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Hazard control by segregation in food factories

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Abstract: Factories are segregated primarily for protecting the product from the environment, segregation of raw materials and finished product, segregation of wet and dry materials, provision of mechanical and electrical services and health and safety issues (e.g. boiler rooms, chemical stores, fire hazards, noise limitation). Ready-to-eat (RTE) products factories have begun to further segregate or ‘zone’ production areas for food safety or hygiene reasons. A series of higher hygiene zones have been created to protect the product from microbiological cross-contamination events after it has been heat treated or decontaminated. There has also been the recognition that non-microbiological hazards, particularly allergens, and label declaration issues such as ‘suitable for vegetarians’, ‘organic’, ‘does not contain GM materials’ or ‘Kosher/Halal’ have to be controlled by segregating them from other product ingredients.

Key words: segregation, zoning high care, high risk.

13.1 Introduction

To provide protection from general contamination (physical, chemical and biological hazards) during manufacture, food has historically been protected by a barrier system, made up of up to three barriers (Holah and Thorpe, 2000). With the advent of enhanced hygiene control in high hygiene areas, however, this has now been extended to four barriers (Holah, 2003), as shown in Fig. 13.1. These encompass the site (1), the factory building (2), a high risk or high hygiene zone (3) and a product enclosure zone (4). The barrier system has two intrinsic properties. Firstly, each barrier is designed to minimise the presence, or challenge, of a given hazard on subsequent barriers. Secondly, the degree of control of the production environment increases such that finally, fully processed products are manipulated in controlled environments in which contaminants are actively excluded.
With respect to segregation requirements, foods and drinks can be broadly divided into low and high risk products dependent on their stability or whether they will be further processed by the food manufacturer or the final consumer. Low risk products, typically either raw materials or ambient shelf-stable products, include eggs, raw meat and fish, fruit, vegetables, dried goods, canned foods, oils and fats, bakery and baked products, food additives/ingredients and beverages. High risk products, typically short shelf-life ready-to-eat foods, include cooked and smoked meat and fish, prepared vegetables, prepared fruit, milk, cream, cheese, yoghurt, ice cream, sandwiches and ready meals and generally require refrigeration at chill temperatures.

The number of factory barriers required will be dependent on the nature of the food product, the nature of the hazard and the profile of the final consumer, and will be established from the hazard analysis and critical control points (HACCP) study. For some products, for example spring onions, these could be graded and packed in the field (barrier 1), though for low risk products, the first two barriers only are likely to be required. For high risk products, the use of the third barrier is required for microbiological control. The fourth barrier is necessary for aseptic or ultra-clean products in which the elimination of external contamination is required, though some fully cooked ready-to-eat products with extended shelf-life may benefit from the additional controls this barrier affords.
Food products designed for sections of the population at greater risk to food poisoning microorganisms, e.g. infants, the elderly or hospital patients, may also be produced or packed within high risk areas.

Traditionally, high risk products were perceived as products in which spoilage and/or pathogenic microorganisms could grow such that shelf-life was microbiologically orientated. Products such as nuts (particularly peanuts), confectionery, snacks, and breakfast cereals were seen as low risk because their low water activity ($a_w$) prevented microbiological growth. This perception is changing, however, and it may be that high risk foods should be extended to include food products in which pathogenic microorganisms, particularly those with low infectious doses, e.g. *Salmonella*, could survive in the product (though not grow) until the point of consumption.

Whilst not absolutely necessary because of hazard control, manufacturers may choose to process food in higher hygiene zones for other reasons. This may be because of local legislation, or they believe that in the near future their product range will include higher risk products and it makes financial sense to develop the infrastructure to produce such products at an earlier stage, or simply because they believe it will facilitate brand protection.

### 13.2 Barrier 1: site

Attention to the design, construction and maintenance of the site, from the outer fence and the area up to the factory wall, provides an opportunity to set up the first of a series of barriers to protect production operations from contamination. This level provides barriers against environmental conditions, e.g. prevailing wind and surface water run-off, unwanted access by people and avoidance of pest harbourage areas. At the site level, a number of steps can be taken including:

- The site should be well defined and/or fenced to prevent unauthorised public access and the entrance of domestic/wild animals, etc.
- The factory building may often be placed on the highest point of the site to reduce the chance of ground level contamination from flooding.
- Well-planned and properly maintained landscaping of the grounds can assist in the control of rodents, insects and birds by reducing food supplies and breeding and harbourage sites. In addition, good landscaping of sites can reduce the amount of dust blown into the factory.
- Open waterways can attract birds, insects, vermin, etc, and should be enclosed in culverts if possible.
- Processes likely to create microbial or dust aerosols, e.g. effluent treatment plants, waste disposal units or any preliminary cleaning operations, should be sited such that prevailing winds do not blow them directly into manufacturing areas.
- An area of at least 1m immediately adjacent to buildings should be kept free of vegetation and covered with a deep layer of gravel, stones, paving or
roadway, etc. This practice helps maintain control of the fabric of the factory building.

