Check list for purchase/sale of production equipment
– with focus on hygiene

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This guideline is developed with the support of the Danish Ministry of Science, Technology and Innovation.

Published for the Centre by:

TEKNOLOGISK INSTITUT

Holbergsvej 10
DK-6000 Kolding

www.teknologisk.dk

ISBN: 87-7756-750-1

Summary

The check list is a collection of sensible, important and relevant clarifying questions to ensure that all aspects concerning product safety are touched on. The list is intended for use in connection with development and order processing, and with the purchase/sale and renovation of both processing lines and individual parts of equipment used in connection with the production of foods, feedstuffs and pharmaceuticals.

Certain passages of the document offer further motivation and answers to the relevant questions, but the list does not provide solutions for all problems.

These questions focus particularly on areas of relevance to production hygiene, and contribute to finding best possible solution in terms of hygiene.

The focus areas are: Product-based risk zones, Project Progress; Cleaning, Documentation, Legislation/Guidelines.

The list does *not* focus on aspects such as: Statutory requirements, personal safety, mechanic stability and process yield/quality, all of which are also important parameters in connection with industrial equipment. The focus is primarily directed towards the hygienic aspects.

Key words

Equipment, Processing lines, Foods, Pharmaceutical products, Feedstuffs, Product safety, Hygienic design, Product quality, Cleaning, Legislation, Guidelines, No risk, Low risk, High risk, Flow, Bacteriology, Hygiene specifications, Plant specifications.

Definition and use of guidelines

The purpose of guidelines is to focus on the problem areas there might be in relation to the manufacture, purchase and sale of **machines and equipment** for the feed, food and pharmaceutical industries. The guideline will not focus on the special requirements for buildings in these industries.

The document is broken down into several levels of detail, as reflected in the item numbers of sections and subsections in the document.
Example:

3. Product-risk zones
   3.1. No risk
   3.1.1. Grounds
   3.1.2. Office
   3.1.3. Canteen
   3.1.4. Toilet facilities
   3.1.5. Store room

Item 3 will deal with the more general considerations under the subject heading Product. Then the level of detail is gradually increased and considerations are broken down into partial areas such that item 3.1 deals with problems related to no-risk products, and 3.1.1 examines requirements for equipment that is placed in one of the no-risk areas, more specifically the grounds.

The intention has been to include areas that are known to cause disagreement, either because opinions differ in the industry, or because the manufacturer/buyer/seller has not previously focused on this particular problem area.

The manufacturing companies have the equipment adapted to the processes it will be part of, so the food/feedstuff/pharmaceutical-producing companies will get equipment that is hygienically suited to their premises and to the products they produce. Above all, the equipment should be adapted to the cleaning procedures necessary to manufacture products that meet the food safety requirements of the consumers.

The idea is that, dependent on the situation, the manufacturer/buyer/seller should always be able to pinpoint the problems that need to be solved before a design or sales meeting is held. The document offers no final solutions, but in addition to drawing attention to areas that are known to cause problems, it refers to sources that may offer further clarification.

This guideline is prepared by a task group under the competence centre of the Danish stainless steel industry and is one in a collection of guidelines. The others are:

Guideline no. 1: Cabling and electrical cabinets
Guideline no. 2: Check list for purchase/sale of production equipment
Guideline no. 3: Conveyors
Guideline no. 4: Stainless steel in the food industry
Guideline no. 5: Design of piping systems for the food processing industry
Guideline no. 6: Installation of components in closed processing plants for the food processing industry

Enjoy!

Contents

1. Domain

This guideline is a check list for manufacturers, purchasing officers and salesmen of equipment for the feed, food and pharmaceutical industries. We have picked five focus areas. Under each area, we have listed a number of relevant problems/focus questions that should be dealt with during the manufacturing, purchasing or sales process. Each area is treated in detail in a number of subsections.

The focus areas are: Product-based risk zones, Project planning, Cleaning, Documentation, Legislation/Guidelines.

2. Limitations

The document is a check list of sensible and relevant questions that should be answered in connection with manufacturing, purchase/sale and renovation of processing lines and equipment for the manufacture of foods, feedstuffs and pharmaceuticals.

The list does *not* focus on aspects such as: Statutory requirements, personal safety, mechanic stability and process yield/quality, all of which are also important parameters in connection with industrial equipment. The focus is primarily directed towards the hygienic aspects.

3. Product-based risk zones

An important focus point is the production for which the equipment is intended, which is not just a question of whether the products are **liquid** or **solid**, and whether they should be categorised as **dry production** or **wet production**, but rather of how easily affected they are by pollution (transference) of unwanted substances to/from the equipment. Please note that equipment for dry production might be required to resist water in connection with cleaning.

Pollution not only refers to bacteriological pollution but also to cross-contamination from other products or equipment which transfer unwanted substances to the product through migration and oil leaks. It is important to establish the interaction – or lack of – between product and equipment. **Corrosion and drainability** are important words. Thus, saline deposits are known to cause corrosion, making the correct choice steel material even more important. For further information, see the competence centre guideline no. 4.

Later in this guideline, we will focus on the type of product that is to be produced. Note that not all products are equally rugged. Some are more resistant than others. Requirements may change – in particular during the production phase. The purchasing officer/sales person should therefore know whether or not the equipment sold meets the special requirements that apply.

Based on this, the product and the equipment belonging to the different areas of production are divided into three risk zones:
No risk, low risk and high risk.

The access ways between the zones represent a problem of their own and often include hygiene where the staff is requested to change clothes and footwear, and to wash hands. This will also apply to fitters. Always be aware of these special requirements. The same tools should not be used in both low-risk and high-risk zones. It might prove prudent to have several sets, and to mark these with a colour code, indicating in which area they belong.

3.1. No risk

The *No risk* concept is not used very often in the manufacturing of foods, feedstuffs and pharmaceuticals.

Areas like offices, canteens, packaging rooms and store rooms are normally not regarded as risk zones, and it is tempting to categorise them as *no-risk* zones and consequently relax the equipment requirements in these areas.
That is a mistake. The risk of cross-contamination (transference of unwanted particles) from these areas to the actual production areas is ever present and should be reduced to a minimum.

An important focus area is the definition of the hygiene design requirements necessary in these areas based on an assessment of the risk of cross-contamination *to* other production areas. Another is the special customer requirements made by the buyers of the manufactured goods to these areas.

For example, some English customers demand that the office chairs used in rooms adjacent to manufacturing rooms should be made in a material that is cleanable with water.

