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EHEDG Update

General hygienic design criteria for the safe processing of dry particulate materials

This article is an extended summary of the report prepared by: The Subgroup on Dry Materials Handling of the European Hygienic Equipment Design Group (EHEDG). It is the xth in the series of EHEDG summaries published in TIFS. Copies of the full report (EHEDG Doc. 22 prepared in March 2001) by J.L. Duffey, G. Hauser, H. Hutten, K. Mager (Chairman) R.R. Maller, K. Masters, G.M.H. Meesters, W. Rumpf and G. Schleining are available from CCFRA at (pubs@campden.co.uk). Information about EHEDG can be found on the website at www.ehedg.org

Introduction

This is the first EHEDG document in which essential requirements for powder handling processes are highlighted. The design of equipment, and methods to ensure the hygienic and safe processing of dry food materials are covered. Liquid to dry solid processes (like spray drying, fluid bed coating and agglomeration), and wet solid to dry solid processes (like fluid bed drying and mixing) are included, but de-watering systems (e.g. centrifuges, decanters and filters), which produce slurries and wet cakes, are not.

Typical aspects of hygienic equipment design including cleaning of equipment, prevention of contamination, and microbial growth are considered. If wet cleaning is applied, the design criteria described in other documents also apply (EHEDG, 1993a, 1993c, 1996). If dry cleaning is needed the procedures are described in this document.

The design criteria for handling dry materials must consider:

- the eventuality of disassembly/accessibility for cleaning and inspection
- the moisture content of the product
- safety aspects including the formation of dust and exposure to it

Properties of dry materials relevant to handling

Dry materials or particulates in powder, agglomerate or granulate form can be characterized in many ways. Generally powders are defined as consisting of individual particles, and sub-structures which have a diameter smaller than 150 μm. Larger particulates are often composed of many smaller particles and sub-structures achieved spontaneously by the natural phenomena of adhesion and electrostatic forces. With regard to microbial stability of dry products, when the water activity is below 60%, little to no microbial growth will occur.

Dry materials can be characterized by both their single particle and their bulk characteristics. Typical *single particle* characteristics include: density, hardness, moisture content, porosity, shape, size, softening point, and stickiness. Relevant *bulk* characteristics include: degree of aeration, resistance to attrition, bulk density, dustiness, dust explosion class, flowability, glass transition temperature, moisture/volatile content, size distribution, solubility, electrostatic properties and wettability. It should be emphasized that the bulk characteristics of industrial dry materials are at least as important as their single particle characteristics, and for each material and that the most important characteristics influencing materials handling will vary.

Flowability is an important characteristic for dry material retention in equipment, and generally improves with an increase in particle size and particle sphericity, and a decrease of moisture content, fines content, surface stickiness and in neutralisation of surface energy/charge.

Cleaning

The criteria for hygienic design of equipment and plants for dry materials handling depends upon the moisture content of the dry material and the method of cleaning. The choice of cleaning procedure depends upon whether the plants or equipment to be cleaned is a designated dry or wet processing area or zone.

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The ability to clean equipment used in the processing of food material is essential to maintain standards of hygiene and dry material quality by:

- preventing cross-contamination and/or co-mingling of material during a production change to another material
- preventing degraded material arising from deposits remaining in the equipment
- preventing material remaining in the equipment under conditions that would cause microbial growth with possible contamination

What constitutes hygienically safe dry materials processing equipment depends upon the actual product and equipment involved. Acceptable safety can range from product contact surfaces being visibly free of any contaminating source to surfaces requiring a high level of hygiene involving regular monitoring using appropriate test methods.

The frequency of cleaning depends upon the dry material and processing equipment involved. Equipment should be cleaned at appropriate intervals to prevent malfunction and dry material contamination that would adversely affect both the quality of the dry material produced and a safe equipment operation. Deposit formation increases the frequency of cleaning.