- Storage of equipment, utensils, pallets, etc, outside should be avoided wherever possible as they present opportunities for pest harbourage.
- To help prevent flying insects from entering buildings, security lighting should be installed away from factory openings so that insects are attracted away from them.

### 13.3 Barrier 2: factory building

The building structure is the second and a major barrier, providing protection for raw materials, processing facilities and manufactured products from contamination or deterioration. Protection is both from the environment, including rain, wind, surface runoff, delivery and dispatch vehicles, dust, odours, pests and uninvited people, etc, and internally from microbiological hazards (e.g. raw material cross-contamination), chemical (e.g. cleaning chemicals, lubricants) and physical hazards (e.g. from plant rooms, engineering workshops, etc.).

With respect to the external environment, whilst it is obvious that the factory cannot be a sealed box, openings to the structure must be controlled. There is also little legislation controlling the siting of food factories and what can be built around them. The responsibility, therefore, rests with the food manufacturer to ensure that any hazards (e.g. microorganisms from landfill sites or sewage works, or particulates from cement works, or smells from chemical works) are excluded via appropriate barriers. The following factors apply:

- The floor of the factory should ideally be at a different level to the ground outside. By preventing direct access into the factory at ground floor level, the entrance of contamination, e.g. soil (which is a source of environmental pathogens such as *Listeria* spp. and *Clostridia* spp.) and foreign bodies, particularly from vehicular traffic (forklift trucks, raw material delivery, etc.) is restricted.
- Openings should be kept to a minimum and exterior doors should not open directly into production areas. External doors should always be shut when not in use, and if they have to be opened regularly, should be of a rapid opening and closing design.
- Plastic strips/curtains are acceptable in interior situations only, as they are easily affected by weather. Where necessary, internal or external porches can be provided with one door, usually the external door on an external porch, being solid and the internal door being a flyscreen door and on an internal porch, it would be the opposite configuration. Air jets directed over doorways, designed to maintain temperature differentials when chiller/freezer doors are opened, may have a limited effect on controlling pest access.
- The siting of factory openings should be designed with due consideration for prevailing environmental conditions, particularly wind direction and drainage falls.
The concept of hazard analysis as applied to new-build and refurbishments suggests that hazards should be considered and potentially eliminated at the design stage. For example, glass is seen as the second or third major food hazard after pathogenic microorganisms and, if relevant, allergens. It should be possible to eliminate glass as a construction material (windows, inspection mirrors, instrument and clock faces, etc.). If used, however, e.g. as viewing windows to allow visitor or management observation, a glass register, detailing all types of glass used in the factory, and their location, should be composed.

- Windows should be glazed with either polycarbonate or laminated. Traditionally, designers sought to design food processing areas without windows to control the glass hazard. Recent studies by some food manufacturers may suggest, however, that allowing employees to see out of the building, particularly into the countryside, may increase productivity.

- Where opening windows are specifically used for ventilation (particularly in tropical areas), these must be screened and the screens be designed to withstand misuse or attempts to remove them. Flyscreens should be constructed of stainless steel mesh and be removable for cleaning.

- If a filtered air supply is required to processing areas and the supply will involve ducting, a minimum level of filtration of >90% of 5 micron particles is required, e.g. G4 or F5 filters (BS EN 779), to provide both suitably clean air and prevent dust accumulation in the ductwork.

Within the internal environment, most factories are segregated into food production areas (raw material storage, processing, final product storage and dispatch) and amenities (reception, offices, canteens, training rooms, engineering workshops, boiler houses, etc.). The prime reason for this is to clearly separate the food production processes from the other activities that the manufacturer must perform. This may be to control microbiological or foreign body hazards arising from the amenity functions, but is always undertaken to foster a ‘you are now entering a food processing area’ hygienic mentality in food operatives.

Food production areas are typically segregated into raw material intake, raw material storage, processing, packaging and final product warehouse and dispatch. In addition, the flow of ingredients and products is such that, in ideal conditions, raw materials enter at one end of the factory (dirty end) and are dispatched at the opposite end (clean end). Other good basic design principles given by Shapton and Shapton (1991) are:

- The flow of air and drainage should be away from ‘clean’ areas towards ‘dirty’ ones.
- The flow of discarded outer packaging materials should not cross, or run counter to, the flow of either unwrapped ingredients or finished products.

The key differential between segregation barriers at this and the next level (high care/high risk areas), is that food operatives are freely able to move between the segregated areas without any personnel hygiene barriers (though hand washing may be required to move between some areas).
Whilst a range of ingredients is brought together for processing, they may need to be stored separately. Storage may be temperature orientated (ambient, chilled or frozen) or ingredient related, and separate stores may be required for fruit and vegetable, meat, fish, dairy and dry ingredients. Other food ingredients such as allergens, and non-ingredients such as packaging, should also be stored separately. Segregation may also extend into the first stages of food processing, where for example the production of dry intermediate ingredients, e.g. pastry for pies, is separated from the production of the pie fillings. The degree of segregation for storage and processing of ingredients and intermediates is predominantly controlled by the exclusion of water, particularly in how they are cleaned:

- **Dry cleaning.** This applies to areas where no aqueous cleaning liquids are used, only solvents, vacuum cleaners, brooms, brushes, etc. Whilst these areas are normally cleaned dry, occasionally they may be fully or partially wet cleaned, when limited amounts of water are used.
- **Wet cleaning.** This applies to areas where the entire room or zone is always cleaned wet. The contents (equipment, cable trays, ceilings, walls etc), are wet washed without restrictions on the amount of cleaning liquid used.