Disinfestation (pest control) constitutes a third important focus area: Are doors, walls and windows designed to offer the best possible protection against infestants? Do the door-closing systems work, even in connection with the installation of new equipment? Will the installation of new equipment lead to periods with increased risk of pest invasion? Who is responsible for preventing this?

3.1.1. Grounds

Authorities as well as customers often make requirements to the grounds of the factories. If equipment is to be used on the grounds, certain requirements should be clear.

Examples:

- Could there be a requirement that petrol-powered or gas-driven forklifts may be used outside, but not enter the production store room?

or

- Are there any special requirements that access ways to the refuse container be free of earth and pebbles?

or

- Are there, in relation to pest control, any requirements that all bushes and trees be removed from a certain part of the grounds?

3.1.2. Office

In addition to what would normally be expected, there might be requirements for special cleaning of these areas, particularly with regard to offices from which there is direct access to the manufacturing rooms.

Example:

- Are there any requirements that office chairs be cleanable with water?

3.1.3. Canteen

The setting up of a canteen requires special attention to efficient ventilation, particularly in connection with smoking sections. Customers of the food industry often demand that employees do not wear the same clothes in production areas as in smoky rooms. There might be special requirements for cleaning in these areas together with requirement for use of special equipment.

Example:

- Some food manufacturers have experienced customers demanding that glass equipment not be used in canteens that are adjacent to production rooms. Do similar requirements apply at your company?

3.1.4. Toilet facilities

There will often be special requirements relating to toilet facilities in buildings where there is production.

Examples:

- Are there any requirements for the use of only disposable paper towels and liquid soap from dispensers?
- Would a similar requirement at your company also apply to toilets that are not immediately adjacent to production areas, but to e.g. the canteen/offices?

3.1.5. Store room

Regardless of whether a store room is used for packaging, spare parts or products, the risk of cross-contamination to production should be taken into account. An unfortunate layout of the store room may lead to cross-contamination of the packaging/part and spread from there to production. Therefore, the packaging/part should be wrapped while stored in the store room.

In many manufacturing companies, the use of wood/paint is not allowed on the premises, including the store rooms. Condensation around the piping may be a problem, especially as not all store rooms are heated.

Examples of focus questions:

- Are there special requirements for equipment materials used in the store room area?
- Will condensation from the piping give rise to moisture damage of the packaging?
- Are there any special requirements from the customers of the investing company to the layout of the store room area?

3.2. Low risk

Low-risk area is a description used in production areas where the products are packaged, for instance in cans, glasses and bags. It can be areas where the products are stored before they are transferred for further packaging, for instance in cartons or on pallets. It may also be areas where products with natural wrapping are stored before they are transferred for further processing. Examples of naturally wrapped products are apples with peel, grain with husk, eggs with shells and whole fish with skin.

Furthermore, the Low risk concept comprises the areas of production where products are stored before undergoing the process of removing or eliminating elements of risk. These can be areas immediately before a heat-treatment or filtering process. The purpose of heat treatment is to kill microbes, whereas the purpose of a filtering process could be to remove pebbles from flour. Some companies have less rigorous requirements for equipment and machines in these areas, compared to the requirements that apply to high-risk areas. This is mainly because the products rarely come into direct contact with the equipment, or because of the knowledge that the products will subsequently undergo a process that removes the elements of risk. It is, however, essential to know exactly which processes the products will subsequently undergo. If the philosophy is that elements of risk are removed subsequently, and the product only undergoes a filtering process, it would be highly unfortunate if the equipment did not meet these requirements.

3.2.1. Packaging, Low risk

In connection with packaging machines, there will be requirements for special cleaning (see section 4 for further information).

You should always establish which products these types of packaging can be used for. In low-risk areas, we expect products to have been packaged once, which explains why the requirements for the packaging equipment in this area are not quite as rigorous. However, there might be rigorous requirements even in this area, for instance from customers for special handling.

- Are there conditions, such as cold/heat, increased pressure load and humidity – partly from the products that are to be packaged, and partly from the further transport and storage – that should be taken into account during manufacturing of the packaging machines?
- Is the packaging expected to be recyclable/reusable?
- Are there special requirements for biodegradability of the packaging?
- Does heat, cold or sunlight influence packaging durability? If so, how will this influence the packaging handling equipment we supply?
- Are there labelling requirements – special label size or glue to be used?
- Is it possible to maintain traceability from raw material to end product?

3.2.2. Foods, feedstuffs, pharmaceuticals in low risk
Food handling machinery is often, despite the low-risk label, subjected to requirements for a high degree of applied hygiene design. Purchasing officers and sales persons alike should as a minimum establish the following:

- Is the product dry/wet? It is a requirement for ever more types of equipment that they resist cleaning with water, although they are intended solely for dry products. Therefore, it should be established whether water/humidity will be present during the manufacturing process, and whether cleaning of the equipment requires water.
- Are there any risks of changes to the product through thermal load from the equipment, such as frictional heat, heating of pumps and motors?
- Are there any requirements that products maintain a certain temperature on their way from the raw materials to the finished goods inventory? Are there any requirements for a maximum holding time in order to keep the cooling chain intact?
- Is it possible to maintain traceability from raw material to end product?
- Are there requirements for a low noise level in connection with experiments on animals?

3.3. High risk (Ultra high risk)

High-risk products comprise particularly delicate products. These are products that have undergone a process removing or eliminating a risk, and which have **not yet been packaged/protected** from a new pollution. Such processes may be heat treatment processes, during which microbes are killed, filtering processes, removing pebbles and impurities, or magnetic treatments removing metal.

High-risk areas are production areas/machines where the previously mentioned products are manufactured or stored. Some industries use the term Clean Room Technology for such areas. Other guidelines distinguish between areas with direct product contact and areas with indirect product contact. For examples of definitions, see the pictures on the following page.

It should be established which of these definitions the machine supplier should take into consideration.

