

HACCP Considerations in Cleaning and Sanitizing Multi-Use Synthetic Garments

By

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Protective apparel comprised of synthetic fabrics is used widely in the food processing industry. Although the lighter weight polyethylene aprons are designed for single use, some synthetic garments having a more durable composition are used multiple times before discarding. Problematic, however, is the ability to adequately clean and sanitize these garments between applications to provide a garment free of physical and microbial contaminants as required under regulatory performance standards established for the food industry under 9 CFR Subchapter E “Regulatory Requirements Under the Federal Meat Inspection Act and Poultry Products Inspection Act”, Part 416 “Sanitation” and Part 417 “Hazard Analysis and Critical Control Point (HACCP) Systems.”

Synthetic garments have found a role in reducing costs for the food processing industry. For single-use apparel the cost of the garment and the costs saved in labor and laundering expense make single-use apparel economically desirable. However with more durable and more costly synthetic protective apparel, re-use of synthetic garments has become commonplace in the food industry to extend the life of the garment and make its use more economical. Unfortunately, attention has primarily been focused on “cost of garment” economics with little or no consideration regarding if or how that synthetic garment can be adequately cleaned and sanitized before it is returned to service.

Focus on HACCP verification of process has recently intensified with the release of the USDA Food Safety and Inspection Service (FSIS) document entitled “Draft Guidance: HACCP Systems Validation in March, 2010. This document mandates that validation documentation be provided for all critical control points that could lead to contamination of food product. As a potential source of microbial contaminants, re-used synthetic garments would be subjected to validation documentation to assure that the garment was adequately cleaned and sanitized between uses. Validation documentation must be provided (1) through peer reviewed articles that have demonstrated that the process does meet performance criteria, (2) through internal facility documents indicating the process is valid, and/or (3) through the collection of periodic performance data (microbial sampling) validating the process.

The meat and poultry processing industry has relied almost exclusively on manual cleaning and sanitizing practices when re-using synthetic garments. These practices rely, in turn, almost exclusively on the employee to clean/sanitize his or her apron or gown

whether at home or on site. Manual processes are fraught with numerous challenges in providing adequate cleaning and sanitizing for synthetic protective apparel. These challenges include (1) human behavioral factors and employee adherence to assigned responsibility; (2) inadequate time allotted to the task of cleaning and sanitizing; and (3) processes that are not necessarily uniform or rigorous to provide the consistency required for effective cleaning and sanitizing.

Challenges to effective cleaning and sanitation also may arise from intrinsic material composition and construction of the garment. Both define the garment's ability to be adequately cleaned and sanitized. Obvious is the general construction of the garment. Typically the garment has a large surface area and because the fabric is not a hard surface, it is difficult to clean and therefore, difficult to sanitize. Also fasteners, grommets, or other difficult to clean areas (e.g., seams, repaired areas) may lead to incomplete cleaning and sanitizing. Less obvious are the characteristics of the material used in the garment's construction. These characteristics include the material's ability (1) to maintain tensile strength; (2) to maintain a smooth, non-stick finish; and (3) to maintain a non-porous surface through multiple use and cleaning/sanitizing processes.

Examination of these challenges demonstrates the scope of uncontrollable variables that make any manual, employee-responsible process unreliable and continuously subject it to scrutiny and question regarding its effectiveness. It is unlikely that validation documentation could be obtained for a manual cleaning/sanitizing process due to the inherent inconsistencies and shifting variables of a manual process.

It is therefore necessary to evaluate both the garment and the process by which the garment is to be cleaned and sanitized as two separate, but integral critical control points. The garment must provide in its construction and in its material composition the ability to be effectively cleaned and sanitized over the lifetime of its use. Once it is determined that the garment meets that required criteria, the process of cleaning/sanitizing must be shown to be consistent and effective for that garment.

No Specific Federal Guidance

Review of regulations issued by the Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA) through the Food Safety and Inspection Service finds little guidance in addressing the qualities that synthetic garments should exhibit for re-use or specific cleaning/sanitizing or laundering standards required of synthetic garments. This may be somewhat understandable since synthetic garments originated as single-use items and are deemed disposable.