In addition to segregating dry areas with a requirement to exclude water, other areas may need to be segregated due to excessive use of water, which can lead to the formation of condensation and the generation of aerosols. Such areas include tray washer and other cleaning areas.

The control of microorganisms within food processing areas can only adequately be controlled by the inclusion of third level (high care/high risk) barriers following product decontamination treatments. Other hazards, however, have to be managed at the second barrier level, particularly allergens. This is to prevent the possibility of accidental contamination of products not containing allergens (and particularly those products not labelled as ‘may contain allergens’) with allergens intended for use in other products. Ideally, manufacturers who manufacture allergenic and non-allergenic products should do so on separate sites such that there is no chance of cross-contamination from different ingredients. This issue has been debated by food manufacturers in both Europe and the USA with the conclusion that, whilst only a very small percentage of the population remain affected by allergen issues (perhaps 2–3%), it is unlikely to be economically viable to process on separate sites. Segregation of allergenic components will have to be undertaken, therefore, within the same site.

As a preferred alternative to separate factories, it may be possible to segregate the whole process, from goods in through raw material storage and processing to primary packaging, on the same site. If this is not possible, segregation has to be undertaken by time, e.g. by manufacturing non-allergen containing products first and then manufacturing allergen-containing products last. Thorough cleaning and disinfection is then undertaken before the manufacture of the non-allergen containing products is then resumed. If segregation by time is to be considered, a thorough HACCP study should be undertaken to consider all aspects of how the allergen is to be stored, transported, processed and packed, etc. This would include
information on any dispersal of the allergen during processing (e.g. from weighing), the fate of the allergen through the process (will its allergenic attributes remain unchanged?), the degree to which the allergen is removed by cleaning and the effect of any dilution of residues remaining after cleaning in the subsequent product flow.

To a lesser extent, and because it is not a safety issue, label declaration issues such as non-organic components in organic foods, genetically modified organism (GMO) components in GMO-free products, vegetarian foods with non-vegetarian components, and ‘non-religion’ processed components in religious based foods (e.g. Kosher or Halal), have all caused food manufacturers to think about how raw materials are segregated. Whilst the presence of e.g. meat residues in a vegetarian product is not a safety issue, it will be an ingredients declaration issue, which could lead to poor brand perception. As for allergenic materials, segregation is usually by time and by the use of separate ingredient stores. Stores containing key components, e.g. meat in a factory producing vegetarian components, may be locked to prevent inadvertent use of the these ingredients when not scheduled, and the locking and unlocking of such stores can be recorded in the quality system.

In the future, as techniques improve with respect to product authenticity testing, there may be the requirement to segregate legally defined components. For example, consider the case of a meat manufacturer producing beef and then pork sausages on the same line. If he sold pork sausages with e.g. 50% beef content, something has either gone wrong in the process or he is making false claims. If, however, only an intermediate clean is undertaken between products and a small amount (e.g. 0.5%) of beef content was found in his pork sausages, is this ‘illegal’ or is it that residues from the previous beef sausage run can now be detected in a subsequent pork sausage run? Because such low levels of a component can be detected, does the meat manufacturer now have to undertake deep cleans between meat species or have segregated pork and beef sausage lines?

Other than for preventing product contamination, segregation within factories may be required for food operative health and safety reasons. This may be for protection against chemicals, such as the requirement for separate chemical stores, or for the protection from a particular process, e.g. the dosing of chlorine into a product washing system. The requirement for segregation and compartmentalisation of specific heat processes, e.g. ovens and fryers, or fire hazards such as bulk storage of oils and fats, has long been recognised in the food industry, and these areas are segregated with incombustible materials. Because of fires in chilled food factories that, through the use of false ceilings giving rise to large open spaces above processing areas that allowed the rapid (and unseen) spread of fires, compartmentalisation of this roof space is strongly recommended. In addition it may be necessary to segregate particularly noisy pieces of equipment (see Reducing noise exposure in the food and drink industries, Food Information Sheet No. 32; http://www.hse.gov.uk/pubns/fis32.pdf).

Finally, segregation is also now considered as a method of increasing manufacturing flexibility. For example, by splitting down large processing areas into smaller sub-units (e.g. a single 12-line meat slicing hall into 3 fully segregated
sub-units of 4 slicing lines), cross-contamination between lines can be eliminated. This is particularly the case when some lines need to be shut down for cleaning or maintenance whilst the others need to remain in production. Many large, multi-site, international food manufacturers are also considering the layout and segregation of new and existing factories such that they are suitable for multi-product food processing. This allows the manufacturer the flexibility to change the nature of the product produced at the factory within a short time period, to take advantage of ever changing economic conditions.