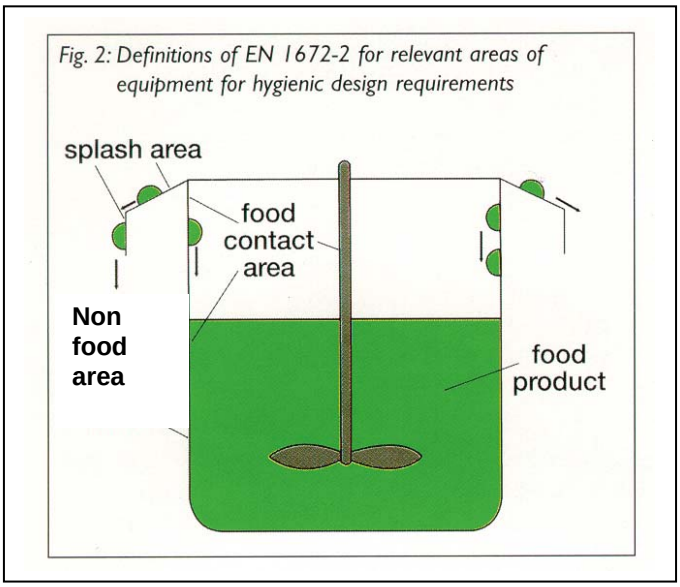


Fig. 2: Definitions of EN 1672-2 for relevant areas of equipment for hygienic design requirements

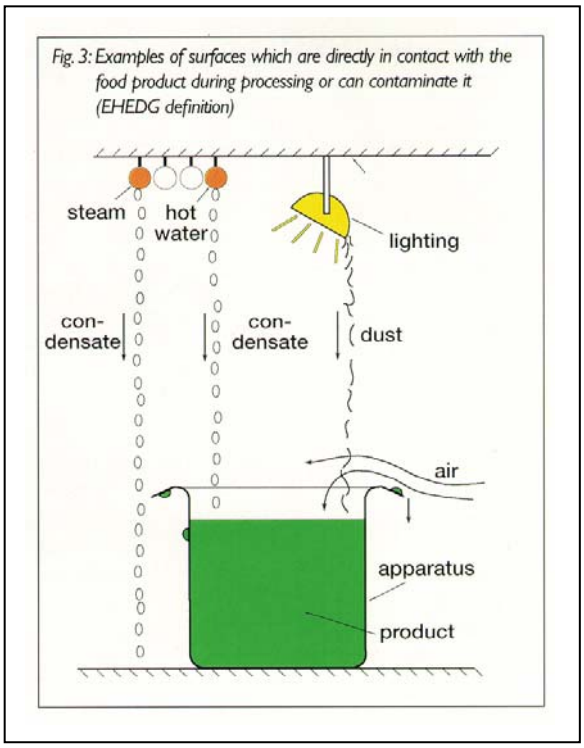


Fig. 3: Examples of surfaces which are directly in contact with the food product during processing or can contaminate it (EHEDG definition)

For equipment in these areas, the hygienic design requirements are particularly rigorous. Many industries have laid down special industry-specific requirements. One example is requirements regarding roughness of the applied steel, e.g. requirements for materials, surface structure, joints and special drainability requirements (see also under www.staalcentrum.dk: *VidenTANK – Love, standarder, guidelines).*

Furthermore, some industries operate the concept of Ultra high risk. We have seen this used in connection with particularly sensitive productions, such as the manufacture of injection fluids or of boiled, shelled shrimps, before the product is frosted. It may also be in connection with gravies and heat-treated products which have not yet been cooled, and with the propagation of yeast and enzymes for further manufacture. Such products are delicate and easily destructible by even minor contaminations. Therefore, hygienic requirements in these areas will be particularly rigorous and may include requirements that machines allow disinfection so as to be completely free of microbes.

3.3.1. Product contact packaging, High risk

Focus questions for packaging for this area are:

- How should the packaging be packaged? Is it packaged so as not to be contaminated when it is made ready for use? Many companies demand double packaging so that the outer layer is removed before the product packaging enters the high-risk area.
- Have provisions been made for storing the residual packaging during cleaning? Can residual packaging be disposed of and stored safely?

- Have machines for cutting processes, sealing processes etc. been designed so that off-cuts can be removed without ending up in the product?
- Is storage on special plastic pallets required?
- Are there any requirements that the packaging be double-packaged so that the outer layer does not enter the production room but is removed immediately before the actual packaging is made ready for use?

3.3.2. Foods, feedstuffs, pharmaceuticals in High risk

The products come into direct contact with equipment/machines, which requires a high standard of hygiene. We distinguish between wet and dry production. Dry production comprises processes where water is neither a part of the production nor the cleaning.

The purchasing officer as well as the sales person should note in which type of production environment the machine will be placed, and which special machine requirements this will entail. The many hygienic design guidelines contain useful advice in this respect. See e.g. www.EHEDG.org or www.staalcentrum.dk.

In connection with feedstuffs, cross-contamination can have fatal consequences. When transferred to another product, trace elements like copper residue from a production may have serious consequences. Similarly, serious consequences may result from the transfer of GMO-containing products to GMO-free products. Some feedstuff machines produce both animal and plant products. It is paramount that these two types are not mixed, and it is possible to clean the machines completely prior to changing production between these product types.

For some pharmaceuticals, even the transference of micro particles from one production to another can have fatal consequences.

Important focus questions are:

- Are machines designed to enable cleaning?
- Are machines drainable so as to prevent accumulation of old products or water?
- Can the machine be easily disassembled to allow cleaning of all areas within the time available to the cleaning staff, and will it be dry at the desired time of production?
- Are the product and the machine surfaces compatible, i.e. no risk of corrosion and no migration of substances from machines to product?
- Are all seals and joints designed to allow cleaning and not to change shape during production, which would entail the risk of old product accumulating in cracks and crevices?
- Which special requirements are there for the maintenance of this equipment?
- Which type of disinfection should the equipment be able to withstand?
- What is the required level of cleaning (see also section 5)?
- Should the machines be cleanable with water and soap, or is it expected that the machines be completely cleaned by vacuuming?
- Are there special requirements for water/air supply for these machines?

4. Planning

In connection with planning there are many factors to take into account. These might be statutory requirements, quality requirements of the company and special wishes of their customers. It is important to ensure the proper hygiene design all the way from the placement of buildings to the entire plant and down to the individual bolt/weld.

Hygiene design focuses on details as well as connections at the factory. In connection with purchase/sale, it is important to consider which part the individual piece of equipment plays. Thus, a piece of equipment that was originally designed for low-risk production can be placed in a high-risk room, and must therefore meet the more rigorous requirements that apply there.

4.1. Factory descriptions

The placement of the factory and its connection to other buildings and surroundings. Important focus points are: Humidity of the area, temperature fluctuations and the closest neighbours, such as fields that generate a lot of dust during harvest time, increases focus on the airflow in the rooms.
Tropical areas where humidity is considerably higher than in northern Europe increases focus on mildew growth and corrosion.
Floating factory ships or factories in a marine environment, where a high salt content in the air is expected, increase focus on corrosion.