The FDA does recognize that "linens" (defined as "fabric items such as cloth hampers, cloth napkins, table cloths, wiping cloths, and work garments including cloth gloves") can serve as vehicles to contaminate meat and poultry products if inadequately cleaned and sanitized. The *FDA Food Code 2009* and its "*Annex 3 - Public Health Reasons /Administrative Guidelines - Chapter 4, Equipment, Utensils, and Linens*" states:

- “Linens that are not free from food residues and other soiling matter may carry pathogenic microorganisms that may cause illness”;
- “Clean linens shall be free from food residues and other soiling matter”; and
- “Linens, cloth gloves, and cloth napkins are to be laundered between uses to prevent the transfer of pathogenic microorganisms between foods or to food-contact surfaces.”

The *FDA Food Code 2009* offers no specific standards that apply directly to multi-use synthetic garments although standards applicable to “linens” could through association be applied to synthetic garments by extrapolating “fabric” to encompass materials other than cloth and by assuming “work garments” can be other than cloth. As a standard operating practice applied to “linens” for mitigating microbial cross contamination, it would be hard to argue that this tenet would not also apply to synthetic garments. However, no standard or guidance is offered for any protective garment, cloth or synthetic fabric to what constitutes “laundered”, either by qualitative or quantitative measure.

A slightly more definitive stance is cited through USDA regulations under 9 Code of Federal Regulations (CFR) Subchapter E “Regulatory Requirements Under the Federal Meat Inspection Act and Poultry Products Inspection Act”, Part 416 “Sanitation.” As stated in “Employee Hygiene” (Section 416.5) under (b) “Clothing”, “Aprons, frocks, and other outer clothing worn by persons who handle product must be of a material that is disposable or readily cleaned.” Additionally this section states that “Clean garments must be worn at the start of each working day and garments must be changed during the day as necessary to prevent adulteration of product and creation of insanitary [sic] conditions.” No definitions are provided to what constitutes “clean” by either a qualitative or quantitative measure.

In absence of specific guidance in the *FDA Food Code 2009* or in 9 CFR 416.5(b), the meat or poultry processing facility still retains the responsibility to determine risks that might be inherent in its processes and develop protocols to eliminate or mitigate those risks. A focal point of this assigned responsibility is the “Hazard Analysis and Critical Control Point (HACCP) Systems” (9 CFR Part 417) developed to identify, prioritize, and control potential problems. Existing protocols and practices require review to determine if these protocols and practices can contribute to cross-contamination of meat or poultry products. In assuring that these protocols and practices meet regulatory standards two factors need to be assessed: (1) Surface cleanability due to the characteristics of the garment’s material composition and construction and (2) The ability to adequately clean and sanitize the garment via the cleaning/sanitizing procedures used.

Material Construction and Compositional Factors

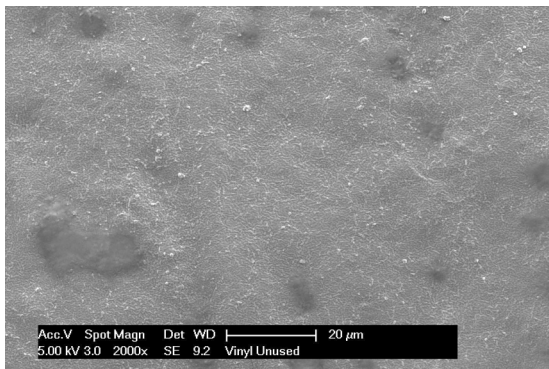
Assessment of a garment’s construction and composition and its ability to be adequately cleaned and sanitized should be viewed as the initial critical control point when a garment is evaluated for potential re-use. There are no guidance factors or standards by which this evaluation should be conducted, thus placing the responsibility on the facility for

documenting the suitability of the garment to be adequately cleaned/sanitized. From a perspective of construction, the use of grommets, buttons, and fasteners should be avoided, as these are typically difficult to clean. Less obvious is the composition of the garment's material, which over time and conditions of use may impact cleaning/sanitizing effectiveness.

