UniFirst UniSafe® Service and Product Protection Process

Workwear Solutions for Food Product Safety

A laboratory study to measure the effectiveness of UniFirst UniSafe Service as a pathogen reduction methodology in the laundering and processing of food industry work garments.

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Food Safety Background

When food is your business, product safety is non-negotiable. Careful controls are critical to minimizing cross-contamination risks and achieving regulatory compliance. That's why Hazard Analysis & Critical Control Points (HACCP)/Global Food Safety Initiative (GFSI) plans are necessary—to help prevent contamination within food manufacturing, processing, distribution, and retail operations, and to ensure the general safety of food products.

Food safety is an important public health priority. Foodborne illness (sometimes called "foodborne disease," "foodborne infection," or "food poisoning") is a common, costly—yet preventable—public health problem. The Centers for Disease Control and Prevention (CDC) estimates that each year roughly one (1) in six (6) Americans (or 48 million people) get sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases.[1] FoodNet conducts active, population-based surveillance for laboratory-confirmed infections caused by *Campylobacter*, *Cryptosporidium*, *Cyclospora*, *Listeria*, *Salmonella*, Shiga toxin–producing *Escherichia coli* (STEC) O157 and non-O157, *Shigella*, *Vibrio*, and *Yersinia* in 10 sites covering 15% of the U.S. population (48 million persons in 2011).[2] The CDC has provided the following statistics:

> Estimates of foodborne illness can be used to direct food safety policy and interventions. Data from active and passive surveillance and other sources estimates that each year 31 major pathogens acquired in the United States caused 9.4 million episodes of foodborne illness (90% credible interval [CrI] 6.6–12.7 million), 55,961 hospitalizations (90% CrI 39,534–75,741), and 1,351 deaths (90% CrI 712–2,268). Most (58%) illnesses were caused by norovirus, followed by nontyphoidal *Salmonella* spp. (11%), *Clostridium perfringens* (10%), and *Campylobacter* spp. (9%). Leading causes of hospitalization were nontyphoidal *Salmonella* spp. (35%), norovirus (26%), *Campylobacter* spp. (15%), and *Toxoplasma gondii* (8%). Leading causes of death were nontyphoidal *Salmonella* spp. (28%), *T. gondii* (24%), *Listeria monocytogenes* (19%), and norovirus (11%). [3]

Waves of well publicized recalls of potentially contaminated foods have raised ongoing concerns that some food items consumers eat may not be safe. To help alleviate these worries, the United States government adopted the Food Safety Modernization Act (FSMA) in 2011. The Act aims to ensure the U.S. food supply chain is consistently safe by shifting the focus from *reacting* to contamination incidents to *preventing* them. This legislation empowers the Food and Drug Administration (FDA) to inspect and audit the quality systems of food manufacturers, processors, distributors, and retailers. Inspectors investigate potential contamination risks in such organizations and can mandate full product recalls (a step that was "voluntary" prior to FSMA). As a result, food facilities such as meat processors, butcheries, dairies, groceries, restaurants, and the like are required to evaluate all potential hazards in their operations, implement and monitor effective measures to prevent possible contamination, and have a detailed plan to take corrective actions as necessary.

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[1] Centers for Disease Control and Prevention; http://www.cdc.gov/foodborneburden/estimates-overview.html

[2] Morbidity and Mortality Weekly Report, Incidence and Trends of Infection with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 1996–2012

[3] Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson M-A, Roy SL, et al. Foodborne illness acquired in the United States—major pathogens. Emerging Infectious Diseases. 2011 Jan. http://dx.doi.org/10.3201/eid1701.P11101

UniFirst UniSafe® Service for Food Facilities

Work garments worn by food industry employees need to be maintained, processed, hygienically cleaned, and managed effectively so they do not become a potential source for food contamination. To help address this need, UniFirst Corporation, a uniform service and supply company operating throughout the U.S. and Canada, developed its UniSafe Service for food-related facilities. The goal of this specialized garment safety program is to effectively eradicate bacterial contaminants that can colonize on food service employees' workwear.