4.1.1. General drawing of the entire factory, ground plan

- Will the purchase of machine parts/equipment necessitate a change in the present partitioning?
- What influence would it have on hygiene if the status of some rooms were changed from Low risk to High risk?
- Consider if a change of the access ways might be necessary if the equipment is too large to pass through them.

4.1.2. General drawing, machine placement

- If important changes are made to the general drawings, who will make sure they are updated?

4.1.3. Product flow

- Are there any drawings of the product flow? Will a new purchase mean changes in the existing flow and thus affect the other machines?

4.1.4. Flow of waste

- Will waste from new equipment conflict with the existing product flow?
- Will the drainage system be able to handle this new load, or will it fill up too quickly?

- Will a flow of waste that changes direction of flow in the case of overfilling block other production?
- How is the layout of the sewerage? Will a new machine change flows in the existing sewerage?
- Are special screens or drain traps required in connection with the drainage system?

4.1.5. Airflow

In high-risk rooms there is likely to be overpressure to keep out extraneous particles. Thus, establishing local extraction on machinery and/or new suction sockets from a central dust removing plant could change the overpressure in the room and cause the need for adjustment.

- Will the supply or carrying off of air from new machinery change the pressure in the room?
- Will the equipment release heat/cold, which will influence airflow through the factory?
- Will the installation of new equipment result in holes in walls, ceilings or floor that might change the overpressure/underpressure conditions in the room?

4.1.6. Figures for consumption – electricity, water, gas etc.

- Will new equipment change the existing electricity supply?
- Does the purchase/sales agreement state who will be responsible for correctly updating existing diagrams?
- Will the existing mains supply enough power even at peak loads?
- Will the new equipment entail changes in water flow?
- Will the existing pipe system be able to handle the extra load? Will the equipment change e.g. the water pressure in the entire system?

4.1.7. Quality of supplies for the factory

Always note the requirements for supplies like steam, water, gas, air and electricity.

- Are there requirements for purity – both in terms of limiting values for the number of microbes, as well as of the quantity and particle size.
- Will it be necessary to install extra filters for the equipment to reach its potential?
- Are there security measures in the event of a power failure?

4.2. Plant descriptions

The plant description focus points are: Coherence in the hygiene design of a processing line, including the combination and relative placement of machines.

4.2.1. Joining technologies

Hygiene problems often occur when the joints have not been made properly; these could be joints in the machine part or the joint/connection between two machines.

- Will product residue accumulate in the connection between machines?

- Will the customer make requirements for the permanent joints and welds in terms of e.g. verified welding logs?
- Will the seals maintain their strength and function when interacting with the product that is to be manufactured?

4.2.2. General routes

The installation of lines/equipment/components may lead to a change in conditions for the existing equipment. Therefore, you may want to establish:

- If the installation of new equipment will change the general transport routes of the company, with regard to products as well as packaging.
- If the installation of equipment/processing lines will lead to a necessary change in personnel behaviour.
- If the installation will change the general routes of electricity, process water, cooling water, steam and sewage system.
- If the installation will lead to the necessary extra insulation of existing equipment to prevent temperature changes there.
- If there are enough draining points, and if the integration of new equipment will lead to dead ends on the existing pipe system.

See also the guideline of the stainless steel industry on the installation of components in closed processing plants for the food industry.

4.2.3. Conveying (belts, flow etc.)

- Are there any requirements that conveyor belts be removable during cleaning?
- Are there guarantees of a certain level of hygiene when cleaning has been completed?
- Has it been stated how the individual conveyor belts should be cleaned, and has the process been specifically described for the selected belt type?
- Have automatic/semiautomatic cleaning systems/CIP been mounted for the cleaning of conveyor belts?

See also the steel industry guideline on conveyors.

4.2.4. Working platform and access ways

- Do the platforms meet the same requirements for hygiene design as the machines with which they are in contact?
- Do the delivered platforms ensure sufficient possibilities for the cleaning of machines?
- Will a drainable drip pan be mounted on platforms that are placed above other production equipment?

4.2.5. Ergonomics

- Is the machine designed to ensure ergonomically sound working postures for the cleaning staff as well?
- Is the cleaning staff able to access/reach the areas of the machine that require the most thorough cleaning?

- Have design principles been applied that ensure sound working postures without heavy lifts during the cleaning, setup and production phases alike?

4.2.6. Cabling and electrical cabinets

- Are there any special requirements for the cablings?
- Are there special requirements for electrical cabinets?

See also the steel industry guideline on cabling.

4.3. Machine descriptions

4.3.1. Capacity/functionality

Capacity is often a decisive matter in connection with the purchase of new machines and plants.

- Will machine capacity match the capacity of previous and subsequent processes?
- How is functionality tested – method, frequency? At which point during the process – before delivery/after setup?
- Who will participate in/be in charge of this functionality test?

4.3.2. Service

The company should know the service requirements of the machine to ensure that it remains not only in full working order, but also in hygienically perfect condition.

- What are the recommended service intervals?
- How long will one service check take?
- Are there any requirements that other machines in the area be stopped while service is carried out?
- Will the service entail discharge of e.g. ammonium, oil or the like?
- Does the supplier offer a service agreement for the machine? If so, what do these service agreements comprise?
- Are there matters in connection with freight and delivery of e.g. spare parts that need to be taken into account?

4.3.3. Space/access

The machine will take up a certain amount of space in production.

- Are there special matters during operation, such as doors that need to be opened, which will increase/change the space requirements?
- Are there special matters during cleaning that will increase/change the space requirements?
- Many machines come with a number of doors that need to be opened to enable cleaning. Will special storage devices for demounted doors be needed in connection with cleaning?

4.3.4. Disassembly

- Does the machine require service during the day?

- Will changes of e.g. knives be needed during production?
- Are refills of various types of materials required during production?
- Can these operations be performed without requiring subsequent cleaning and without the use of extremely complicated special tools?

4.3.5. Operation/stoppage time

As the operational time is decisive to production, it is important to keep track of the number of necessary stoppages per day, as well as their duration. Stops for service could be in connection with the change of tools, refill of fuels, replacement of seal etc. Knowing these factors will lead to a better overall evaluation of the machine.