Cleaning procedures

Suitable cleaning procedures for dry food material processing plants include both dry and wet methods, and relate to the type of food material involved. For dry powders having a water-activity below 60%, microbial growth possibilities can be rated as negligible, and dry cleaning methods are a possibility. For moist powders microbial growth possibilities are high, especially in warm and humid conditions. Wet cleaning procedures are necessary and product contact surfaces of stainless steel or equivalent are required. With oil and fat containing (non-water related) sticky powders, possibilities exist for deposit formation on product contact surfaces and dry material quality degradation through heat and/or mechanical handling. Wet cleaning procedures are necessary and product contact surfaces of stainless steel or equivalent are required.

Dry cleaning

Dry cleaning is applicable for dry food material contact surfaces where:

- dry material remaining in the equipment as loose layers or dust covering does not present any risk of degrading the quality of the dry material subsequently produced
- possible cross-contamination of dry material during a production change to another material presents no problem to the quality of the dry material subsequently produced
- dry material remaining in the equipment does not present any risk of microbial growth occurring due to the prevailing moisture content, temperature, and humidity conditions
- dry material is non-hygroscopic, non-sticky

Manual dry cleaning

Dry cleaning procedures should be focused on removal of the main deposits and product-layers by a vacuum cleaner followed by brushing and/or scraping the surfaces. Dust formation should be avoided as much as possible. The deposits achieved by this method must be carefully discharged or removed by a vacuum cleaner. Cleaning with pressurized air should be avoided as this creates dust clouds that can transfer contaminants to other areas (and if used, the air should be of processing air quality and filtered).

Equipment suitable for manual dry cleaning must be safely accessible. If equipment has to be dismantled to gain access, dismantling must be possible without the use of special tools and lifting tackle.

The use of mechanical procedures (brushes, scrapers) results in the recovery of a secondary quality grade material. Use of dense particles results in recovered material mixed with the cleaning aid and therefore cannot be used unless an economic and effective separation technique is available or if the inert cleaning aid acts as an additive for the dry material mixture to have another end-use.

Hand-held cleaning equipment used on food material contact surfaces:

- must not be used for any other purpose or on any other material
- must be regularly cleaned and maintained
- must be clearly marked and stored in a clean and dry location

Damaged hand-held cleaning tools must not be used as there is a risk of broken parts remaining in the equipment and passing to the dry material discharge area during subsequent operation, with possibility of product contamination during the filling of bags or silos, etc.

Semi-automatic dry cleaning

Acceptable procedures include the use of

- in-place air jets and retractable nozzles that blow or sweep dry material off a contact surface into the product collecting area

- dense particles such as rice, crystal sugar and plastic pellets conveyed as an abrasive medium through ductwork handling dry material
- vacuum cleaning

Semi-automatic procedures also require availability of access points, inspection ports, and manholes for visual inspection of surfaces after cleaning.

Use of air jet cleaning methods will result in the recovery of dry material within the quality specification as long as the surfaces being cleaned are not fouled with degraded material and the air used is of processing air quality and filtered.

Wet cleaning

Wet cleaning can be carried out on dry food material contact surfaces where:

- dry material remaining in the equipment as deposits or as light powder layers represents a real risk of degrading the quality of the dry material subsequently produced
- any cross-contamination of dry material during a production change to another material cannot be permitted
- dry material remaining in the equipment represents a real risk of microbial growth occurring due to prevailing moisture content, temperature, and humidity conditions
- dry material is hygroscopic and/or has a low softening point that gives rise to deposit formation on contact surfaces.

Wet cleaning can be conducted manually, semi-automatically or automatically but is always followed with a rapid drying out procedure.

Manual wet cleaning

The cleaning procedure will normally start by the removal of the main deposits by a dry cleaning procedure. The product contact surfaces are then pre-soaked either by hot or cold water with or without detergent.

Finally, the equipment is cleaned by means of brushes, scrapers or waterhoses. After removal of as much water as possible by draining, the equipment has to be immediately and thoroughly dried out by passing warm air through the equipment before production of dry material can recommence.

Equipment suitable for manual wet cleaning must be properly designed, accessible and be safe to do so. If equipment has to be dismantled to gain access, dismantling must be possible without the use of special tools or lifting tackle.

