THE DAIRY PRACTICES COUNCIL®

GUIDELINES FOR CLEAN ROOM TECHNOLOGY

Publication: DPC 14

JANUARY 1994

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ABSTRACT

This guideline provides an overview of the essential factors which need to be considered to utilize "clean room" technology to minimize dust, particulate, and microbial contamination in dairy food processing.

PREFACE

This new guideline was developed by Ms. Elizabeth Jedrziewski, Ultra Dairy, Div. of Dellwood Foods, Inc., and Ms. Virginia MacArthur, Hershey Chocolate U.S.A.

It is suggested this guideline is a logical companion to DPC l3, *Environmental Air Control and Quality for Dairy Food Plants*, DPC 56, *Dairy Product Safety (Pathogenic Bacteria) for Fluid Milk and Frozen Dessert Plants*, and DPC 57, *Dairy Plant Sanitation*.

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GUIDELINES FOR CLEAN ROOM TECHNOLOGY

INTRODUCTION

There has been rapid growth of clean room technology in the last two decades, particularly in the electronics industry (manufacturers of semi-conductors) and the pharmaceutical industry with the goals of eliminating dust, particulate, and microbial contamination. The increasing consumer demand for improved product quality and extension of shelf life has led various food industries to evaluate clean room technology, especially those techniques aimed at control of microbial contamination. This technology, when used in combination with new construction, processing, and packaging technologies, has yielded both product quality and safety improvements for the food industry.

Thus, in order to assure purity, or in some cases comply to regulatory standards, an increasing number of food product manufacturers are adopting "clean room" technology.

CLEAN ROOM DEFINITION

Many literature sources, when discussing clean room technology, refer strictly to air quality. However, for the purpose of this guideline, various aspects of building design and construction will be included to provide a total systems approach.

Every design feature, internal component, material used, and operating practice must either be neutral in terms of contaminant generation or actually contribute to cleaning the environment.

For the dairy industry, this is an especially important consideration due to the microbially sensitive nature of dairy products. Opportunities to minimize microbial contamination must be given careful consideration during both initial plant design and product development. This must then be supported by appropriate maintenance, sanitation, and monitoring procedures.

The most common uses of clean room technology in the dairy industry are in conjunction with aseptic, extended shelf life, and cultured processes. Due to variations in the processing and filling technologies for these operations, a manufacturer may choose to have an entire clean room for maximum flexibility. However, from a Hazard Analysis Critical Control Point (HACCP) approach, there may be only one critical control area in the process. In such a case, isolation of this small area can save the processor the expense of an entire clean room by localizing control.

Vertical laminar flow devices such as portable clean rooms or downflow hoods can isolate a critical control point area and continually "wash away contamination". A clean room approach to the surrounding room is still recommended.

GENERAL CONSTRUCTION

Floors

An impervious growth surface is essential. Due to the difficulty in obtaining maintenance-free totally sealed floors and smooth grouting, tile floors are not preferred. A monolithic floor coating specifically chosen with the intended product, cleaning chemicals, and traffic in mind would be preferred. Other options would include very durable clear urethanes that can be used alone or in combination with epoxy floor paints. Paint used must be acceptable for use in food plants for the conditions present.

Wood, metal tiles, and resilient flooring materials such as vinyl, tile or linoleum should not be used due to absorbency, rough surfaces, and tendencies toward scratching. Whatever surface is chosen, proper preparation of the substrate is essential.

Footbaths containing a sanitizing solution should be placed at all entrances to filling, clean, or other processing areas. The sanitizing solution used will depend on the type of product and sanitizing agen ts used within the plant. The footbath solution strength must be monitored, and the footbaths should be emptied, cleaned, and refilled at least daily. The intervals required for maintenance will be affected by the foot traffic incurred, and the type and quantity of organic material introduced as contamination. Refilling once a day may not be adequate. Monitor ppm active ingredient available via a dip stick test kit for the particular sanitizer used. After frequent testing, i.e. every two hours per site for a period of one week, the estimated interval required for maintenance of a particular location can be determined.

Floor Drains

Listeria and other organisms are frequently isolated from floor drains. Because of this, floor drains should not be located underneath or near filling equipment. In fact, some literature suggests locating the drains outside of the filling area, accessing the drains by drainage holes through wall bases.

Wherever the location, the drains must be constructed and maintained to insure proper drainage. Drains must be individually trapped so that contamination cannot be transferred from one section of the plant to another through the drains. They must be readily accessible for cleaning.

Drains should be frequently brush-cleaned with a manual cleaning solution and then sanitized with a 200 ppm active chlorine solution or equivalent. Ideally, drains should be sanitized at start-up and after clean-up at the end of the processing day. A more frequent schedule may be necessary in some operations.

Not only is the location of a drain important, but also its size. The floor should have proper slope leading to the drain. **Under no circumstances should high pressure hoses be used to clean drains**. Such action encourages aerosolization of microflora in drains including Listeria moncytogenes. High pressure spraying should never be conducted in a production/packaging area during food processing. When possible, drain pans on equipment should drain directly to the drains or into pails which may be poured directly into the drains.