13.4 Barrier 3: high care/risk areas

The third barrier within a factory segregates an area in which food products are further manipulated or processed following a decontamination treatment. It is therefore an area into which a food product is moved after its microbiological content has been reduced. Many names have been adopted for this third level processing area, including ‘clean room’ (or ‘salle blanche’ in France) following pharmaceutical terminology, ‘high hygiene’, ‘high care’ or ‘high risk’ area. In some sectors, particularly chilled, ready-to-eat foods, manufacturers have also adopted opposing names to describe second barrier areas such as ‘low risk’ or ‘low care’. Much of this terminology is confusing, particularly the concepts of ‘low’ areas, which can imply to employees and other people that lower overall standards are acceptable in these 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, indeed, put greater pressures on the ‘barrier system’ separating the second and third level processing areas.

To help clear this confusion, the Chilled Food Association in the UK (Anon, 1997) established guidelines to describe the hygiene status of chilled foods (based upon microbiological criteria) and indicate the area status of where they should be processed after any heat treatment. Three levels were described: high risk area (HRA), high care area (HCA) and good manufacturing practice (GMP) zones. These zones can be updated to the following definitions:

- **HRA** – an area to process components, *all* of which have been heat treated to \( \geq 90^\circ C \) for 10 minutes (for psychotrophic *Clostridium botulinum* spores) or \( \geq 70^\circ C \) for 2 minutes (for vegetative pathogens), and in which there is a risk of contamination between heat treatment and pack sealing that may present a food safety hazard. All components in high risk will have received a minimum 6 log reduction in vegetative microorganisms.

- **HCA** – an area to process components, *some* or *none* of which have been heat treated to \( \geq 70^\circ C \) for 2 minutes, but *all* will have undergone a decontamination treatment (e.g. washing) and in which there is a risk of contamination between heat treatment and pack sealing that may present a food safety hazard. All
components in high care will have received a minimum 1–2 log reduction in vegetative microorganisms.

- **GMP** – an area to process components, *none* of which have been heat treated to $\geq 70^\circ C$ for 2 minutes, or have undertaken a decontamination treatment, and in which there is a risk of contamination prior to pack sealing that may present a food safety hazard.

In practice, GMP operations are carried out in the second barrier level of processing. In addition, the definition of HCA has been extended to include an area to further process components that have undergone a decontamination treatment, e.g. fruit and vegetables after washing in chlorinated water, or fish after low temperature smoking and salting.

Much of the requirements for the design of HRA and HCA operations are the same, with the emphasis on *preventing* contamination in HRA and *minimising* contamination in HCA operations (Anon, 1997). In considering whether a high risk or high care area 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 more economic to build to the highest standards from the onset of construction rather than try to retrofit or refurbish at a later stage.

The requirements for third barrier level high care/risk segregation for appropriate foodstuffs is now recognised by the major food retailers worldwide and is a requirement in the *BRC Global Food Standard* (Anon, 2008) and the Global Food Safety Initiative (http://www.globalfoodsafety.com).

In general, high care/risk areas should be as small as possible, as their maintenance and control can be very expensive. If there is more than one high care/risk area in a factory, they should be arranged together or linked as much as possible by closed corridors of the same class. This is to ensure that normal working procedures can be carried out with a minimum of different hygienic procedures applying.

Some food manufacturers design areas between the second ‘low risk’ and third ‘high risk’ barrier zones and use these as transition areas. These are often termed ‘medium care’ or ‘medium risk’ areas. These areas are not separate areas in their own right as they are freely accessed from low risk without the need for the protective clothing and personnel hygiene barriers as required at the low/high risk area interface. By restricting activities and access to the medium risk area from low risk, however, these areas can be kept relatively ‘clean’ and thus restrict the level of microbiological contamination immediately adjacent to the third level barrier.

The building structure, facilities and practices associated with the high care/risk (referred to as simply ‘high risk’ in the following text) production and assembly areas provide the third barrier level. This barrier has been under constant development since the late 1980s/early 1990s as part of a three-fold philosophy designed to help reduce the incidence of pathogens, particularly *L. monocytogenes*, in finished products and, at the same time, control other contamination sources.
There are a number of major sources of pathogens that could access the second factory barrier including from the raw materials, dust/dirt from the external environment, the employees and any microbiological laboratories in which pathogens are handled. To protect the product being further manipulated in the high risk area from such pathogens, the philosophy is undertaken to:

- Provide as many barriers as possible to prevent the entry of *Listeria* into the high risk area.
- Prevent the growth and spread of any *Listeria* penetrating these barriers during production.
- After production, employ a suitable sanitation system to ensure that all *Listeria* are removed from high risk prior to production recommencing.

Together with the building structure, the third level barrier is built up by the use of combinations of a number of separate components or sub-barriers, to control contamination that could enter high risk from the following routes:

- Structural defects.
- Product entering high risk via a heat process.
- Product entering high risk via a decontamination process. This may include product entering high risk that has been heat processed/decontaminated off-site but whose outer packaging may need decontaminating on entry to high risk.
- Other product transfer.
- Packaging materials.
- Liquid and solid waste materials.
- Food operatives, maintenance and cleaning personnel, etc, entering high risk.
- The air.
- Utensils, which may have to be passed between low and high risk.