Acceptable procedures include use of hand-held:

- brushes and containers of washing liquid (water/detergent)
- water hoses

Hand-held cleaning equipment used on food material contact surfaces:

- must be cleaned immediately after use and must not be used for any other purpose or on another material.
- must be regularly inspected for damage and must be maintained. However, damaged brushes must not be used, as there is a risk of further damage occurring during use and broken parts remaining in the equipment which can pass to the dry material discharge area during subsequent plant operation and contaminate dry material in bags and silos, etc.
- must be clearly marked and stored in a clean and dry location

Semi-automatic wet cleaning

A semi-automatic cleaning procedure, sometimes referred to as washing-in-place (WIP) is a wet cleaning procedure of fully or partially assembled equipment specifically designed for this purpose where visual inspection and approval of cleanliness of a washed surface is required before equipment can be operated.

Semi-automatic cleaning systems involve use of washing nozzles placed or lowered into ductwork and/or silos or vessels that require cleaning. These nozzles can be in the form of fixed spray balls, nozzles or jets, or rotating spray devices (liquid turbine driven). Each nozzle or jet sprays water, detergent or cleaning fluid over a given contact surface area, and the nozzles or jets are located so that the entire dirty contact surface is subjected to direct impingement by the cleaning spray.

Safe dismantling equipment is necessary in order to install a semi-automatic cleaning washing device and also to give access for inspection.

Cleaning liquids are normally collected from drainage ports on equipment and recirculated within the cleaning piping system. Separate holding tanks are used for washing water, detergents or special liquids (with wetting agents, emulsifiers, acids and alkalis) as required by the food material processing operation.

Rinsing with clean water completes the washing operation. The whole cleaning sequence can be automatically controlled (computerized). Dirty cleaning water and washing liquids are treated according to local liquid effluent requirements.

After cleaning, draining, and inspection, all equipment has to be immediately and thoroughly dried out

by passing warm air through the equipment before production of dry material can recommence.

Automatic wet cleaning

Automatic cleaning-in-place (CIP) is a fully automated cleaning procedure for equipment specifically designed for this purpose where there is no need to dismantle any parts of the equipment to locate cleaning nozzles or to inspect surfaces for cleanliness after washing.

Automatic cleaning systems feature fixed mounted cleaning devices/nozzles in vessels, ducts, silos, etc., interconnected with piping to recirculation pumps and the cleaning liquid storage tanks, one each to hold the various cleaning media used, i.e. water, detergents, alkalis, etc.

All valves in the piping system are remote controlled. The duration of the sequence of the cleaning cycle is automatically controlled (computerized) and the cleaning program is selected according to the type of plant operation and material processed. Automatic drying out of the equipment is also part of the cleaning sequence and the equipment must remain closed after the cleaning operation.

After cleaning and draining all the equipment has to be immediately and thoroughly dried out by passing warm air through the plant before production of dry material can recommence. Frequency of periodic validation of the cleaning procedure depends upon the dry food material being processed.

Construction materials

Construction materials for equipment coming in contact with food (including associated adhesives) must be food grade (FDA-approved or national equivalent).

Selection of construction material depends upon the dry materials, method of cleaning and cleaning agents to be used.

Metals

Hygienic dry materials handling is best conducted with product contact surfaces of stainless steel. Suitable grades are SS 304, 304L (EN 1.4301/1.4306) and SS 316, 316L (EN 1.4401/1.4404). Aluminum and aluminum alloys (coated and non-coated) might also be used as dry material contact surfaces where only dry cleaning is applied.

Non-metals

Plastics (e.g Polycarbonate, PEEK, PVDF, PA and PTFE) and elastomers (e.g. NBR, Viton, Silicon, FEP-silicon) may be used, but contact should be limited where the dry material is abrasive. These materials must retain their original surface condition when exposed to the processing and cleaning conditions.

Fabrics and non-metallic filter materials used in connection with the cleaning of air involved in dry materials handling systems must be non-toxic, cleanable, and not impart contaminating smell to the dry material. Non-metallic surfaces can create electrostatic charges on the material, which can be problematic.

Hygienic design criteria

Dry materials handling must take into account the possibility for material lump formation, creation of dust explosion conditions, high moisture deposit formation in the presence of hot air, and material remaining in the equipment after plant shutdown (even if a degree of self-emptying is achieved).