- How much real operational time, stoppage time and cleaning time is necessary in connection with one production day?
- It is essential that the machine is designed to ensure a minimum disassembly time and setup time after cleaning. How much time should be calculated for cleaning, including disassembly, drying and assembly?
- How many stops are needed during one production day – the time between two cleaning intervals?

4.3.6. Design

The intended application of the machine determines its design with regard to cleaning. Machines for conveyance and handling of packaged products are not subjected to the same hygiene requirements as machines that involve direct product contact (see previous sections on No risk, Low risk and High risk).

- Are there wishes/requirements that the design be in accordance with certain guidelines? If so, which?
- Are there local requirements for equipment designs?
- Are there special requirements for the choice of materials? This includes whether the machine must resist certain detergents?

4.4. Training

Agreements on education and training constitute a very important focus point.

- Which agreements on training are made in connection with the transfer of equipment/equipment lines?
- Which agreements on training are made in connection with test runs?
- Which agreements on training are made in connection with the education of the actual operational staff, now and in the future?

4.5. The order of planning

An important focus point is the order in which the individual machines/machine parts are mounted. For example, it would be highly unfortunate if slide rails were welded over a plastic conveyor belt after the belt had been mounted, as sparks from welding/cutting

might burn holes in the belt and at the same time increase the risk of corrosion of the metal equipment.

- Have the correct order of mounting the individual machines/machine parts been considered?
- Has cleaning during the mounting and test period been arranged?
- Does the company wish to follow a certain purchasing procedure?
- How often will the chief installation engineer inspect the installations?

4.5.1. Setup routines

It is important to know which requirements are made for staff routines when the machine is to be mounted/demounted.

- Are there any requirements for the use of special tools?
- Are there special agreements on the change of clothing/footwear that also the installation engineer should be aware of?
- Are there rules prohibiting soda bottles and food in the production rooms in connection with setup of new equipment, even outside production hours?
- What are the requirements for washing hands when frequenting the production rooms?

5. Cleaning

Cleaning is crucial in connection with the manufacture of foods, feedstuffs and pharmaceuticals.

We distinguish between CLEANING = the removal of dirt (oil, grease, proteins, salts, sand, pebbles, gravel etc.) and DISINFECTION = the destruction of microbes.

When choosing/selling equipment, it should be considered whether the equipment can be cleaned by well-known routines, or whether it will be necessary to establish a new cleaning procedure. In this, you should consider if the cleaning agents can be used parallel to the ones that are already in use at your company, and whether a change might influence the equipment currently used.

As cleaning is a daily cost, it is important to make sure that it can be performed rationally. To establish this, specific tests can be performed in cooperation with the cleaning contractor. This should provide a good picture of the cleaning process. Based on this, improvements to ensure easy and efficient cleaning can be made in cooperation with the contractor.

Many machines require some sort of disassembly prior to cleaning. It will appear from the cleaning instructions how the demountable parts should be cleaned and where they should be placed during cleaning. They may be hung on the machine, placed in a cleaning rack/cart or cleaned in a dish washer. Make sure that doors requiring cleaning can be fixed in a cleaning-friendly position.

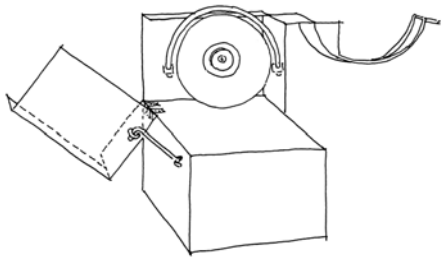
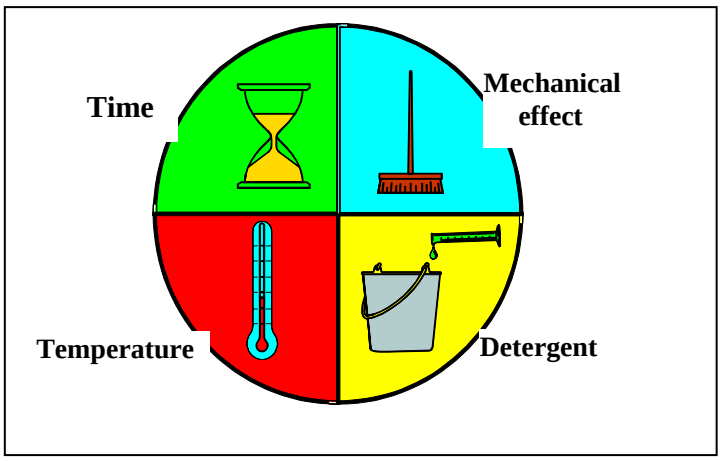


Illustration from "Fødevaremaskiner – Hygiejne og sikkerhed" (Food-processing machines – Hygiene and safety)

The same applies to cleaning of production rooms.
Ensure that the chosen method of cleaning does not simply shift the dirt from place to another. For instance, high-pressure cleaning tends to spray dirt onto ceilings instead of removing it.



Cleaning is an interaction of method (the mechanical effect), time, temperature and detergents.

The focus points are: Hygiene standard and hygiene zones – cleaning level or production hygiene requirements – cleaning methods and detergents/disinfectants.

5.1. Hygiene standard and hygiene zones

Ask about the field of activity of the factory in question. The best position for the desired piece of equipment is established. Please note that even different sections of the machine may be subjected to different requirements. Be particularly aware of the following zones: Product-contact zones, spray zones, operation panels, sections above product-contact zones and other surroundings.

5.1.1. Define area

- Define the area of the factory where the equipment belongs as well as the requirements for this particular production zone.

5.2. Cleaning level or production hygiene requirements

Often, there are different perceptions of *clean*, and it is important that the individuals involved agree on a level.

5.2.1. Define visual level after cleaning

Visually clean is not a clearly defined concept. It will vary significantly according to who is evaluating the cleaning. It should be agreed whether visible remains after wet cleaning are acceptable. If so, the dryness of such remains should be defined. Likewise, it should be described whether dust after dry cleaning is acceptable, or whether the level is *visually clean* – defined by assessments with white cloths. Examples of relevant questions:

- What is the limit for acceptable cleaning? Define *visually clean*.
- Does this level apply to all areas (including floors/ceilings)?
- If a test using a white cloth shows visible remains, does this mean that the level has not been reached?