### 13.4.1 Structure

Structurally, creating a third barrier level can be described as creating a box within a box. In other words, the high risk area is sealed on all sides to prevent microbial ingress. Whilst this is an ideal situation, we still need openings to the box to allow access for people, ingredients and packaging, and exits for finished product and wastes. Openings should be as few as possible, as small as possible (to better maintain an internal positive pressure) and should be controlled (and shut if possible) at all times. Similarly, the perimeter of the box should be inspected frequently to ensure that all joints are fully sealed.

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

- Processed materials and possibly some ingredients.
- Processing equipment and all associated cleaning and maintenance tools.
- Staff concerned with the operation of such equipment.
- Packaging materials.
- Finished products.
There is a philosophy, which has considerable support, that states that all other requirements should be considered as secondary to these five basic requirements and, wherever possible, should be kept out of the high risk processing area. This aids in cleaning and disinfection and thus contamination control. These secondary requirements include:

- Structural steel framework of the factory.
- Service pipework for water, steam and compressed air; electrical conduits and trunking; artificial lighting units; and ventilation ducts.
- Compressors, refrigeration units and pumps.
- Maintenance personnel associated with any of these services.
- Office and computer equipment, sensory and quality laboratories.
- Notice boards and other wall adornments.

### 13.4.2 Heat treated product

Where a product heat treatment forms the barrier between low and high risk (e.g. an oven, fryer or microwave tunnel), the heating device must be designed such that as far as is possible, the device forms a solid, physical barrier between low and high risk. Where it is not physically possible to form a solid barrier, air spaces around the heating equipment should be minimised and the low/high risk floor junction should be fully sealed to the highest possible height. Other points of particular concern for heating devices include:

- Heating devices be designed to load product on the low risk side and unload in high risk.
- Good seals are required between the heating device surfaces, which cycle through expansion and contraction phases, and the barrier structure that has a different thermal expansion.
- Sealing is particularly critical at the floor level where ovens may sit on an open area or ‘sump’. Sumps can collect debris and washing fluids from the oven operation, which can facilitate the growth of *Listeria*, and these areas should be routinely cleaned (from low risk).
- Ovens should not drain directly into high risk. In addition, when being cleaned, cleaning should be undertaken in such a way that cleaning solutions do not flow from low to high risk.
- If oven racks of cooked product have to be transferred into high risk for unloading, these racks should be returned to low risk via the ovens, with an appropriate thermal disinfection cycle as appropriate.
- Any ventilation system in the cooking area should be designed so that the area is ventilated from low risk; ventilation from high risk can draw into high risk large quantities of low risk air.
- Early installations of open cooking vessels (kettles) as barriers between low and high risk, together with (occasional) low level retaining or bund walls to prevent water movement across the floor and barriers at waist height to prevent the movement of people, whilst innovative in their time, are now seen as...
hygiene hazards (Fig. 13.2(a)). It is virtually impossible to prevent the transfer of contamination, by people, the air and via cleaning, between low and high risk. It is now possible to install kettles within low risk and transfer cooked product (by pumping, gravity, vacuum, etc.) through into high risk via a pipe in the dividing wall (Fig. 13.2(b)). The kettles need to be positioned in low risk at a height such that the transfer into high risk is well above ground level (installations have been encountered where receiving vessels have had to be placed onto the floor to accept product transfer). Pipework connections through the walls should be cleaned from high risk such that potentially contaminated low risk area cleaning fluids do not pass into high risk.

Fig. 13.2 (a) Schematic early low risk (white coated worker)/high risk divide around kettles. (b) More acceptable schematic arrangement in which cooked product is gravity fed or pumped into high risk through pipework. The schematic shows the kettles or cooking vessels mounted on mezzanines, as earlier attempts at segregation had the kettles floor-mounted such that the kettle exit pipe was too close to the floor in high risk.
13.4.3 Product decontamination

Fresh produce and the outer packaging of various ingredients may need to be decontaminated on entry into high risk. Decontamination is undertaken using validated and controlled wet systems, using a washing process incorporating a disinfectant (usually a quaternary ammonium compound) or dry systems, using UV light. Wet systems are used when the surface of the material to be decontaminated is soiled, e.g. logs of cut meat produced at one factory and then sent to the high risk area of another factory to be sliced. Critical parameters are the orientation of the spray bars, spray pressure, the concentration of the disinfectant and the speed of the conveyor. Dry systems are used when the surface of the material to be decontaminated is relatively clean; for example, in the same meat slicing factory, cans of corned beefed for slicing could be decontaminated by UV at the entrance to high risk. For UV tunnels, critical parameters are the orientation and intensity of the lamps and the speed of the conveyor.

Early tunnel design for wet spray systems placed the tunnel approximately half in low risk and half in high risk. Whilst this formed an effective barrier, disinfectant wash sprayed onto the floor of high risk making it very wet and encouraging the growth and spread of microorganisms, including *Listeria*. Best practice is now to place the tunnel almost entirely in low risk such that spray is retained in this area. Spray can be further reduced with an air knife to blow residual liquid off products prior to entry into high risk (Fig. 13.3).