Product contact surfaces

Product contact surfaces should be smooth and resistant against dry material contact and also against liquid chemicals used in wet cleaning. Product contact surfaces therefore should be free of crevices, pitting, pinholes and any hairline cracking that can cause material penetration and cleaning difficulties. A roughness standard of $Ra < 0.8$ μm is recommended where there is a risk of microbial growth associated with high moisture content in the dry material or wet cleaning.

In order to carry out a dry cleaning operation, contact surfaces should be fully accessible for safe manual cleaning and inspection. For a hygienic wet cleaning operation, contact surfaces should not be horizontal, but have a slight slope to facilitate drainage of cleaning solutions. The possibility for product contact on sharp internal corners ($r < 6$ mm) and recesses, etc., where dry material can accumulate, should be avoided. Windows and inspection ports mounted in product contact surfaces should be flush with the surrounding surfaces to minimise dry material build-up. When using non-metallic materials as contact surfaces, the porosity of the materials should be investigated with regard to ease of cleanability.

Welding

Welds must be accomplished in a way that avoids susceptibility to accumulation of dry material and localised corrosion. It is important to ensure that the metallurgical properties of the weld material are as close as possible to the parent metal. General criteria for welding are described in the EHEDG Doc 9 (EHEDG, 1993b) "Welding stainless steel to meet hygienic requirements". Intermittent (spot) welding of dry product contact surfaces is in principle not acceptable.

Normally, the surface roughness of welds does not meet the recommended figure of $Ra \leq 0.8$ μm. The cleanability of these parts in relation to the actual dry material being handled should be validated.

Static seals (gaskets) for duct and flange connections

Static seals should be of an elastic material, have a non-porous surface and be cleanable. Static seals should

be clean before assembly and the possibility for penetration of dry material into the gasket or seal during equipment operation should be avoided. PTFE can be used as a static seal in combination with an elastomer (food grade, FDA-approved or national equivalent). The PTFE should be of high-density resilient quality. Metal-to-metal contact duct assemblies and paper-type gaskets between flanges can be applied where a plant operates at atmospheric pressure and requires no wet cleaning.

Inflatable seals, e.g. for valves (Fig. 1) or around access doors and operable inspection ports should be used to prevent dry material build-up around the mounting frames.

Flexible connections

Flexible connections between duct ends are always liable to cause dry material build-up between the flexible material and metal duct surface. Telescopic connections should be avoided because of gaps at the duct ends (Fig. 2) causing hygienic and operational risks. A build up of material between the ducts cannot be avoided, but must be minimized.

A flexible plastic material avoiding any crevices must seal the duct ends. Ring clamps for mounting flexible connections should be placed close to or right at the duct end to minimize dead areas for dry material build-up.

Flexible connections must be easy to disconnect. Therefore the distance between the duct ends must be large enough to accomplish ease of flexible connection assembly and disassembly, and inspection of internal conditions of the ducts. Inflatable seals can be used where disconnecting is often necessary (e.g. for discharge or filling systems).

Dynamic seals for shafts

Unsealed shafts in equipment contacting product are not recommended. Both lipseals and mechanical seals can be used in dry materials handling. The actual seal design is selected according to whether it is under pressurized, vacuum or atmospheric, conditions, and the degree of acceptable leakage.

Since liquid flushed seals normally present operational problems in dry materials handling processes, air purge seals are recommended to prevent dust entering the seal. The air purges also act to maintain the seal dry during operation and assist in drying out the seal after equipment wet washing. Filtered air or nitrogen should be used to prevent product contamination by ingress of dirty air.

Shaft entries that are sealed require extra attention in equipment handling of dry material. In principle, all dynamic seals can leak, but leakage is minimized by frequent and proper inspection, maintenance, and cleaning. Since seals and their housings generate local areas where material can collect causing microbial growth opportunities and a source of product contamination, there should be ready access to seals for cleaning and inspection.

Bearings

No bearing should be in contact with dry material. If unavoidable, bearings can be protected by seals. It should always be evaluated whether air purging of bearings during operation is required.