The UniFirst UniSafe Service program includes a portal-to-portal process, called the Product Protection Process (PPP), designed to minimize cross-contamination risks associated with uniforms and other food worker garments. The UniFirst PPP begins at customer facilities and extends throughout all garment handling, laundering, and finishing procedures to deliver hygienically clean garments to food-related workers on a regular schedule. The program is based on principles set forth in HACCP and GFSI application guidelines, and addresses risks involved with the process. All garments are sorted, hygienically cleaned, dried, finished, and poly-wrapped (optional) using UniSafe Standard Operating Procedures (SOPs), which address all the Critical Control Points (CCPs) and processing steps. This proprietary program has been instituted in UniFirst servicing plants and UniFirst personnel involved in the handling of food-related customer garments receive UniSafe Service-specific training. The detailed steps in UniFirst's PPP are identified in the following flow chart.

UniFirst Product Protection Process (PPP)
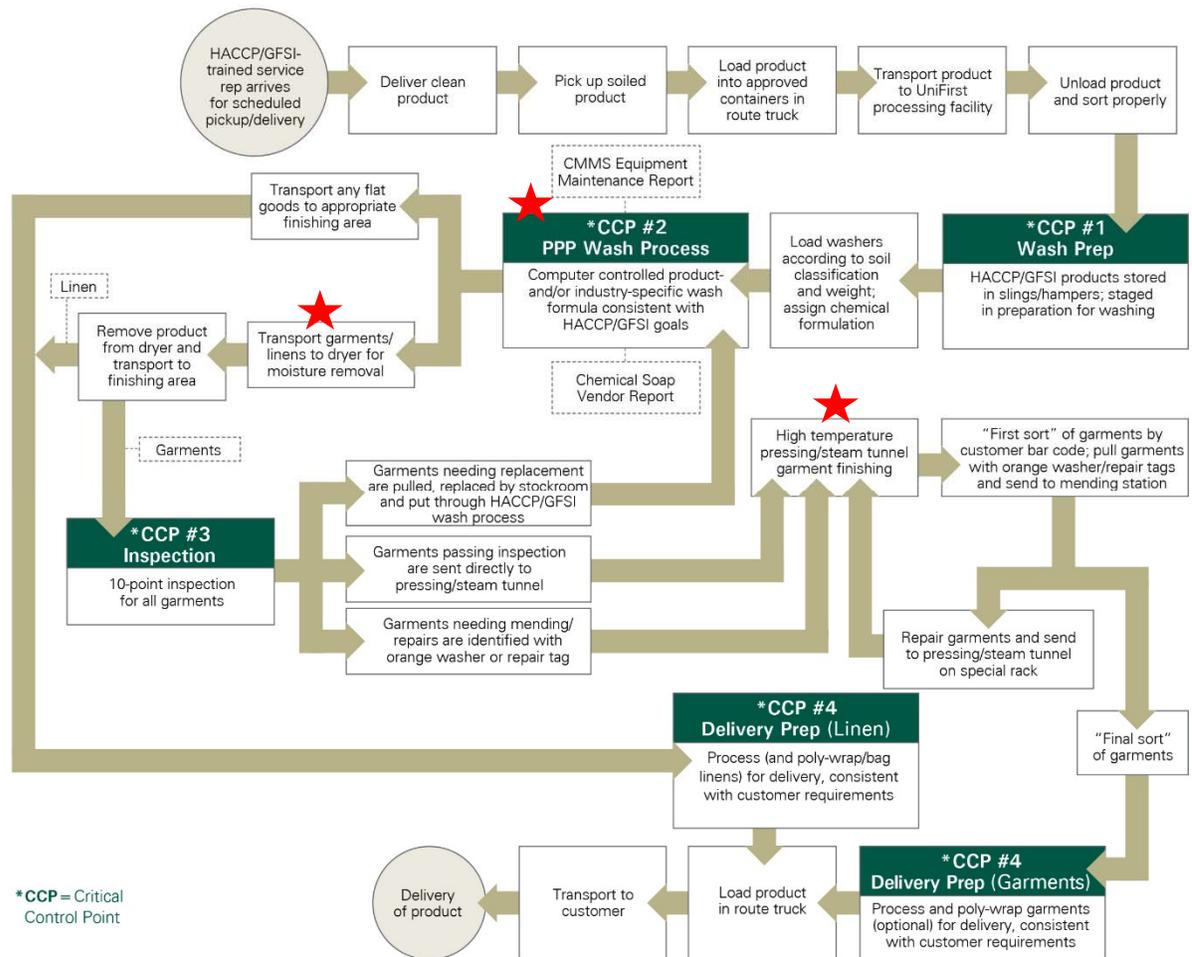
The UniFirst PPP has three (3) primary stages (annotated by ⭐) where microbial contamination is effectively eradicated:

