by changes to the structure such as repairs and closures of pest entrances and niches, including caulking, removing ledges and catchments and applying new surfaces, but costs can prove prohibitive.

Other aspects of good warehousing practice, e.g. stock rotation and, where applicable, insect-proof packaging, also reduce pest population pressure. The retention of polythene sheeting on a stack after a fumigation is an effective means of preventing reinfestation, as demonstrated in trials and current practice in south-east Asia (Annis and Graver, 1990). Other measures include sieving, screening, separation by projection and aspiration. Whereas none of these methods is capable alone of achieving sufficient control, they can be useful in combination with other measures. The topic of physical removal and exclusion was reviewed with other physical control methods by Banks and Fields (1995).

17.4 Chemical control of pests

For most of the twentieth century chemical control was the mainstay of the agricultural and food industries, but of late there has been increasing pressure to minimise chemical use and reliance on pesticides in the interests of avoiding long-term health and environmental consequences. Chemicals still play a vital role in the protection of food commodities and products, but the compounds remaining available for use are declining in number and more attention is being paid to non-chemical alternative control measures.

17.4.1 Attractants and repellents

Many compounds exhibit properties which either attract or repel insects. The chemical control of cockroaches, augmenting high standards of hygiene, now relies heavily on the performance of baits which are laid down to attract the insects to take up a lethal or sterilising dose. Most insecticides are repellent and bait formulation can be difficult in their presence. The new generation of gel

formulations is meeting with greater success in the control of cockroach pests (Appel, 1990; Durier and Rivault, 1999), replacing insecticidal sprays as a control strategy.

For other food pests, use has been made of chemicals produced by the pests themselves to act as cues for mating or food location. These chemicals, produced by one member of a species and transmitted externally to another member of the same or another species, influence the behaviour or physiology of the receiving individual. Such compounds are known as semiochemicals, of which the most studied group are the sex pheromones. In most cases the female releases a chemical into the air that both attracts and sexually stimulates males of the same species. The sex pheromones of several storage pests, both Coleoptera and Lepidoptera, are among the earliest identified pheromone molecules. The primary sex pheromone component of the phycitine moths, Z,E-9,12-tetradecadienyl-acetate (ZETA) (Kuwahara *et al.*, 1971), is highly susceptible to degradation when exposed to light or air, a factor taken into account in formulating baits. Formulations of this chemical have been used to disrupt mating of Indian meal moth in warehouses (Pierce, 1994). Aggregation pheromones are another group of stimulants attracting mobile stages of both sexes to a food source. Pheromones of this type have been identified for many stored product beetles of the families Bostrichidae, Cucujidae, Curculionidae, Nitidulidae, Sylvanidae and Tenebrionidae. The use of pheromones in the food industry has recently been reviewed (Phillips, 1997).

Pheromones can be used as lures in traps to monitor storage pest populations or may be employed as part of a control system via mass trapping, pathogen dissemination or mating disruption (Burkholder, 1985). Trematerra (1994) summarises studies on mass trapping, mating disruption and a combination of insecticide with pheromone lures to control Mediterranean flour moth in flour mills. While populations can be suppressed, techniques based on attractants rarely achieve total disinfestation.

17.4.2 Botanicals and natural products

These compounds are derived from plants, and include plant alkaloids, secondary metabolites and essential oils. At present, the only botanical in widespread use in developed countries for protection of stored food products is pyrethrum extract. Others, such as azadirachtin, an active principle from neem, are under continuing investigation. Botanicals may have limited application in developed countries because of concerns about transferring odours or off-flavours to milled or processed products. A wide variety of botanicals are still used by subsistence farmers in developing countries. Many of these are under active investigation, essential oils in particular attracting much research effort (Shaaya *et al.*, 1997; Huang *et al.*, 1997; Keita *et al.*, 2000; Bouda *et al.*, 2001). As natural products are not readily patented, there is little incentive for companies and other organisations to pay for the toxicological testing required to gain registration for use. This may prove to be a stumbling block for their

successful introduction as pest control agents except perhaps when data are already available to support registration as a food additive.