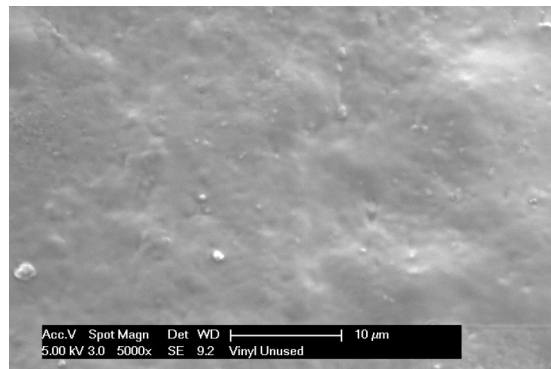
It is known that vinyl, a traditional and common material used in aprons and gowns, is subject to cracking and flecking due to repeated exposure to cold temperatures and repeated exposure to chemicals used to clean and sanitize. Plasticizers used to make the vinyl pliable leach under these conditions, causing the material to become brittle. Microscopic changes to a garment such as pitting, cracking or flecking can potentially change the dynamics of the material's surface and potentially lead to a reduced ability to clean and sanitize the garment. Cracks, fissures, and flecking can all provide safe harbor to microorganisms, protecting them from the rigors of washing and germicidal action.

Scanning electron microscopy conducted for PolyConversions, Inc. by the University of Illinois at Urbana-Champaign was employed to view the vinyl apron material to 20,000 magnification to detect changes that might occur to the material during typical meat/poultry processing conditions and typical apron lifetimes. Plate I shows the surface structure of an un-used vinyl apron. The surface structure is smooth and homogeneous prior to use.

PLATE I
Surface Structure of Un-Used Vinyl Apron



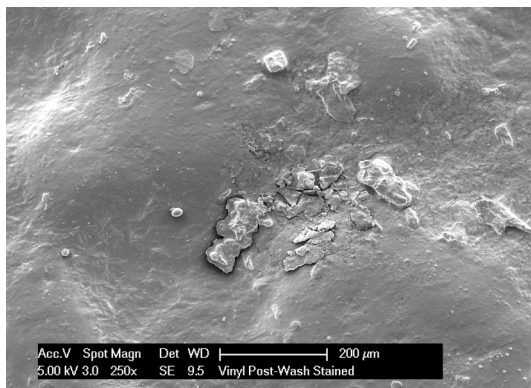
2,000 Magnification



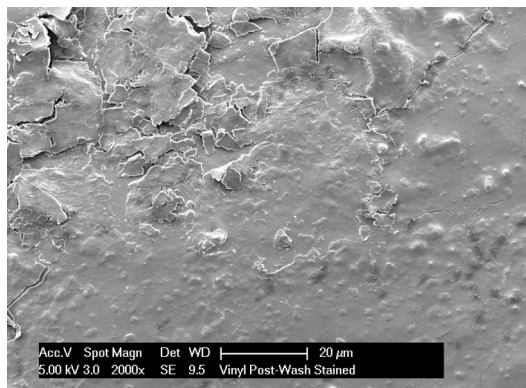
5,000 Magnification

Plate II shows the surface of a used vinyl apron supplied by a large poultry processor at the end of its life cycle. These electron photomicrographs were taken of a red stained area that was still present after washing. Visual analysis demonstrates extensive cracking, pitting, and flecking. Microbial analysis of this red stained area demonstrated a significant residual microbial presence in this area even after washing.

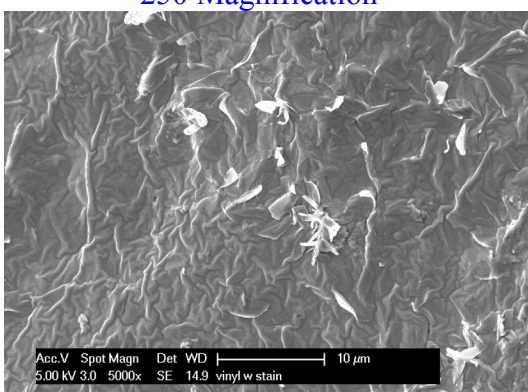
PLATE II
EM Structural Analysis of Stained Area of Used Vinyl Apron