1. Specialized HACCP/GFSI wash cycle
2. Dryer cycle
3. Steam tunnel finishing/garment pressing

The optional poly-wrap stage is an additional preventive measure to help protect cleaned garments from exposure to environmental contaminants after processing, throughout the delivery process, and prior to being worn. Once the garments have gone through the full Product Protection Process, they are packaged and loaded onto a delivery vehicle and transported to the UniFirst customer.

UniSafe Service begins with the delivery of hygienically clean garments and the pickup of soiled ones from the customer facility. Soiled garments are brought to the transport vehicle and loaded into segregated plastic liners. Soiled items are then transported to a UniFirst processing facility to undergo the complete HACCP/GFSI service process that, in addition to drying, steam tunnel/pressing, and other important steps associated with the Product Protection Process, includes four (4) defined Critical Control Points (CCPs):

- **CCP 1** – Soiled garments segregated and stored in slings/hampers; staged in preparation for washing

- **CCP 2** – Garments undergo UniFirst UniSafe HACCP/GFSI wash process

- **CCP 3** – 10-point quality inspection of <u>all</u> garments (with processes to address any flaws that could put food safety at risk; e.g., apparel damage, fabric shedding, loose buttons, faulty elastic wristbands)

- **CCP 4** – Finished garments prepared for redelivery (poly-wrapped, if desired), consistent with customer requirements

UniSafe Processing Steps:

1. **Loading the route vehicle for delivery** – Truck loaded with appropriate segregation containers, bags, and hygienically clean garments.
2. **Delivery of clean garments** – Hygienically clean (poly-wrapped, if desired) garments are delivered to designated area at customer site.
3. **Pickup of soiled garments** – Soiled garments are placed in plastic bags and put on route truck in segregated containers/bins.
4. **Return to UniFirst processing facility (plant)** – Soiled garments are transported to a UniFirst industrial laundry plant.
5. **Unloading soiled garments** – Garments are sorted, identified as "food-related," and segregated using designated slings.
6. **Washing and drying** – Slings loaded with identified "food-related" soiled garments are brought to wash aisle and hygienically laundered with a specified UniSafe HACCP/GFSI wash process and cleaning formula. After the wash cycle, items are loaded into dryers for moisture removal and garment conditioning.
7. **Inspection and garment finishing** – All hygienically clean garments undergo 10-point quality inspections; garments passing inspection go through high temperature steam tunnel or garment pressing; garments failing inspection are routed for mending or replacements and go through the complete Product Protection Process again.
8. **First sort** – All garments are segregated and sorted by delivery schedule, customer, and wearer using proprietary bar code scanning technology.
9. **Final delivery of hygienically clean garments** – Finished, sorted garments (optionally poly-wrapped) are segregated and transported from plant to designated site at customer location or UniFirst branch for final customer delivery.

Laboratory Tests

To measure the effectiveness of UniFirst UniSafe Service and Product Protection Process as a HACCP/GFSI-consistent uniform laundering solution, the effectiveness of the process in reducing food industry-type pathogenic organisms needed to be determined. To scientifically measure this, UniFirst turned to the North American Science Association (NAMSA) for independent, objective laboratory studies.

NAMSA is a microbiology consulting service and GMP testing laboratory with expertise in contamination controls for the medical device industry. NAMSA developed and executed formal protocols based on scientific laboratory methods to assess the microbiological contamination controls used by UniFirst in its UniSafe Service and uniform laundering program for HACCP/GFSI-conscious, food-related customers. The study was based on the guidelines set for controlling biocontamination on garments in laundering processes: ISO 14698 *Annex D and E Biocontamination Control of Laundry Services*, a guidance document for cleaning validations of reusable medical devices; AAMI TIR12:2010 *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers,* a guidance document for culturing microbial organisms; ANSI/AAMI/ISO 11737-1:2006/(R)2011 – *Sterilization of healthcare products – Microbiological methods – Part 1: Determination of the population of microorganisms on product* and applicable General Chapters of the United States Pharmacopeia (USP), and FDA food safety guidelines and requirements.