17.4.3 Fumigation

Fumigation is an important control measure in the food industry for the treatment of incoming raw materials, either before leaving the country of origin or on arrival at the dockside before distribution. It is the primary control procedure applied on discovery of infestation in bulk commodities in store or during transport, and for whole-site treatment of food processing premises. For effective application, fumigation relies on achieving an effective seal on the bulk commodity or building to be treated. Plastic enclosures are in use for bagged products, either as readily available kits with zip seals (Smith, 1988; Newton, 1991; Navarro *et al.*, 1997) or as tents constructed, glued and sealed on site (Nataredja and Hodges, 1990; Annis and Graver, 1990). Polyethylene is often used as fumigation sheeting but better gas retention is obtained with nylon or PVC materials or laminates (Chakrabarti *et al.*, 1995). The number of fumigants in widespread use has been falling steadily in recent years, originally because of concerns over toxicology and the formation of toxic residues, and more recently over concerns with environmental damage and safety of application.

Carbon bisulphide

Carbon bisulphide was one of the first modern era fumigants to be introduced, back in the 1870s (Cotton, 1956). Once widely used as a fumigant for bulk and bagged grain, and applied as a 'liquid fumigant' in a mixture with carbon tetrachloride or alone, in most countries its use has been discontinued and registration has lapsed. Application to large bulk storage is restricted by the potential fire hazard of the material. There is still some use in China and Australia where it is applied to small lots of grain (c. 50 tonnes) in farm storage.

Carbonyl sulphide

Carbonyl sulphide is a promising new fumigant closely related to carbon bisulphide under consideration for registration for grain in Australia (Banks *et al.*, 1993a). The gas is highly penetrative and sorption on to wheat is very low. Stored cereals contain natural levels of the gas and mammalian toxicity is low. The fumigant has shown activity against stored product pests, including *Sitophilus granarius*, *S. oryzae*, *Rhyzopertha dominica*, *Oryzaephilus surinamensis*, *Carpophilus hemipterus*, *Lasioderma serricorne* and *Tribolium confusum* (Plarre and Reichmuth, 1996; Zettler *et al.*, 1997; Weller and Morton, 2001).

Carbon tetrachloride

Carbon tetrachloride was formerly used as a liquid fumigant on grain and in mixture with other halogenated hydrocarbons such as ethylene dichloride and ethylene dibromide, or with carbon bisulphide (see above), as a component of

various liquid fumigant mixtures. These were formerly used widely for treating grain, milling machinery and, in the tropics, on bagged products under gas-proof sheets (Bond, 1984), but have now been withdrawn from use in most countries.

Ethyl formate

Ethyl formate was formerly used as a fumigant for grain and may be reinstated for this purpose in Australia. Otherwise its use is restricted to dried fruit and processed cereal products, and registration has lapsed in most countries. The action of ethyl formate against pests is quite rapid with control being achievable after exposures of only a few hours (Hilton and Banks, 1997). However, the gas is highly sorbed by commodities, especially at raised humidity, and it is difficult to attain adequate distribution. Thus, in practice long exposure times may be needed to ensure adequate penetration of bulk commodities. Typical dosages on dried vine fruits are 3–6 ml per 15 kg pack. Ethyl formate can be corrosive to unpainted metals at high humidity.

Ethylene oxide

Ethylene oxide has been used extensively to reduce microbial contamination in food commodities such as spices and some processed foods and coincidentally provides insect control. It was formerly widely used for insect control on grain (Cartox system) and dates. Because of its flammability, ethylene oxide was generally supplied in mixtures with inert diluents such as CO₂ or HCFCs. Ethylene oxide reacts with chemical constituents of some food commodities producing potentially carcinogenic compounds, such as ethylene chlorohydrin (Wesley *et al.*, 1965). Its use has been withdrawn in the EC, USA and many other countries, but it is still used in China and other parts of the world.

Hydrogen cyanide

Hydrogen cyanide was previously used widely as a fumigant for durable commodities, mills, factories and transport, including aircraft. Largely, it has been superseded by methyl bromide and phosphine, both of which are more convenient, less expensive, and, in many cases, more effective to use. Modern instructions for use of HCN are given in Anon. (1989). These relate particularly to the ASEAN region, but are, in principle, suitable for most countries. Cylinders of liquid HCN are unstable and cannot be stored for long periods. However, HCN can be generated *in situ* from sodium cyanide (Anon., 1989). Its registration has lapsed in many countries.