5.2.2. Define microbiological level after cleaning

In microbiology, distinctions are made between bacteria, yeast and mildew and between live bacteria and bacterial and fungus spores (microbes in a dormant stage). Many microbes are removed by washing, but only actual disinfection (treatment with a microbial killing agent/at high temperatures will ensure that all microbes are destroyed. Results of measurements are often expressed as number of germs/cm^2 which refers to the number of bacteria per square centimetre at predefined temperature and by a predefined sampling process. As a minimum, the following should be defined:

- What is the maximum acceptable bacterial count after cleaning and disinfection?
- Which sampling process and measuring procedure should be used for the check analysis?
- Do the same requirements apply to product contact surfaces as to all other surfaces in the room?

5.2.3. Define requirements for air quality

Air is used in many places in connection with production, e.g. ventilation, airflow for powder flow control. Air extraction from machines for compressed air and vacuum in connection with purification and cleaning processes.

- Inquire about the special wishes/requirements. There may be requirements to both the quantity and quality of air.
- Are there requirements in terms of limiting values for humidity, microbes, oil etc.?

Mobile machinery should comply with DIN EN 60335-2-69/AA. At the same time, it should be decided which of the dust classes, L, M or H, the degree of filtration should comply with. Finally, the supplier should be informed as to whether the machinery is to be used in ATEX zones, and if so, in which.

5.2.4. Define special requirements for water
Water is often used for cleaning. It might be important to remember that water quality can vary greatly dependent on location. The lime, chlorine and ochre contents vary considerably from one region to the next, and abroad variations might even be quite significant. Aboard trawlers, it is customary to wash with sea water, which adds another variation to the concept of water quality.

Therefore, it is important to establish:

- If there are special requirements to water quality, bacteriologically and chemically
- If there are requirements for a special water temperature (cold or hot)?
- If there are requirements for quantities of available water?
- If there are requirements for a certain water pressure?

5.3. Definition of residue water prior to production start

In connection with equipment and cleaning, it might prove desirable to establish whether a cleaning cycle ends with a drying process.

- If the cleaning involves the use of dry ice, does it allow the occurrence of residue water from condensation?
- Make sure to establish how dry the equipment should be after a completed cleaning cycle.

5.4. Production hygiene requirements

Normally, cleaning is seen as an action carried out after production has been completed. There are, however, situations when cleaning/service checks are performed during production. In this connection, the behaviour, need for cleaning and procedures in connection with service should be established.

5.4.1. Definition of behaviour
A clear indication of the desired cleaning behaviour – the order of steps in the cleaning procedure – may have a huge influence on the end result.

- Should machines be cleaned from the top and downwards, or are there special requirements?
- In which order should rooms be cleaned?
- Can the same cleaning equipment be used in all rooms?
- Are there any requirements for especially coloured cleaning equipment for particular rooms?

5.4.2. Definition of the need for continuous cleaning during the production process
This item refers to cleaning certain critical areas while production is continued, such as washing conveyor belts, high-pressure removal of product residue, scraping off product residue etc.

- Inquire about the expectations/requirements for continuous cleaning.

5.4.3. Define the need for procedures in connection with physically interfering with the production process

- Will it, for instance, be necessary to stop a process once every half hour to remove accumulated residue, or to regularly discontinue production for as long as it takes to clean a filter?

5.4.4. Define airflow and pressure conditions

- Are there requirements for overpressure in a room, and could the installation of a new machine cause changes to this overpressure?
- Will routes for cables, water, air hoses etc. result in changes of the air pressure of the room?

5.5. Cleaning method

Before cleaning, clear distinctions should be made between wet and dry cleaning. In areas where dry cleaning is predominant, the introduction of wet cleaning of a single machine may prove disastrous.

5.5.1. Cleaning steps

Typically, a cleaning procedure would include the following steps:

Wet cleaning:

A. Rough cleaning
B. Treatment with detergents
C. Rinse
D. Inspection (possible repeat of B and C)
E. Disinfection
F. Washing-off

Dry cleaning:

A. Rough cleaning
B. Fine cleaning (sweeping, vacuuming, air pressure cleaning)
D. Inspection (possible repeat of B)

- Is cleaning of this machine performed according the normal cleaning steps, or must additional procedures be followed?

5.5.2. Manual cleaning (brushes, sponges etc.)

- Decisions should be made on the brushes/sponges that are to be used. Will the choice of scrubbing action affect the surface?
- In connection with dry cleaning, it should be considered if or how stirring up dust while cleaning a machine will affect the other machines or the staff.

5.5.3. Pressure-based cleaning (low or high pressure)

- Are there any requirements concerning maximum pressure from cleaning equipment?

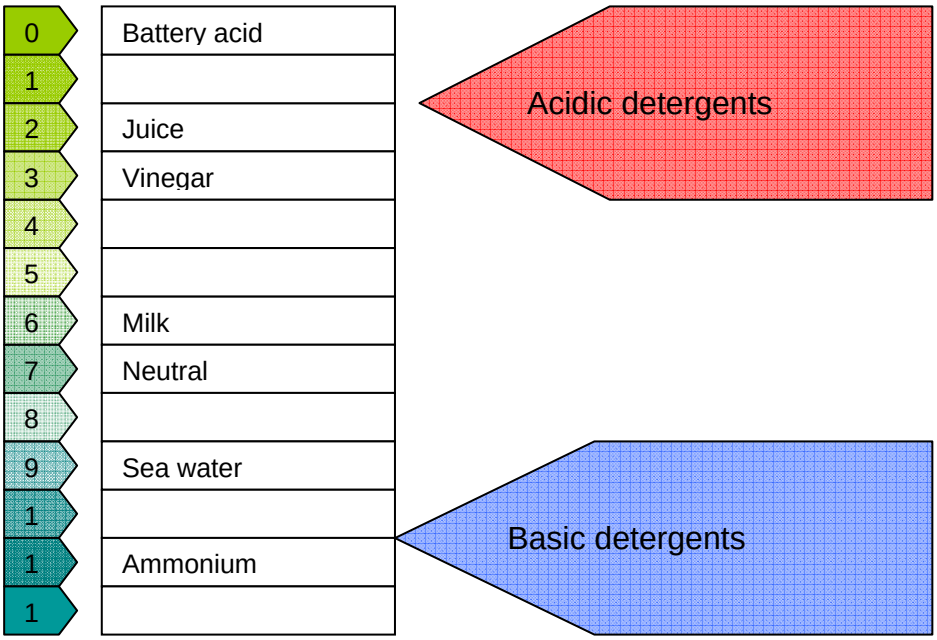
- Are there particularly sensitive areas of the machine that require protection during cleaning, e.g. electric installations?