The following is a summary of the studies conducted by NAMSA to evaluate the ability of UniFirst UniSafe Service to reduce and control microbial contamination during the laundering process and delivery, which includes a poly-wrap bag option for food service work garments. Example items include soiled uniforms, coats, shirts, pants, towels, and aprons. Bacterial cross-contamination from all of these sources is a known cause of concern for both UniFirst and its many food service industry customers. This scientific laboratory analysis was commissioned by UniFirst to quantify pathogen reductions within the company's UniSafe Service and Product Protection Process, and optional poly-wrap garment protection bag.

Test System Development

In order to correctly assess the killing power of UniFirst UniSafe Service and Product Protection Process, the testing had to be done on food service industry relevant organisms. *However, wild type organisms are difficult to work with and can be dangerous to lab personnel. Therefore, using laboratory controlled organisms of similar type as the wild type is preferred, safe, and effectively demonstrates the microbial reduction power of UniFirst UniSafe Service.*

The rationale for the organisms that were chosen for this study was based on the prevalence and types of the organisms most commonly associated with food service handling. The organisms were categorized into groups based on bacteriological characteristics and the laboratory's ability to safely handle and work with the organisms. See Table 1 for selection of organisms used in this study.

Not only did the appropriate organisms have to be determined, but the garments used in the test had to be selected based on their ability to capture a majority of the related challenges garments could pose to the laundering system. In the end, a 100% spun polyester garment was chosen because it is one of the most commonly used garments in the food service industry.

Table 1

Selected Organism	Organism Classification	Related Organisms	Gram Stain Reaction	Growth Characteristics
Escherichia coli	Enterobacteriacea	*Shigella Enterobacter, Salmonella*	Gram negative bacillus	aerobic
Staphylococcus auerus	Catalase positive organisms	*Enterococcus Listeria (rod shaped)*	Gram positive	aerobic
Pseudomonas aeruginosa	Non-enteric, motile organisms	*Vibrio Campylobacter*	Gram negative bacillus	aerobic
Candida albicans	Yeast (Saccharomycetes)	*Crytococcus*	Gram positive	aerobic