Methyl bromide

Methyl bromide has been in widespread use as a fumigant for foodstuffs and stored products for more than 50 years. It has a very wide spectrum of toxic action and is also used as a soil sterilising pre-plant fumigant. As a result of its high toxicity and rapid action against insects, its superior powers of penetration and greater ease of handling, it largely replaced the fumigants hydrogen cyanide and ethylene oxide. Currently, however, the compound is being phased out

except for quarantine and pre-shipment uses by 2005 in developed countries and 2015 in developing countries under the Montreal Protocol, an international agreement on the elimination of ozone-depleting chemicals run by the United Nations Environment Programme (UNEP, 1998).

Methyl bromide can be used under vacuum in chambers to reduce treatment times to 3 or 4 hours. In larger scale fumigations, the time under gas is usually less than 24 h. The rapid speed of action makes methyl bromide fumigation a particularly convenient treatment where the commodity cannot be held for long periods for logistical reasons, such as at ports during import and export. This speed of action is also very important in disinfesting perishable commodities such as fresh fruit and cut flowers. In practice, the downtime for fumigation includes the actual exposure period to the fumigant, the preparation time of the enclosure beforehand and the time at the end of the exposure, when residual gas is aired off from the treated commodity. For a flour mill, even with a fast-acting fumigant like methyl bromide, this can represent $2\frac{1}{2}$ working days.

Phosphine

Phosphine is extensively used as a fumigant for treating cereals and legumes, and after the withdrawal of methyl bromide will be the most commonly used fumigant. It ranks as one of the most toxic fumigants known, and is used at low concentrations. Acting via the oxidative cycle for energy production, effects on pests tend to be slow and long exposures are required, particularly at low temperatures, for kill of all stages. Phosphine penetrates well into commodities and can be removed rapidly by aeration after treatment. The gas reacts with copper, silver and gold and can cause corrosion of electrical equipment (Bond *et al.*, 1984; Brigham, 1998). Formulations releasing phosphine gas are available worldwide. Most contain aluminium phosphide or, less commonly, magnesium phosphide, formulated with ammonium carbamate or urea to lessen the risk of spontaneous flammability which can occur if the gas concentration exceeds 1.8% by volume in air at normal atmospheric pressure. There are many publications describing the application of phosphine to stored grain and other durable commodities (e.g. Bond, 1984; Banks, 1986). Typically, aluminium phosphide preparations are added to the grain, or placed on the grain surface or near the product to be fumigated within the fumigation enclosure. Phosphine is generated *in situ* by the reaction of atmospheric moisture with the metallic phosphide (Bond, 1984). Phosphine is also available commercially in pressurised gas cylinders as a non-flammable 2% mixture in liquid carbon dioxide (Australia, USA and some other countries) and as a 1.7% mixture in compressed nitrogen (Germany).

The use of phosphine should follow these guidelines:

- The commodity temperature should be more than 15°C although certain pests are susceptible down to 5°C with long exposures.
- Exposure periods need to be prolonged for kill of all developmental stages of pests, 15 days being required at 15°C, reducing to 4 days at 30°C (Anon., 1993).

- For aluminium phosphide formulations, the equilibrium relative humidity within the commodity should be more than 30% to ensure full evolution of phosphine from the formulation within the exposure period.
- Well-controlled techniques must be used to avoid the rapid decline of concentration levels in the enclosure and inadequate exposure times, which are known to lead to the rapid development of pest resistance.

As some stages in the life cycle have reduced sensitivity to the gas and carry on developing under gas, the period of exposure has a much more important role than concentration levels in the toxicity of phosphine. Eggs and pupae are often many times more tolerant than larvae and adults. Mites are difficult to control with phosphine since the egg stage is highly tolerant and, unlike insect eggs, development appears to be delayed under gas.

Phosphine is widely used for treating infestation in bulk and bagged grain and grain products in many countries. Shipboard in-transit fumigation with phosphine is now a well-developed technology (Zettler *et al.*, 1982; Leesch *et al.*, 1986). It requires ships of appropriate design and stringent safety precautions (IMO, 1996). Phosphine is also used for treatment of dried fruit, nuts (except walnuts which can pick up a taint and change colour), beverages and most spices. Most pests of dried fruit and nuts are highly susceptible to phosphine and shorter exposure times can be used than with stored grain. In the latter case, longer periods are needed to control *Sitophilus* spp. (Hole *et al.*, 1976). These do not attack dried fruit, nuts, cocoa, coffee or spices.