5.5.4. Cleaning in place (CIP)

Automatic flushing of piping systems is called CIP. This can be performed by use of either stationary or mobile plants that are set with flushing flow rate, detergent content and flush time.

- Establish whether the equipment can be cleaned, using the normal CIP procedure of the company, or if a different flush time, temperature or the use of different detergents is required.
- If a mobile plant is used, has it been established in which rooms the plant can be used?
- If the CIP plant is expanded/reduced, will a change in temperature influence cleaning efficiency?

5.6. Detergents



Acidic

Detergents with a pH value of 0 to 4. Acidic detergents may have a corrosive effect on materials such as aluminium.

Basic

Detergents with a pH value of 9 to 12.

Neutral

Detergents with a pH value around 7.

5.6.1. Which should not be used?

- Do all components withstand the recommended detergent?
- Some seals may swell (change shape) when they come into contact with strongly acidic or basic detergents. Has this been taken into account?
- Does contact with the recommended detergents represent a corrosion risk?

5.7. Disinfectants

Agents with the purpose of killing microbes. These agents are not actual detergents in the sense that they cannot remove dirt, but are used after the actual cleaning to ensure the killing of microbes.

5.7.1. Chlorine agents

These have previously been commonly used in the food industry.

Advantages: Broad-spectred agent killing a wide variety of microbes, tolerates hard water and is also effective at low temperatures.
Disadvantages: May cause toxic gases, may be corroding, respiratory irritant, unstable and with short-lived effect.

- Does the use of chlorine involve any corrosion risk?
- Are there considerations connected to requirements for storage without contact to acidic products?

5.7.2. QAC – Quaternary Ammonium Compounds

E.g. Rodalon (a disinfectant brand).

Advantages: Non-toxic, no irritating odours, less corrosive, thermally stable, broad-spectred agent, long-lived effect.
Disadvantages: Low tolerance to hard water, limited low-temperature activity, unusually effervescent when used in CIP cleaning, the anti-microbial effect varies with different recipes.

- Is the local water quality (hard/soft water) suitable for QAC products?

5.7.3. Alcohols

Disadvantages: Working with alcohols may require special safety precautions, vaporise easily.

- Are there special safety precautions to consider?

5.7.4. Peracetic acid/peroxides

Advantages: Broad-spectred agent, effective range from acidic to moderately alkaline

- Is there any corrosion risk connected to the use of peracetic acid/peroxides?

5.7.5. Iodine compounds
Advantages: Broad-spectred, less irritating than chlorine, less corrosive than chlorine, low toxicity
Disadvantages: Colours porous and plastic material, relatively ineffective against spores, little effect at low temperatures, corrosive at high temperatures (over 50°C), effervescent when used in CIP wash, may have a strong odour.

- Are there any requirements for high temperatures, which may cause corrosion in connection with iodine?

5.7.6. Aldehydes
For instance formalin and glutaraldehyde. These are only used for special tasks.

5.7.7. Steam
Advantages: Only residue is water.
Disadvantages: Rigorous safety requirements in connection with steam.

- Can the company meet the special safety requirements in connection with steam?

5.7.8. UV radiation
Disadvantages: Can be harmful to humans, only works with direct radiation, which makes disinfection of corners and under the machine difficult. May degrade plastics.

- Are there any plastics present which may be harmed by UV radiation?

5.8. After-treatment

Some equipment may need some kind of after-treatment in the shape of lubrication.

5.8.1. After-treatment

- Is there any corrosion risk involved with oiling, assembly lubrication, function lubrication (full or partial)?
- Are special requirements for the lubricants that are used, such as bacteriological requirements, and which have been declared suitable for foods?
- Which should not be used?
- Drying is an important focus point in connection with after-treatment. Does production require that no residue water be present on upstart?

6. Documentation

In connection with manufacture/ordering/purchase/sale of equipment, available documentation is an important focus point. Documentation usually covers, among other things, user manuals, spare part guides, electricity, air, water and hydraulics diagrams. Subjects like documentation of a hygiene or safety assessment of the machine may also be included and relevant.

Documentation in terms of manuals is regulated through the Machine Directive. The Machine Directive dictates that customers are entitled to an adequate user manual in their native language. In addition to manuals, the supplier must also include a declaration of conformity in which the manufacturer declares that important safety measures comply with the Machine Directive. The Machine Directive can be found at http://europa.eu.int/eur-lex/pri/da/oj/dat/1998/l_207/l_20719980723da00010046.pdf.

6.1. End-user needs

Please note that manuals can be different in terms of language, professional content and layout, dependent on whether they are to be used by technical, production or office staff. Buyers can make requirements to documentation. This can be done by viewing the supplier's documentation or via the enclosed test certificates.

Documentation should always render visible end-user needs. Purchase and sales situations should, as a minimum, deal with the following:

- Clarification of scope, form and delivery of the enclosed documentation.
- Clarification of whether the documentation is adequate in terms of operation, maintenance and cleaning.
- Hygiene inspection of the machine (hygiene risk assessment).
- Documentation for the materials used (food approvals).
- Documentation for joints (welds etc.) if relevant, e.g in connection with sealed pipes, pressure etc.
- Documentation for cleanability.

6.2. Manuals

Did the purchase/sales situation allow for agreements on maintenance manuals, user manuals, service manuals and cleaning manuals?

Apart from the statutory documentation, were agreements made on any additional documentation?

7. Legislation, guideline etc.

In many cases, manufacturing rooms, processing lines, equipment and machines will be subject to requirements from authorities, manufacturers or customers. You will be able to find several documents describing such demands. In general, we distinguish between statutory requirements, certification standards and guidelines or common practice.

The knowledge portal www.staalcentrum.dk offers a clear picture of the guidelines, standards, legislation etc. available for specific fields/types of equipment and locations. It is easy to search the material and read a short description of the actual contents. The relevant links lets you order material from the source.

7.1. Statutory requirements

Statutory requirements are laid down by the authorities, and as such they *must* be observed. They are described in acts (national or EU). In Denmark, these acts tend to be implemented through circulars, executive orders and guidelines that explain how these laws are to be interpreted.

7.1.1. Denmark

You can find the statutory requirements that apply to Denmark at www.retsinfo.dk, where they have been divided according to the following guidelines: **Passed acts** *(*Act No. xxx). These have a number of **executive orders** attached to them (Executive Order No. xxx), which constitute a further description of these acts, and the executive orders are in turn implemented into **guidelines** (Guideline No. xxx) and **circulars** (Circular No. xxx).