Feasibility Study

A feasibility study was designed to evaluate the viability of populations of various food service related, clinically relevant, vegetative organisms (*Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli and Candida albicans*)[4] directly inoculated onto garment swatches that were attached to new, full-size food service style garments (Figure 1). This was necessary because vegetative organisms cannot survive for extended periods of time after inoculation on the test articles due to cellular dehydration. The actual study would have a potential timeline of 12 hours from sample preparation to transportation to UniFirst where they would be exposed to the garment processing steps, then transportation back to the lab where the test swatches would be cultured for determination of microbial reduction. In order to accurately assess the killing power of the specific UniSafe Service laundering cycle and steam tunnel process, it was necessary to make sure these processes were killing the organisms and not cellular desiccation. The feasibility study determined how long the test organisms inoculated on the swatches were able to survive.
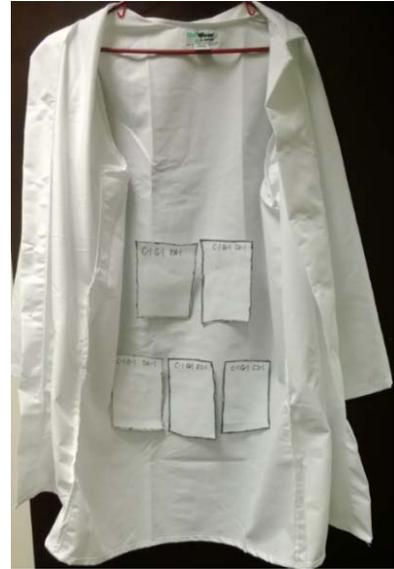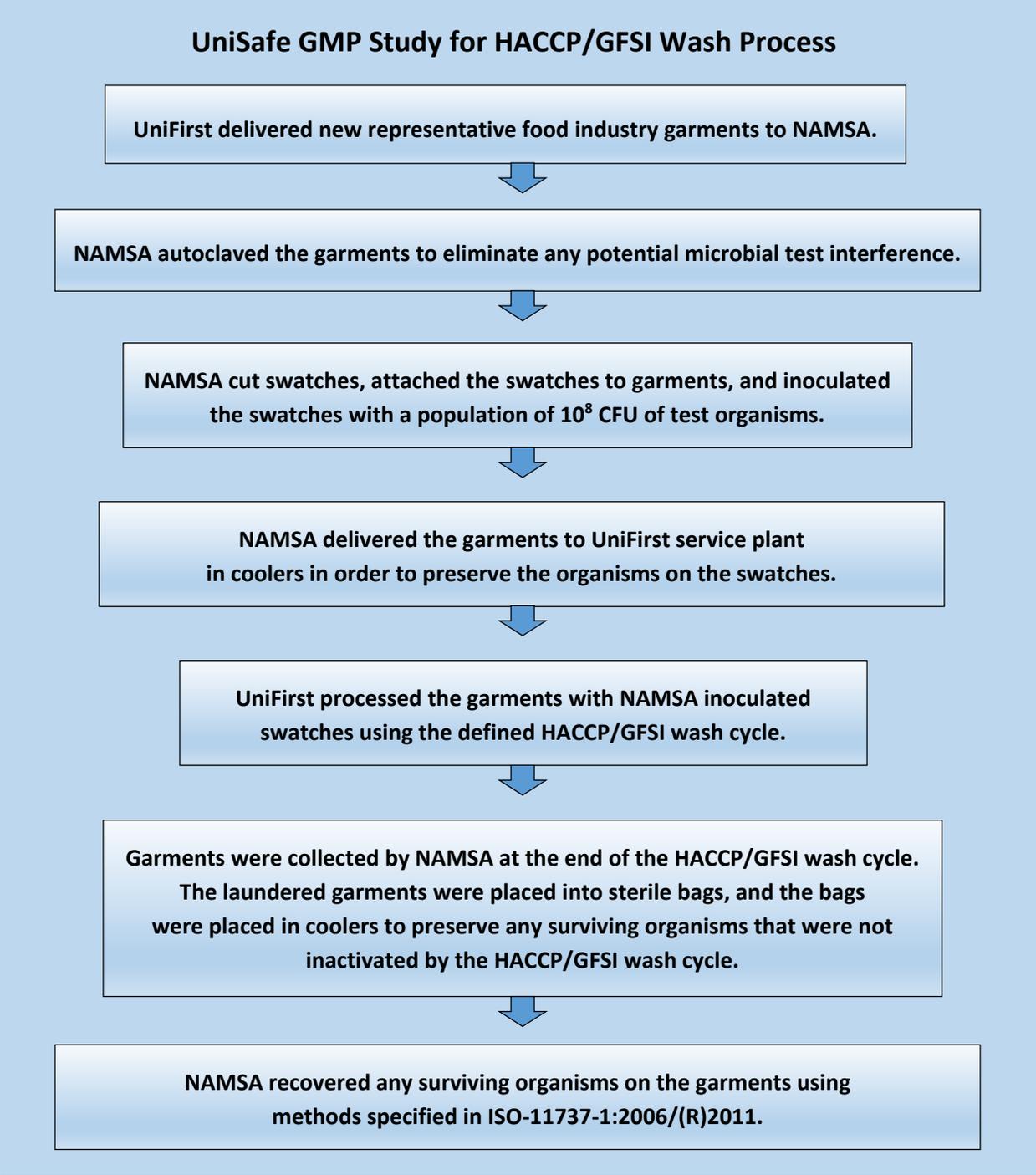

Figure 1

Feasibility Study Results

The feasibility study results indicated the inoculated garments needed to be kept cool to prevent organism die-off; therefore, the garments would need to be transported in coolers. The feasibility study results also indicated that *Pseudomonas aeruginosa* was not a suitable organism for use in the test as it did not survive the minimum 12-hour viability challenge time. It was also demonstrated that these organisms, if present on the garments, do not survive on garments once they are no longer on their host (i.e., person wearing the garment or the wet processing environment) due to dehydration.

Taking into account the results of the feasibility study, the actual study could be designed and conducted. The testing strategy was as follows.