Recent developments in phosphine fumigation technology, including the use of surface application in sealed systems and the supply of non-flammable phosphine formulations in cylinders at about 2% w/w in CO₂ (Winks, 1986; Chakrabarti, 1994; Noyes *et al.*, 1997), have increased the competitiveness and effectiveness of phosphine use compared with other treatment methods. Discussion of recent advances in phosphine treatment of grain against infestation can be found particularly in Highley *et al.* (1994), Donahaye *et al.* (1997) and Bell (2000).

Sulphuryl fluoride

Sulphuryl (sulfuryl) fluoride was developed in the late 1950s as a structural fumigant, mainly for termite control. The efficacy of this product is well researched and understood. It provides good penetration, requires a short fumigation period of approximately 24 hours, and airs off within 6–8 hours. Sulfuryl fluoride is being developed for use in empty food processing facilities and on certain commodities to replace methyl bromide. It is toxic to post-embryonic stages of insects (Kenaga, 1957; Drinkall *et al.*, 1996), but the eggs of many stored product species are very tolerant, especially at lower temperatures, requiring concentrations of over 50 g/m³ and exposures of up to 3 days for complete kill (Bell and Savvidou, 1999; Bell *et al.*, 1999). In this respect it resembles phosphine rather than methyl bromide (Fig. 17.1).

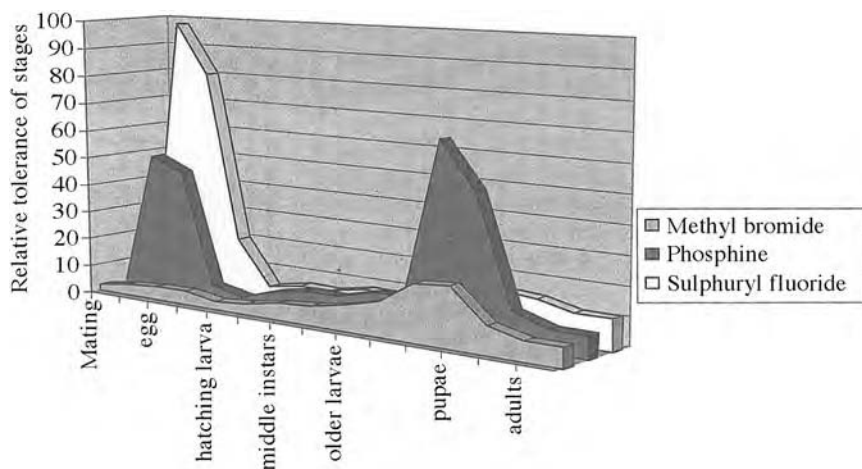


Fig. 17.1 Exposure time and efficacy: variations in tolerance towards three fumigants as insect development proceeds from egg to adult.

Other compounds

Some other compounds have been considered for use as fumigants. *Cyanogen* is under consideration as an alternative grain fumigant and sterilant in Australia. It has been patented for this use. *Methyl iodide* has similar properties to methyl bromide but is more expensive to synthesise. Its activity towards stored product pests has been reported in the literature (Muthu and Srinath, 1974; Kostjukovsky *et al.*, 1997). *Methyl isothiocyanate*, introduced in 1959 by Schering AG as a nematicide under the trade name Trapex, has recently been found effective against grain weevils (all stages) at a very low *ct*-product of 8 g h/m³ (Ducom, 1994). For optimal results, this compound has to be very well mixed with the grain because it is highly sorbed. Recent research indicates that it could be more useful as a treatment method for perishable commodities (Ducom and Vinghes, 1997). Methyl phosphine is under investigation in the UK primarily as a countermeasure to phosphine resistance. It has a specific action against phosphine-resistant strains, being more toxic to these than to susceptible strains, but has a short half-life on commodities (Chaudhry *et al.*, 1997). *Ozone* has a sterilising action against bacteria and viruses, but only limited information is available on its toxicity to insects. Activity has been found against *Sitophilus oryzae*, *Oryzaephilus surinamensis* and *Tribolium* spp. (Yoshida, 1975; Erdman, 1979), but continuous generation of the gas is needed to maintain the concentrations of several hundred ppm required for efficacy. Propylene oxide is in use as a disinfection agent for raisins in the US and has recently been subjected to renewed investigation as an insecticidal fumigant (Isikber *et al.*, 2001).