Hinges

Hinges should not be in contact with dry material. They should be placed only on the outside of equipment and be accessible for easy cleaning and maintenance. Continuous style piano hinges are not recommended.

Fasteners (screws, bolts, nuts)

Fasteners in contact with dry materials should be avoided as much as possible. If this cannot be avoided, metal to metal contact is allowed, but only where no wet conditions occur during operation and cleaning. As equipment dismantling for cleaning, inspection, and maintenance involves loosening of nuts and bolts, ease

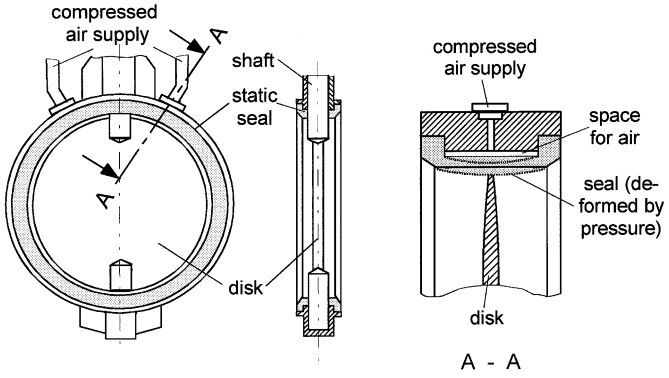

Fig. 1. Example of an inflatable seal of a butterfly valve for dry products.

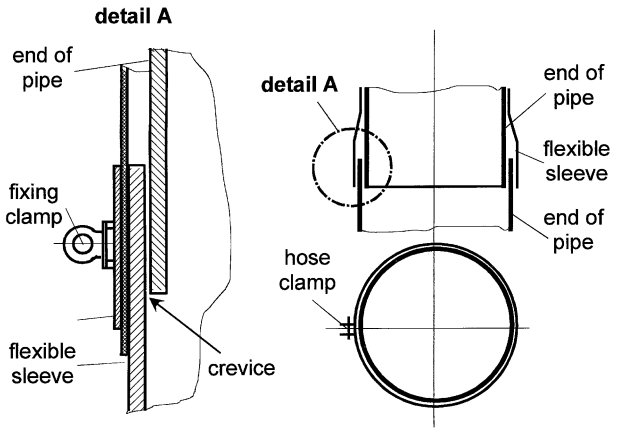

Fig. 2. Telescope-like moveable connection between duct ends causing hygienic risks.

of removal is essential. Any potential thread seizure through over-tightening must be prevented and therefore selection of the nut and bolt material is important. Rivets should not be used for joining surfaces.

Hygienic design criteria for fasteners on equipment used in liquid processing (EHEDG, 1993c) also apply to dry materials handling, and especially when dry materials handling involves a wet cleaning procedure.

External surfaces and insulation

Hygienic design criteria for external surfaces of equipment are given in the EHEDG (1996) *Doc. 13,* "*Hygienic design of equipment for open processing*".

It is recommended to avoid use of, wherever possible, insulation material in order to prevent the possibility of microbial growth or dust build up within the material. If for process, safety and/or environmental reasons, insulation is needed, air insulation is the first recommended option. Visual inspection of insulated surfaces should still be possible to access build-up of dirt. If this is not possible, insulation materials like mineral wool or expanded polystyrene should be used. However, these materials should be used with a full welded protected external surface/cladding since these materials must not be allowed to get moist or wet.

For insulating against cold surfaces, insulation materials must be fully enclosed to prevent ingress of moisture. In cases where condensation may take place on dry product contact surfaces due to creation of cold spots, equipment and silos located outside or in cool processing areas require insulation.

Wiring and cabling

A potential risk of cabling is the contamination caused by the collection of dirt and dust as well as microbial growth. The following hygienic design criteria are required:

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

Powder tightness of equipment

Manual dry materials handling will always be a possible source of dust emission and also, when opening up equipment containing dry material. Therefore any areas of manual dry materials handling and equipment access should be fitted with local air extraction systems.

To prevent possible egress of dry material to the atmosphere, equipment handling dry materials should be powder tight during operation and wherever possible operate under slight vacuum, although this does create the possibility for inward leakage of atmospheric air into the equipment.

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