Brushes used for cleaning floor drains must be used solely for that purpose. They must be cleaned, sanitized, and stored either in a sanitizing solution or stored dry between uses outside of the clean room. Dedicated, color coded brushes should be used for specific service. Separate brushes should be used for internal and external surfaces. It is recommended that wood and natural fiber bristle brushes not be used since they absorb moisture and provide a propagation area for bacteria. Food contact brushes should not be stored with environmental brushes. The FDA requires the segregation of brushes to avoid cross contamination. The condition of brushes must be monitored on a regular basis.

Walls

Walls should be constructed of smooth impervious material.

If concrete block is chosen, all pores should be filled, usually by using two coats of latex block filler, with a 20% mixture of cement. Then, two coats of semi-gloss or glossy enamel should be applied.
Glazed tile or vitreous china is a good option if done properly. The surface finish should be glazed, not dull or rough. Joints should use acid-proof or epoxy grout as a finish coat to seal the cement grouting.

Walls should be cleaned (scrubbed), foamed, or fogged at least once a week.

Ceilings

Ceilings should be smooth with a washable finish. Areas around light fixtures must also be tight and clean. As is true in any production area, lighting fixtures must be protected with shatter-proof material.

Ceilings should be cleaned (scrubbed), foamed, or fogged at least once a week.

EQUIPMENT AND PRODUCT HANDLING

All pasteurized surge tanks should be equipped with a sub-micron (HEPA) air filter, incinerated air, or other source of clean air to protect product from contamination.

When possible, gravity flow from surge tank to filling machine should be employed to eliminate pumps downstream from the pasteurization process.

Conventional gaskets are a potential source of product contamination. To minimize contamination, areas which need attention include 1) minimal use of elbows, fittings, and valves, and 2) inclusion of steam seals on sensitive valves and shafts.

When possible, equipment surfaces should be sterilized with hot water [180˚F (82.2˚C)] for a minimum of 10 minutes. Aseptic and extended shelf life require more heat or chemical treatment in order to render the product zone commercially sterile. Cooling must then be accomplished by sterile cool water, or by chasing with compressed, chilled, and bacteria-free air.

The potable water source may require microbiological analysis for level of contamination and types of microorganisms present. The results will be helpful in the selection of sanitizing agents. Ultraviolet treatment of water may be advantageous.

Conveyors, cases, and corrugation are all sources of microbial contamination. All of these should be kept separate from the filling room. If boxes of product cartons must be taken into the filling room, they should be dusted or wiped off then fogged with chlorine before conveyed into the room. Conveyor belt systems have been shown to be sources of Listeria (Klausner and Donnelly, Pritchard, et.al. in preparation). Cleaning and sanitizing regimens should include both the product contact surface and the underside of the conveyor belt.

When possible, a minimum amount of conveyors (split conveyors to be separate or different at junctions of filling and case-off rooms) should be used to transport cartons outside the filling room where product will be put into cases or corrugation.

Recent literature has indicated that the major source of total aerobes, yeast and mold, and staphylococci in microbial aerosols in milk and ice cream plants were found to be caused by high-pressure water spray used in processing and packaging. A low pressure, chlorinated water supply should be available for sanitizing needs during packaging. During operation, water hoses (spray) should not be used on filling equipment.

AIR HANDLING

The most critical component of clean room technology is air handling. This is because micro-organisms can exist in the air and in water droplets in the air and can easily contaminate product and product contact surfaces.

Recent advances in air handling can now provide air for critical areas in dairy processing plants that is nearly contaminant free. Heating, ventilating, and air conditioning (HVAC) systems now available can be equipped with high-efficiency particulate air (HEPA) filters that typically can remove more than 99.9 percent of particulates down to sub-micron size. A HEPA filter also must be installed on extended shelf life (ESL) packaging systems. The air filtration units must run continuously (24 hours a day, seven days a week) to maintain HEPA filter sterility.

The HVAC/HEPA System must be installed and operated to provide the critical rooms with the cleanest air of the highest pressure so that the air flows from openings in the room outward to adjacent rooms with lower air quality requirements. This also ensures that the air is the correct temperature and humidity. Air exchange rates are typically 12-20 times per hour.

MONITORING

Once proper design has been completed and construction begun (or at least planned), a HACCP approach must be used to identify the Critical Control Points that will require monitoring.

Air quality will most definitely be a critical control point. Please review DPC 13, Environmental Air Control and Quality for Dairy Food Plants for suggested techniques. In addition, a thorough preventive maintenance program must be implemented.

PROCEDURES

Procedures to enumerate micro-organisms on equipment surfaces and in the air can be found in Standard Methods for the Examination of Dairy Products, 16th Ed., APHA.