17.4.4 Insect growth regulators

The term insect growth regulator (IGR) is used to describe compounds which interfere with the life-cycle of pests by action on the hormonal control of development, either as agonists or as antagonists. IGRs now include chitin synthesis inhibitors which affect development by halting moulting. Most IGRs have low toxicity to vertebrates (Menn *et al.*, 1989) and are more pest-specific than conventional contact insecticides. This gives them the advantage of being able to be used in combination with predators and parasitoids (Oberlander *et al.*, 1997). They are, however, generally used in a similar way to contact insecticides and are subject to similar requirements for registration. Offering long-term protection to treated commodities, their long persistence on foodstuffs limits their use where the detectable presence of residues is a problem. They are also relatively costly and normally do not achieve control quickly, adult and larval pests continuing to feed and damage products.

The earliest of the IGRs developed were analogues of juvenile hormones and include methoprene and hydroprene. Some IGRs act against insects via ingestion or contact (e.g. methoprene), while others, such as the chitin synthesis inhibitor diflubenzuron, act only via ingestion. Methoprene has been registered for use in the protection of a variety of stored commodities in a number of countries, including the USA, Australia and the UK. It is effective against many stored product pests, including *Lasioderma serricorne*, *Rhyzopertha dominica*, *Ephesia cautella*, *Plodia interpunctella*, *Trogoderma granarium* and *Oryzaephilus surinamensis*, but not against *Sitophilus* spp. (Snelson, 1987; Mkhize, 1986).

Recent studies with moths (Monconduit and Mauchamp, 1998) indicate that very low level (ppb) treatments with fenoxycarb of the egg or larvae just after hatching cause lethal disruption of moulting throughout the larval period. In these studies, virtually none of the insects survived to the pupal stage. Further studies are needed for development of effective protocols for the use of IGRs in commodity protection.

17.4.5 Smokes and mists

Smokes (solid particles dispersed in air) and mists (liquid droplets dispersed in air) have in the past been popular for use in food processing facilities for the control of flying insects. Their popular linkage with fumigation is misleading as they have no penetrative powers into commodities or voids in structures and are ineffective against insect stages hidden from view. The reliance on smoke bombs and mist dispensers thus does not deal with the root problem of infestation and is best regarded only as a cosmetic action.

17.4.6 Synthetic contact insecticides

Synthetic insecticides include analogues of pyrethrum (pyrethroids), organochlorine (now largely out of use because of persistence in the

environment and residue problems) and organophosphorus compounds. Most are unsuitable for use on processed foods. Although the organochlorine lindane (γ -hexachlorohexane) has long been discontinued as a grain protectant in developed countries, residues are still encountered in grain, indicating continued use of stocks elsewhere in the world. The organophosphorus compounds still form an important group of grain protectants in current use. The stability of deposits on harvested grain varies widely with the particular formulation and ambient conditions. Maximum application rates for raw cereal grains and permitted residue levels have been laid down by the Codex Alimentarius Commission (1992). The rate of degradation increases with both temperature and water activity (moisture content). Furthermore, toxicity to insects increases with temperature. In consequence, persistence of the biological effectiveness will depend upon the insecticide used. For example, typically *dichlorvos* acts quickly and degrades within a few days, while *malathion* takes several weeks, and *pirimiphos-methyl* many months to degrade. Most organophosphorus compounds have limited efficacy against bostrichid beetles (*Rhyzopertha dominica* and *Prostephanus truncatus*).

Dichlorvos is unique among grain protectants in its rapid action against pests and ability to subsequently vaporise off from grain. In the absence of resistance, and where approved, it can be sprayed on to bulk grain within a few days of export to disinfest a cargo. In other circumstances, such as the storage of grain from one harvest to another, there are advantages in applying a compound that breaks down slowly enough to give protection against infestation throughout the storage season. As a whole, grain protectants do not readily penetrate bagged or bulk grain. This restricts their utility substantially as normally they must be applied to the grain during handling, e.g. prior to bagging or during conveying. The use of grain protectants varies widely with country, market preference and local regulations. Where permitted, and where pest resistance is not a problem, they can provide a useful means of preventing infestation. They are also used as sprays on storage structures and the surfaces of bagged or bulk grain as part of a sanitation programme. In addition to dichlorvos, *pirimiphos-methyl*, *chlorpyrifos-methyl*, *fenitrothion*, *etrimphos*, *methacrifos* and *malathion* have all been used in the protection of stored grain or grain facilities, but registrations are becoming fewer as more stringent demands for continued clearance are being made by registration authorities. Currently there are concerns regarding possible toxic effects of low residue levels in food products, and further actions against the long-term use of organophosphates on food commodities are likely in the future.