7.1.2. The EU

EU legislation can be found at www.europa.EU.int/eur-lex.

7.1.3. Europe outside the EU

7.1.4. Asia

7.1.5. The United States, Canada

The legislation is prepared by the United States Department of Agriculture (USDA). See www.usda.gov. They approve, among other things, machines.
The Food and Drug Administration (FDA) is in charge of approval of materials. See also the FDA website: U.S. Food and Drug Administration (**FDA**) www.fda.gov.

Canada operates with a food inspection programme for factories, including the materials allowed. See also http://www.inspection.gc.ca/english/toce.shtml

7.2. Standards

Standards are solutions that are described in a document called a “standard”. By following the directions, one might achieve certification – i.e. an independent party/certifying body will perform an audit to establish whether the directions of the particular standard have been followed and subsequently issue a document/certificate stating that the audited company is in compliance with the standard. ISO 9000 and DS 3027 are examples of standards.

The International Organization for Standardization (ISO) is an international body whose task it is to inform of, measure, handle and eliminate hazards in connection with manufacturing. See also www.iso.org.

7.2.1. Denmark
Danish standards have a nomenclature beginning with the letters DS-XXX. These are standards decided by the Danish Standards Association (see www.ds.dk).

7.2.2. The EU
EN standards are agreements that apply to the entire EU. Many can be acquired through Danish Standard at www.ds.dk.
ICH standards (applying particularly to pharmaceuticals) can be found at www.ich.org.

7.2.3. Asia

7.2.4. The United States, Canada
3-A standards often apply specifically to one type of machines. Learn more at www.3-a.org.
3A Sanitary Standard/3A Accepted Practices are instrumental in improving hygiene design.

7.3. Guidelines

Guidelines are a collection of good pieces of advice or a best practice, describing the most expedient ways to operate. Many guidelines are so widely recognised that they equal standards. They may serve as sales and safety parameters in a marketing context.

FDA guidances: Guidances and guidelines can be found on the Internet.

CDER: *http://www.fda.gov/cder/guidance/index.htm*
CBER: *http://www.fda.gov/cber/guidelines.htm*

7.3.1. EHEDG

European guidelines can be bought at www.EHEDG.ORG.

The Campden and Chorleywood Food Research Association Group is part of an institute in England. They have issued a number of guidances/guidelines for specific machines, descriptions of requirements for hygienic walls, ceilings, floors etc. Learn more at http://www.campden.co.uk.

American Society of Mechanical Engineers (ASME). An American standard that covers i.a. fields within pressure-bearing equipment, which in Europe is governed by EN 13445. See also *www.ASME.org*.

8. Applied methods

The knowledge was acquired from April 2003 to July 2005 through visits to Carnitech, the Biotechnological Institute (now the Danish Technological Institute) and working

meetings with members of group B under the competence centre of the stainless steel industry.
The work has been based on legislation, common practice and standards from EHEDG, Campden & Chorleywood Food Reasearch Association Group and 3-A.

9. Safety and environmental precautions

We would like to emphasise that regardless of the hygiene design chosen, safety and environmental precautions should always have top priority. It is important not to be in conflict with legislation, e.g. by not removing safety guards with the argument that this makes the equipment more hygienic.

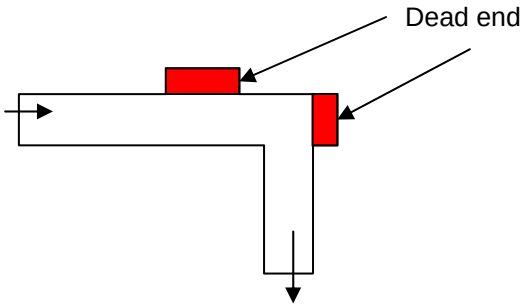
10. Literature

- *Hans Morten Henriksen*: Fødevaremaskiner – Hygiejne og sikkerhed (Food-processing machines – Hygiene and safety), ISBN 87-600-0058-9.
- *Guidelines from EHEDG*
- *EN 1672-2*

11. Concepts/terminology

Please see the EHEDG Glossary (http://www.ehedg.org).
Go to Guidelines > Library > Glossary.

The ATEX Directive	= A description of how pressure tanks should be designed
CAMPDEN	= Abbreviation of Campden & Chorleywood Food Research Association Group, England.
CIP (Clean in Place)	= Cleaning method which does not require disassembly/cleaning of the current setup. Is typically used for cleaning sealed piping systems
Dead end	= Sealed part of a piping system



Drainability = water/liquids are allowed to run off. Normally, an inclination of 3° is considered drainable

Disinfection	= Process than kills microbes
EHEDG	= European Hygienic Engineering & Design Group
FDA	= American Food and Drug Administration – a US department in charge of legislation on foods
GMO	= Genetically modified
HACCP	= Hazard Analysis and Critical Control Points – a quality-management system which, by control of critical points in production, ensures the optimal process in terms of protecting the product against chemical/physical and microbial risks.
Corrosion	= Changes in the material – e.g. rust, cracks, small unwanted holes. Corrosion of plastic manifests itself as a spongy swelling of the material.
Cross-contamination	= Pollution (transference) of unwanted substances to the product from equipment, environment or staff.
Cooling chain	= The series of process steps a product passes through before it reaches the consumer. For cooled products, it is paramount that none of the individual steps involve the risk of temperature changes in the product.
Migration	= Transfer by contact of chemical substances from one material to another. For example, plasticizers used in plastic may be transferred to children who suck on toys made from this plastic. In connection with food, the concern is that substances from the packaging may migrate to the products.
No risk	= Expression indicating less rigorous hygiene requirements.
Pathogene	= Disease-producing agents.
Disinfestation	= Pest control and control of related measures.
Cleaning	= Process removing visible dirt. Does not necessarily entail the killing of microbes (see Sterile).
SIP	= Sanitation In Place – ”cleaning of closed circuits”
Traceability	= Individual parts of the product can be traced back to where they were originally produced.
Sterile	= Free of living microbes
Sterilization	= Process that kills microbes

Dry production	= Less than xx per cent water in the product.
Wet production	= More than xx per cent water in the product.
USDA	= U.S. Department of Agriculture – department in the US, working with legislation and monitoring, particularly in connection with the agricultural sector

For further reference, see www.EHEDG.org where a number of terms are explained.

12. Change protocol

This is the first edition. Future changes will be listed here.