As with heat barriers, decontamination systems need to be installed within the low/high risk barrier to minimise the free space around them. As a very minimum, the gap around the decontamination system should be smaller than the product to be decontaminated. This ensures that all ingredients in high risk must have passed through the decontamination system and thus must have been decontaminated.

Fig. 13.3 Disinfectant spray tunnel placed almost entirely within low risk to reduce wash spray penetration into high risk.
For companies that also have ovens with low risk entrance and high risk exit doors, it is also possible to transfer product from low to high risk via these ovens using a short steaming cycle that offers surface pasteurization of the container/packaging without ‘cooking’ the ingredients.

13.4.4 Other product transfer
All ingredients and product packaging must be de-boxed and transferred into high risk in a way that minimises the risk of cross-contamination into high risk. Some ingredients, such as bulk liquids that have been heat treated or are inherently stable (e.g. oils or pasteurised dairy products), can be pumped across the low/high risk barrier directly to the point of use. Dry, stable bulk ingredients (e.g. sugar) can also be transferred into high risk via sealed conveyors.

For non-bulk quantities, it is possible to open ingredients at the low/high risk barrier and decant them through into high risk via a suitable transfer system (e.g. a simple funnel set into the wall), into a receiving container. Transfer systems should, preferably, be closable when not in use and should be designed to be cleaned and disinfected, from the high risk side, prior to use as appropriate.

13.4.5 Packaging
Packaging materials (film reels, cartons, containers, trays, etc.) are best supplied to site ‘double bagged’. When called for in high risk, the packaging material is brought to the low/high risk barrier, the outer plastic bag removed and the inner bag and packaging enters into high risk through a suitable hatch. The hatch, as with all openings in the low/high risk barrier, should be as small as possible and should be closable when not in use. This is to reduce airflow through the hatch and thus reduce the airflow requirements for the air handling systems to maintain high risk positive pressure. For some packaging materials, especially heavy film reels, it may be required to use a conveyor system for moving materials through the hatch. An opening door, or preferably a double door airlock, should only be used if the use of a hatch is not technically possible and suitable precautions must be taken to decontaminate the airlock after use.

13.4.6 Liquid and solid wastes
On no account should low risk liquid or solid wastes be removed from the factory via high risk and attention is required to the procedures for removing high risk wastes. 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 high risk drains should enter the collection drain at a higher point than the low risk drains, so that if flooding occurs, low risk areas may flood first. The drainage system should also be designed such that drain
access points that can be used for drain cleaning or unblocking (rodding) are outside high risk areas.

Solid wastes in bags should leave high risk in such a way that they minimise any potential cross-contamination with processed product and should, preferably, be routed in the reverse direction to the product. For small quantities of bagged waste, existing hatches should be used, e.g. the wrapped product exit hatches or the packaging materials entrance hatch, as additional hatches increase the risk of external contamination and put extra demands on the air handling system. For waste collected in bins, it may be necessary to decant the waste through purpose built, easily cleanable (from high risk), waste chutes that deposit directly into waste skips. Waste bins should be colour coded to differentiate them from other food containers and should only be used for waste.

13.4.7 Personnel
The high risk changing room provides the only entry and exit point for personnel working in or visiting high risk and is designed and built to both house the necessary activities for personnel hygiene practices and minimise contamination from low risk. 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 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 outside/high risk barriers because the level of potential pathogen contamination in low risk (from raw materials), both on the operatives’ hands and in the environment, is likely to be higher.

A generic layout for a changing room should accommodate 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 captive (remain in high risk), high risk footwear is displayed/ dried. Boot baths and boot washers are not recommended as a means of decontaminating footwear between low and high risk areas as they are not an effective means of microbial control. Essentially they do not remove all organic material from the treads and any pathogens within the organic material remaining are protected from any subsequent disinfectant action. In addition, boot baths and boot washers can both spread contamination via aerosols and water droplets that, in turn, can provide moisture for microbial growth on high
risk floors. The use of boot washers in high risk should only be used to help control the risk of operatives slipping (if the floors are particularly slippery) by controlling food debris build-up in the treads of the boots.

- An area designed with suitable drainage for boot washing operations. Research has shown (Taylor et al., 2000) that manual cleaning (preferably during the cleaning shift) and industrial washing machines are satisfactory boot washing methods.
- Hand wash basins to service a single, hand wash. Hand wash basins must have automatic or knee/foot operated water supplies, water supplied at a suitable temperature (that encourages hand washing) and a waste extraction system piped directly to drain. It has been shown that hand wash basins positioned at the entrance to high risk, which was the original high risk design concept to allow visual monitoring of hand wash compliance, may give rise to substantial aerosols of Staphylococcal strains that can potentially contaminate the product.
- Suitable hand drying equipment, e.g. paper towel dispensers or hot or high velocity 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 or turnstiles are possible such that doors/barriers only allow entrance to high risk if a key stage, e.g. hand decontamination has been undertaken and detected by a suitable sensor.
- CCT cameras as a potential monitor of hand wash compliance.
- Alcoholic hand rub dispensers immediately inside the high risk production area.