Synthetic pyrethroids (e.g. *deltamethrin*, *bioresmethrin*, *permethrin*, *cyfluthrin*) are quite stable on grain and their insecticidal activities may persist for up to 2 years (Snelson, 1987). Their action is much less sensitive to temperature than that of organophosphorus insecticides. Pyrethroids are active against bostrichid beetles at a much lower dosage than for most other insect pests of durables. A disadvantage of these pesticides is their relatively high cost. In many situations pyrethroids are added in combination with a synergist, piperonyl butoxide, to increase effectiveness and reduce cost.

17.5 Biological control of pests

Biological agents which range from microbiological pathogens to predatory insects are generally host specific and are best considered as preventive control measures, avoiding the build-up of pest populations. Arthropod parasitoids and predators occur naturally in stored commodities, but rarely suppress a storage pest before unacceptable damage occurs. Therefore, mass-release or augmentative approaches are needed to overwhelm pests before they can do harm. Pathogens of insects include bacteria, viruses, protozoa, nematodes and fungi. This wide spectrum of organisms occurs naturally though not necessarily in the stored food environment. They therefore have to be applied to the specific situation where the choice has been made for their use as control agents.

17.5.1 Bacterial pathogens

The toxin-producing bacterium *Bacillus thuringiensis* (Bt) is the principal pathogen in use for control of lepidopterous pests and some other species. It requires a high pH, found in the gut of Lepidoptera and some beetle species, for optimal replication. In the stored product field, commercial formulations provide a control method for almond moth and Indian meal moth when applied to grain as an aqueous suspension or as a dust. These are effective when all the grain is treated, or when just several inches of the surface layer are treated, because lepidopterous larvae usually live near the surface of the bulk. Strains of *Bacillus thuringiensis* (Bt) have been tested for moth control on other durables (McGaughey, 1987; Vail *et al.*, 1991), but already resistance by pests in stored products to Bt has been observed (McGaughey and Beeman, 1988). Bt is exempt from a tolerance level in the USA, but not in other countries, for use as a stored product protectant. Residual activity against susceptible insects can last for more than a year (McGaughey, 1987). Vail *et al.* (1991, 1996) report the screening of several lines of transgenic walnut with high levels of the insecticidal crystal protein fragment that arrest development or kill larvae of codling moth, navel orangeworm and Indian meal moth, the principal pests of stored walnuts in California.

17.5.2 Fungal pathogens

Entomopathogenic fungi have long been known to have potential for combating insect pests but there have been concerns over their specificity of action and safety (Laird *et al.*, 1990). One species, *Beauveria bassiana* (Balsamo) Vuillemin, has recently been revisited as an active research topic for use against pests of grain and pulses (Adane *et al.*, 1996; Hildago *et al.*, 1998). Another genus of fungal pathogens with potential for stored product pest control is *Metarhizium*.

17.5.3 Parasites and parasitoids

Many species of ichneumonoid, bethyloid or chalcidoid wasps utilise stored product insects as hosts. The primary target pest species are moth larvae or eggs and various beetle larvae. Some of the more effective parasitoids are the ichneumonoid braconid *Bracon* (= *Habrobracon*) *hebetor* (Say), which attacks moth larvae (Press *et al.*, 1982; Brower and Press, 1990; Cline and Press, 1990) and the chalcidoid trichogrammatids *Trichogramma evanescens* Westwood and *T. pretiosum* Riley which attacks eggs (Brower, 1988a, 1988b). The ectoparasitic bethylids *Cephalonia gallicola* Ashmead and *C. tarsalis* Ashmead attack the larvae of several beetle species.