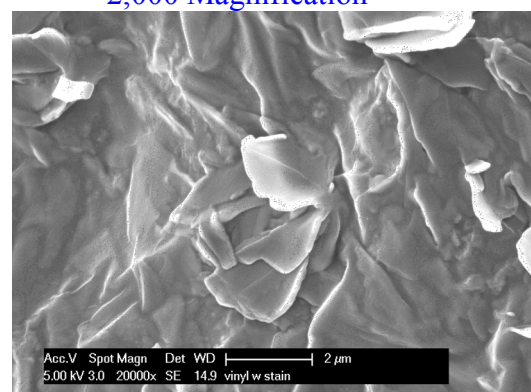
250 Magnification



2,000 Magnification



5,000 Magnification



20,000 Magnification

Thus, synthetic garments selected for re-use should avoid materials that are negatively influenced by the conditions under which the garment may be used or washed/sanitized. Synthetics that use plasticizers or other chemicals that can potentially leach should be avoided. PolyConversions, Inc. VRTM contains no plasticizers and is not subjected to compositional change during typical meat/poultry processing conditions. VRTM is a unique polyolefin, non-porous laminate material, that meets the durability factors and cleanability factors required of multi-use garments. This material has been used in the manufacture of aprons, gowns, sleeves, and other products to provide both employee and food product safety. Studies conducted previously have demonstrated that this material resists adhesion to oils, fats, greases, and meat/poultry residues and easily cleans with common detergent surfactants and moderate water temperatures. Additionally, VRTM gowns and aprons have enhanced cleanability due to the absence of fasteners, grommets, and seams. This material is resistant to cold and remains stable to temperatures of 160⁰F.

Cleaning and Sanitation Factors

Federal standards do not define “clean” linens, nor do they define conditions or processes by which to wash or launder fabric (synthetic or cloth) garments or articles. In absence of any guidance or standards, it remains the responsibility of the facility to define these

parameters and to document that they achieve effective cleaning and sanitizing for multi-use synthetic garments.

For proper sanitizing to be achieved, the synthetic garment must be effectively cleaned to remove fats, oils, greases and meat/poultry residues that interfere with the sanitizing process. Effective cleaning requires hot water, a detergent (surfactant), and sufficient agitation to remove those materials that harbor microorganisms or that could interfere with the germicidal process.

Selection of a proper germicide is also critical. Only germicidal agents approved by the U.S. Environmental Protection Agency (USEPA) can be used and only in accordance with label instructions approved by that agency. Concentrations of the germicide determine whether it is a rinse or no-rinse formulation. The labeled instructions also contain information on the effectiveness of the formulation on selected microorganisms. It is important to note, specifically with bleach (sodium hypochlorite), that organic materials such as meat/poultry residues and their oils and greases may significantly reduce the effective concentration of the germicide and render it ineffective.

However even when employing proper cleaning and sanitizing chemicals and conditions, the process may still be ineffective if the garment's surface and component parts have not been completely treated. This is especially true for any manual cleaning process that attempts to cover the complete surface area of the garment and any seam or fastener that may be present. Additionally attempting to "wipe" off greases, oils, and meat residues followed by the use of a germicidal agent will always be subjected to time constraints, employee training, and employee behavior.

The variables associated with all aspects of manual cleaning and sanitizing must be eliminated to have a consistent and uniform process that is reliable and effective each time for each garment. The only mechanism by which to eliminate these variables is to engineer them out through process automation. Process automation incorporating standard, documented cleaning and sanitizing conditions eliminates the human factor variables and standardizes the process for it to be consistently effective.

The use of an automated commercial laundering process can meet the expectations required of the cleaning and sanitizing process for synthetic garments if properly applied to the garment's construction and material composition. Such a process can meet the requirements of HACCP validation to assure that each garment is properly cleaned and sanitized to eliminate microbial and other potential adulterations to the food products.

Part II and Part III of this series will discuss an automated laundering process that has been applied to PolyConversions, Inc. VRTM garments. Part II will show the research and provide the process criteria used to clean and sanitize VRTM garments. Part III will provide data demonstrating the economic justification for incorporating an automated synthetic garment laundering process in meat and poultry processing facilities.

About the Author

Nelson S. Slavik holds a Ph.D. in microbiology from the University of Illinois at Urbana-Champaign (1975) and has previously served on the University of Illinois faculty within the Department of Health and Safety Studies. He is president of Environmental Health Management Systems, Inc. (Niles, Michigan) and consults with healthcare and the food processing industry regarding environmental and health and safety regulations, microbial decontamination, hazardous waste management, and hazardous materials management. He currently serves as a regulatory and technical consultant to Polyconversions, Inc. and consults with the food industry on microbiological safety issues and the efficacy of germicidal treatment of reusable and disposal products.

About PolyConversions, Inc.

PolyConversions, Inc. (www.PolyCoUSA.com) was founded in 1993 to research and develop exclusive splash and aerosol protective materials and apparel designs for industrial applications. Manufacturing strictly in the U.S.A., PolyConversions produces under the trademark *VR* Protective Wear designed as a cost effective durable replacement for vinyl and other traditional protective apparel impervious materials.

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