13.4.8 Air

The air is a potential source of pathogens and air intake into the high risk area, and leakage from it, has to be controlled. Air can enter high risk via a purpose built air handling system or can enter into the area from external uncontrolled sources (e.g. low risk production, packing, outside). For high risk areas, the goal of the air handling system is to supply suitably filtered fresh air, at the correct temperature and humidity, at a slight overpressure to prevent the ingress of external air sources, particularly from low risk operations.

The cost of the air handling systems is one of the major costs associated with the construction of a high risk area and specialist advice should always be sought before embarking on an air handling design and construction project. Following a suitable risk analysis, it may be concluded that the air handling requirements for high care areas may be less stringent, especially related to filtration levels and degree of overpressure. Once installed, any changes to the construction of the high risk area (e.g. the rearrangement of walls, doors or openings) should be carefully considered as they will have a major impact on the air handling system.

Air quality standards for the food industry were reviewed by Brown (2005) and the design of the air handling system should consider the following issues:
• Filtration of air is a complex matter and requires a thorough understanding of filter types and installations. The choice of filter will be dictated by the degree of microbial and particle removal required (BS EN 779). For high care applications, a series of filters is required to provide air to the desired standard and is usually made up of a G4/F5 panel or pocket filter followed by an F7/9 rigid cell filter. For some high risk operations an H10 or H11 final filter may be desirable.

• The pressure differential between low and high risk should be in excess of 5 Pascals or, through openings, an airflow of 1.5 m/sec or greater may be required to ensure that one-way flow is maintained. The desired pressure differential will increase as both the number and size of openings, and also the temperature differentials, between low and high risk increases. As a general rule, openings into high risk areas should be as small and as few as possible. Generally 5–25 air changes per hour are sufficient to remove the heat load imposed by the processing environment (processes and people) and provide operatives with fresh air, though in a high risk area with large hatches/doors that are frequently opened, up to 40 air changes per hour may be required.

• The requirements for positive pressure in high care processing areas are less stringent and the minimum requirement is a balanced air flow such that low risk air does not flood into high care. Ceiling mounted chillers together with additional air make-up are typical.

• As well as re-circulating temperature-controlled air, the system may need to be designed to dump air directly to waste during cleaning operations and to re-circulate ambient or heated air after cleaning operations to increase environmental drying. With respect to drafts, the maximum air speed close to workers to minimise discomfort through ‘wind-chill’ should be 0.3 m/sec. This is typically achieved with air socks, positioned directly over the product lines.

• UK Government-sponsored work at Campden BRI and the Silsoe Research Institute investigated the measurement of both air flows and airborne microbiological levels in actual food factories, from which computational fluid dynamics (CFD) models were developed to predict air and particle (including microorganism) movements (Anon, 2001). This has allowed the design of air handling systems that provide directional air that moves particles away from the source of contamination (washrooms, hatches, doors, people, etc.), in a direction that does not compromise product safety.

• Relative humidity should be typically 50–60% to restrict microbial growth in the environment, increase the rate of equipment and environment drying after cleaning operations and provide operative comfort. Low humidity can cause drying of the product with associated weight and quality loss, whilst higher humidity maintains product quality but may give rise to drying and condensation problems that increase the opportunity for microbial survival and growth.

• If the high risk area is to be chilled, there may be conflict between any national regulations on workroom temperatures and the desire to keep food products cold. To help solve this conflict a document, *Guidance on achieving reasonable working temperatures and conditions during production of chilled foods*
(Brown, 2000), was published, which extends the information provided in HSE Food Sheet No. 3 (Rev) *Workroom temperatures in places where food is handled* (http://www.hse.gov.uk/pubns/fis03.pdf).

- Air handling systems should be installed such that they can be easily serviced and cleaned.

### 13.4.9 Utensils

Wherever possible, any equipment, utensils and tools, etc, used routinely within high risk should remain in high risk. This may mean that requirements are made for the provision of storage areas or areas in which utensils can be maintained or cleaned. Typical examples include:

- The requirement for ingredient or product transfer containers (trays, bins, etc.) should be minimised, but where these are unavoidable they should remain within high risk and be cleaned and disinfected in a separate wash room area.
- Similarly, any utensils (e.g. stirrers, spoons, ladles) or other non-fixed equipment (e.g. depositors or hoppers) used for the processing of the product should remain in high risk and be cleaned and disinfected in a separate wash room area.
- A separate wash room area should be created in which all within-production wet cleaning operations can be undertaken (Fig. 13.4). The room should preferably be sited on an outside wall that facilitates air extraction and air make-up. An outside wall also allows external bulk storage of cleaning chemicals that can be directly dosed through the wall into the ring main system. The room should have its own drainage system that, in very wet operations, may include barrier drains at the entrance and exit to prevent water spread from the area. The wash area should consist of a holding area for equipment, etc.,

![Fig. 13.4 Schematic plan of a utensil and equipment washroom area constructed on an external wall to facilitate the removal of condensation from the washroom area (whilst keeping high risk production dry) and the supply of cleaning chemicals.](image-url)
awaiting cleaning, a cleaning area for manual or automatic cleaning (e.g. traywash) as appropriate and a holding/drying area where equipment can be stored prior to use. These areas should be as segregated as possible.