Bracon hebetor has commercial use in South Africa for reducing the need for fumigation of stacks of bagged grain (Anon., 1991) and is used to control Indian meal moth in stored peanuts in the south-eastern USA. The ichneumonid *Venturia canescens* (Gravenhorst) has been used for the control of *Ephestia* moths (Press, 1989). Baker and Throne (1995) utilised an insecticide-resistant strain of the chalcidoid pteromalid *Anisopteromalus calandrae* (Howard) for control of malathion-resistant rice weevils on malathion-treated wheat. Flinn *et al.* (1996) report effective control of the lesser grain borer in large-scale bulk wheat at moderately high temperatures with the pteromalid parasitoid *Choetospila elegans* (Westwood).

17.5.4 Protozoan pathogens

Sporozoan parasites are common and widespread among stored product insects, causing debilitating illnesses and reducing population growth (Arbogast, 1984). Larvae and adults of *Cryptolestes* spp., *Tribolium* spp. and the moth *Sitotroga cerealella* may harbour pathenogenic schizogregarines such as *Farinocystis tribolii* Weiser and *Mattesia dispora* Naville in their hind gut. The microsporidian *Nosemia whitei* Weiser is a common pathogen of *Tribolium* spp. and other beetle species, while *N. plodiae* Kellen and Lindegren infects phycitine moths. The potential of these organisms as control agents merits further research and development.

17.5.5 Predators

The effectiveness of the predatory warehouse pirate bug, *Xylocoris flavipes* (Reuter), in regulating stored product beetle and moth populations has been evaluated (Press *et al.*, 1975; Brower and Mullen, 1990). After the introduction of large numbers of pirate bugs in storage premises, populations of *Tribolium castaneum* were suppressed quite rapidly (Press *et al.*, 1975). The histerid beetle *Teretrius* (*Teretriosoma*) *nigrescens* (Lewis) has been used successfully to suppress populations of the serious maize pest *Prostephanus truncatus* in the laboratory and in the field (Rees *et al.*, 1990; Giles *et al.*, 1996).

Predatory mites are another group of predators, preying on insect eggs and small larvae. The pyemotid mites *Pyemotes ventricosus* (Newport), *P. tritici*

L.-Fossat & Montagne, *Acarophenax dermestidarum* Rack and *A. tribolii* Newstead and Duvall prey mostly on insects, while the ascid mite *Blattisocius dentriticus* (Berlese) and the cheyletid *Cheyletus eruditus* (Schränk) prey on stored food mite species.

17.5.6 Viruses

Entomopathogenic viruses (primarily baculoviruses) have been studied for the control of storage moth pests (Hunter and Drexel, 1970; Hunter *et al.*, 1973; Cowan *et al.*, 1986; Kellen and Hoffmann, 1987), but have not been isolated from storage beetles. Crystalline occlusion bodies containing the virus are the natural choice for insecticidal action. Virus particles attack the larval gut but surviving adult females may pass the infection on to eggs laid. The granulosis virus (PGV) of *Plodia interpunctella* and the nuclear polyhedrosis virus (CGV) of *Ephesia cautella* have been tested as a part of integrated control programmes in the USA (e.g. Vail *et al.*, 1993).

17.6 Threats to successful control

17.6.1 Pest resistance

Any chemical with a specific mode of action is vulnerable to the development of resistance in pest species. Resistance is known to all the major classes of chemical control agents and to many physical and biological control methods also. The natural spectrum of tolerance to a toxicant is an excellent indicator of the potential for resistance to develop among pest species. Hence, the fumigant methyl bromide has a comparatively narrow tolerance spectrum among insects and few instances of resistance have been reported after over 50 years of use, while the fumigant phosphine has a very wide tolerance spectrum evident even among the developmental stages of the same species, and pest resistance has become a real problem.

All the organophosphorus insecticides have generated resistance of sufficient magnitude to cause control failures and there is often strong cross-resistance between compounds. For control of lesser grain borer in Australia, for instance, the use of organophosphorus compounds is no longer an option (Collins, 1994). High levels of resistance to the fumigant phosphine have been measured in the laboratory in several species of stored-product beetle pests originating from parts of Africa and the Indian subcontinent, following frequent use of the fumigant in conditions of poor gas retention (Taylor, 1989; Price and Mills, 1988). There have been control failures attributable to this resistance in both continents. Insect populations are capable of developing resistance to phosphine relatively easily where there is malpractice. Short fumigation periods (e.g., less than 3 days) employing low concentrations of phosphine at high ambient temperatures provide the ideal conditions in which insect resistance can develop.