STANDARDS

Some recommendations for bacterial standards for equipment and utensil surfaces do exist. However, sampling equipment (swabs, sponges, RODAC plates, etc.) and plating procedures vary greatly. Some plant programs "pick a pathogen" and send environmental swabs to an independent testing lab at weekly or monthly intervals. While this practice serves to indicate the "hot-spots" in the plant, most plants also need to establish an in-house program to determine the microbial condition of the plant, the plant equipment, and the effectiveness of the sanitation program.

Quality assurance laboratories should not be placed within an area adjacent to the production area as specific tests may include enriching for pathogenic bacteria. There should be a minimum of cross traffic flow between the laboratory and those individuals directly associated with the production of product.

The first step in establishing a program is to define the objectives of equipment, swabs, environmental swabs, and air sampling plans. For example, is the program directed at identifying specific sources of pathogens in the plant, detecting areas of psycrotrophic organisms at the filling areas, determining the number of viable organisms or the number of particles in the air, or any other specific needs?

Secondly, decide on sampling points for each area within the objectives of each plan. High traffic areas, equipment with a lot of extended run time or maintenance, or other specific areas may need more attention.

The next step is to determine the mechanics of the microbiological (or particulate) analyses to be performed. For example, how frequently will each area be tested, what sampling method will be employed, which organisms will be enumerated, how will results be interpreted?

Lastly and most important, standards must be established for each sample point in the program. Each plant should establish its own values for what constitutes a clean area. The results of routine testing are meaningless unless these values are determined.

RECOMMENDED STANDARDS FOR AIR IN FILLING ROOMS

These are some reported standards. Each facility must determine their own acceptable standards. The standard values recommended by Biotest (the RCS Sampler) in industrial plants where perishable food stuffs are produced is a range of <200 to <500 cfu/m3.

Diversey Corp. has reported that approximately 250 cfu/m3 is an acceptable level of microbial air quality in dairy filling operations. Typical (achievable) standards are <300 cfu/m3 for bacteria and less (100-200 cfu/m3) for yeasts and molds.

SURFACES

Because different sampling methods are used and different areas are swabbed, it is difficult to print recommended values; however, the following are some values for food contact surfaces, after cleaning and before sanitizing:

- < 100 cfu SPC or APC
- < 10 cfu yeast and molds
- < 3 cfu coliforms

When monitoring surfaces for microbial contamination via culturing, it is recommended that a calcium alginate swab be specified since fibers dissolve in ringers or sodium citrate solution. Use of this specific swab helps assure recovery of all microorganisms.

CLOTHING AND EMPLOYEE PRACTICES

Among the most serious sources of contamination are employees. A stationary human operator can emit between 100 to 100,000 bacteria colonies per hour (?), that are often potentially harmful organisms.

Contamination potential due to personnel traffic must be minimized. Only authorized personnel in proper attire should be allowed in the clean room. One sound method of differentiating areas is to create a vestibule where clean outer garments, hair and beard nets, and clean footwear can be donned. This area is also the place to locate a hand sanitizing station and footwear bath or spray. This practice must be enforced for all persons entering the clean room, including management, maintenance, plant visitors, and others. All entrances to the processing area should contain footbaths and hand dip stations.

The following general principles should be enforced in any dairy processing plant, but are essential in a plant with a clean room environment.

1. Provide, wash, and maintain outer clothing for plant personnel.

2. Employees must wear a clean uniform when at work.

3. Uniforms and footwear must be stored on premises in a clean locker.

4. Maintenance personnel must maintain same standards as set forth in #2 and #3.

5. All employee uniforms should be color coded by department to control the movement of employees into restricted areas.

6. Parts and equipment touched by personnel must be freshly sanitized.

7. Personal hygiene should be observed by supervision on a daily basis.

8. Rings, hairpins, earrings, watches, etc. should not be worn in production areas.

9. Showers and hand washing facilities should be available in the plant area as well as near the toilet. They should be properly maintained.

10. Signs should be posted in the toilet area (wash hands before leaving).

11. Footwear sanitizing baths or sprays should be monitored routinely for proper disinfectant strength.

12. Employees with obvious illnesses, infected cuts, abrasions, etc., should be excluded from processing areas or other activities which can contaminate product, product-contact surfaces or packaging material. The use of tobacco or tobacco products, chewing gum or other food consumption is not permitted in any production area.

13. Hand washing facilities must be properly designed and conveniently located near work stations. A knee or foot-operated hand washing facility is preferred. A quick drying hand sanitizer should be used following liquid soap and water. Employees should be instructed on proper hand washing technique.

14. Employees suspected of alcohol or drug abuse should be excluded from job functions where poor judgment may compromise product safety.

15. When the use of disposable, single service gloves is necessary to handle exposed product contact surfaces during a production run, they must be maintained in an intact, clean and sanitary condition. Single service gloves should be thrown away whenever they become torn, contaminated or if removed for any reason.

REFERENCES

Foti, Debra. Environmental Monitoring; Part II: Monitoring the Plant Air, Diversey Corp., International Biocide Laboratory.

Mans, Jack. 1992. Clean Air: More Critical Than Ever, Dairy Foods, 93:12.