- All cleaning equipment, including hand tools (brushes, squeegees, shovels etc.) and larger equipment (pressure washers, floor scrubbers and automats etc.) should remain in high risk and be colour coded to differentiate between high and low risk equipment if necessary. Special provision should be made for the storage of such equipment when not in use.
- Cleaning chemicals should preferably be piped into high risk via a ring main (which should be separate from the low risk ring main). If this is not possible, cleaning chemicals should be stored in a purpose built area.
- The most commonly used equipment service items and spares etc., together with the necessary hand tools to undertake the service, should be stored in high risk. For certain operations, e.g. blade sharpening for meat slicers, specific engineering rooms may need to be constructed.
- Provision should be made in high risk for the storage of utensils that are used on an irregular basis but that are too large to pass through the low/high risk barrier, e.g. stepladders for changing the air distribution socks.

13.5 Barrier 4: product enclosure

The fourth barrier is product enclosure and has the objective of excluding contamination, particularly from microorganisms, from a commercially sterile product. The fourth barrier approach is essential for the production of aseptic foods, but is also being used for the production of some chilled, ready-to-eat foods. Aseptic machines tend to be fully automated with the object of packing a product into a specific container. Product enclosure systems allow a degree of manual intervention and further manipulation of the product prior to packing and can be undertaken by physical segregation (a box within a box within a box) or by the use of highly filtered directional air currents.

With respect to physical segregation, ‘glove boxes’ offer the potential to fully enclose product with the ability to operate to aseptic or ultra-clean conditions. Glove boxes for the food industry work in the same way as glove boxes for the medical, microbiological or pharmaceutical industry, in which the food is enclosed in a sealed space, totally protected from the outside environment, and manipulated through gloves sealed into an inspection window. They work best if the product is delivered to them in a pasteurised condition, is packed within the box and involves little manual manipulation. The more complicated the product manipulation, the more ingredients to be added, the faster the production line or the shorter the product run, the less flexible glove boxes become. Operating on a batch basis, pre-disinfected glove boxes give the potential for a temperature controlled environment with a modified atmosphere if required, that can be disinfected on-line by gaseous chemicals (e.g. ozone) or UV light.
Glove boxes may also offer some protection in the future to foodstuffs identified by risk assessments as being particularly prone to bioterrorism. Glove boxes are only necessary, of course, if people are involved in the food production line. If robots undertook product manipulation, there would be less microbiological risk and the whole room could be temperature and atmospherically controlled!

Where the use of glove boxes is impractical, partial enclosure of the product can be achieved by the use of localised, filtered airflows. The high risk air handling system provides control of airborne contamination external to high risk but provides only partial control of aerosols, generated from personnel, production and cleaning activities, within high risk. At best, it is possible to design an air handling system that minimises the spread of contamination generated within high risk from directly moving over product. Localised airflows are thus designed to:

- Provide highly filtered (H11/12) air directly over or surrounding product and its associated equipment. The air is generated into a box which has a top and sides that direct the air downwards, and a floor that collects the air and wastes or recycles it. In some cases the ‘base’ of the box may be missing and the air is directed to waste.
- Provide a degree of product isolation ranging from partial enclosure in tunnels to chilled conveyor wells, where the flow of the filtered air provides a barrier that resists the penetration of aerosol particles, some of which would contain viable microorganisms.

By chilling the air, it is possible to keep chilled product cold whilst operating the high risk area at ambient conditions. Economically, it is also very expensive to cool the whole of the high risk area down to simply maintain low product temperatures, thus localised chilling could both cut costs and enhance product safety. Even at the lowest level of product enclosure, localised air conveyor wells (Fig. 13.5), a 1–2 log reduction of microorganisms from the

![Fig. 13.5](image-url) Chilled air is supplied from air ducts on either side of a product conveyor. The chilled air retains the product temperature and its movement, spilling over the duct surfaces, provides a barrier to microorganism penetration.
surrounding air can be demonstrated within the protected conveyor zone (Burfoot et al., 2001).

### 13.6 Future trends

The trend for fresher foods with no preservatives, but with extended shelf-lives, is likely to continue such that control of the food protection environment to prevent product recontamination, following any product decontamination prior to packaging, will remain a critical food safety issue. For short shelf-life RTE products, the nature of the hazard may change, however. For the last 20 years or so the target pathogen has been *Listeria*, but with development of severe acute respiratory syndrome (SARS), bird flu and swine flu in recent years, the future target may well be viruses.

It is also likely that the segregation lessons learned for the control of *Listeria* in short shelf-life RTE products can be applied to the control of *Salmonella* in low water activity RTE products such as chocolate, cereals and nut-based products.

Finally, advances in automation or the adoption of robots, which may mean that high risk food production can be undertaken without the use of employees, may reduce the size of high risk operating environments and could lead to modified atmosphere production as well as modified atmosphere packing (MAP).

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