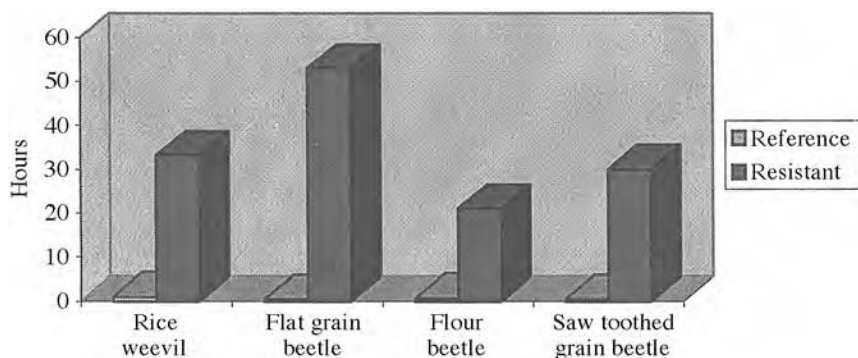


Fig. 17.2 Time for 50% knockdown of beetle strains exposed to phosphine.

Phosphine resistance can now be detected by a rapid knock-down test, exposing adult beetles in desiccators to 0.35–0.4 mg/l (Savvidou *et al.*, 1994). Whereas susceptible beetles are all knocked down within a couple of hours, resistant insects can remain active for over a day (Fig. 17.2).

Resistance management is an important consideration when using phosphine. The considerable volume of work on phosphine resistance and mode of action is reviewed by Chaudhry (1997). The effect of resistance to phosphine can at present be overcome provided that the required gas concentration can be maintained for the longer exposure periods needed for kill of the more tolerant strains. In leaky situations such as silos or floor stores, insect control may be carried out by a continuous input of fumigant atmosphere by injecting a phosphine–carbon dioxide mixture from a pressurised cylinder into an airflow system (Winks, 1990) or directly from cylinders to selected parts of the bulk via metering valves (Bell *et al.*, 1993b). However, for conventional dosing, the degree of gas-tightness of the enclosure should be improved as far as possible so that gas may be retained for a sufficient period. A closed-loop circulation system can be installed to keep an even gas concentration level throughout the structure (Noyes *et al.*, 1997). In spite of such efforts, multiple dosing may still be necessary for efficacy against resistant strains.

Resistance has become a major consideration in the continued use of many contact insecticides and fumigants such as phosphine. With only a restricted number of compounds available for use the situation is serious. Solutions to resistance such as alternating or rotating the use of toxicants have been proposed but are difficult to administer. Better prospects ensue from measures aimed at reducing selection for resistance, such as use of physical or biological alternatives, or by pursuing research to develop agents such as methyl phosphine which have specific activity against resistant strains.

17.6.2 Registration and compound availability

Although the availability of pest control agents to treat commodities is much relied upon in every country, the stored product market in any one country or

state does not offer the prospect of cost recovery to multinational chemical manufacturers trying to develop and register new products. Each country has its own registration procedures and decides upon the acceptable daily intake (ADI) level for each compound and defines the maximum residue level (MRL) to be allowed in treated products. In addition there are many other data requirements that have to be supplied by potential registrants. The cost of registration of a new active ingredient can thus prove prohibitive for a particular market. The stored product and food sector is highly complex, being very much subdivided on a commodity basis, requirements differing between commodities and products. Though the problem for registration of new active ingredients, and even for new formulations of an existing active ingredient, has been highlighted, governments have generally not provided any realistic support for such minor use areas. As a result the number of chemicals remaining available for stored food protection is very small, and as registrations lapse or are withdrawn, few replacements are entering the pipeline. Attempts have been made within the European Union to harmonise registration procedures but member states have until 2010 to bring their systems into line. This may be too late to avoid gaps appearing in the pest control armoury for a wide range of products.

17.7 Conclusion

The control of stored product insect pests remains an active field of research and practice. The pursuance of measures ensuring good sanitation is of paramount importance. Storage of goods most often leads to problems where there are long residence times and a lack of checking for the presence of pests. Systems have been devised for the early warning of insect presence by pheromone trapping or placing of bait bags. Continual stock rotation is vital for avoidance of problems. This chapter has focused on some of the specialist control procedures available for use when insect or mite populations are discovered, but the real solution to the problem lies in the devising of measures to avoid their establishment in the first place.

17.8 References

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