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[4] Centers for Disease Control and Prevention; http://www.cdc.gov/foodborneburden/estimates-overview.html

UniSafe® Testing Strategy

The study was designed with (1) accuracy, (2) precision, (3) selectivity, (4) sensitivity, (5) stability, and (6) reproducibility in mind. The UniSafe GMP study is illustrated in the flowcharts below.

UniSafe GMP Study for HACCP/GFSI Wash Process

UniFirst delivered new representative food industry garments to NAMSA.

↓

NAMSA autoclaved the garments to eliminate any potential microbial test interference.

↓

NAMSA cut swatches, attached the swatches to garments, and inoculated the swatches with a population of 10^8 CFU of test organisms.

↓

NAMSA delivered the garments to UniFirst service plant in coolers in order to preserve the organisms on the swatches.

↓

UniFirst processed the garments with NAMSA inoculated swatches using the defined HACCP/GFSI wash cycle.

↓

Garments were collected by NAMSA at the end of the HACCP/GFSI wash cycle. The laundered garments were placed into sterile bags, and the bags were placed in coolers to preserve any surviving organisms that were not inactivated by the HACCP/GFSI wash cycle.

↓

NAMSA recovered any surviving organisms on the garments using methods specified in ISO-11737-1:2006/(R)2011.

UniSafe GMP Study for Steam Tunnel

UniFirst delivered a new set of representative food industry garments to NAMSA.

↓

NAMSA autoclaved the garments to eliminate any potential microbial test interference.

↓

NAMSA cut swatches, attached the swatches to garments, and inoculated the swatches with a population of 10^8 CFU of test organisms.

↓

NAMSA delivered the garments to UniFirst service plant in coolers to preserve the organisms on the swatches.

↓

UniFirst processed the garments with the NAMSA inoculated swatches using high temperature steam tunnel exposure.

↓

Garments were collected by NAMSA at the end of the steam tunnel process. The steam processed garments were placed into new sterile bags and the bags were returned to coolers to preserve any surviving organisms that were not inactivated by the steam tunnel exposure.

↓

NAMSA recovered any contamination on the garments using methods specified in ISO-11737-1:2006/(R)201.

The microbiological tests conducted were designed to assess the microbial load reduction capabilities of UniFirst UniSafe Service, including garment delivery cross-contamination prevention with optional poly-wrap protection bags. The tests conducted represent an exaggerated contamination scenario, as garment samples were inoculated with excessive quantities of bacteria (approximately 100 million CFU). Fabric swatches were used to localize the bacterial inoculation more readily and to make laboratory sampling as accurate and reproducible as possible. The swatches were cut from extra garments provided, made of the same materials as their host garments, in order to remain consistent with the actual processing conditions. Three (3) indicator organisms were chosen to represent the different types of bacterial and fungal pathogens that are common sources of microbial contamination within the food industry and were robust enough to survive the test sample transportation. The three (3) test organisms were used to challenge the main stages of the UniFirst PPP where microbial lethality and reduction of cross-contamination takes place:

1. HACCP/GFSI wash cycle
2. Steam tunnel finishing/garment pressing cycle
3. Optional poly-wrap garment bagging

The test organisms selected to test the efficacy of UniFirst UniSafe Service and Product Protection Process were:

Escherichia Coli (E. coli) – An organism that can be an indicator for meat/poultry contamination and fecal contamination. *E. coli* has been the organism identified as the cause of many deaths and major food recalls.

Staphylococcus aureus – An organism that produces exotoxins related to food poisoning.

Candida albicans – A potentially harmful yeast that is widespread in the baking and brewery industries.

UniSafe® Process Testing

Fabric swatches (16 cm^2 area, Figure 2) were inoculated with the indicator organisms, attached to full garments (matching fabric types), and packed into coolers for transport to UniFirst. Once at UniFirst, the garments were removed from their coolers and sterile bags and exposed to each step of UniFirst UniSafe Service. Each step was challenged separately in order to quantify the microbial reduction power of each step. Each step was tested three (3) times with three (3) food garments. The repeat testing demonstrates consistency and reproducibility. After exposure to each individual processing step, the garments were collected and placed individually into new sterile bags and back into the coolers for transportation back to the lab. Positive control garments containing inoculated swatches that were exposed to all the study conditions, with the exception that they were not exposed to any of the microbial reduction steps of UniFirst UniSafe Service, were transported along with the test garments. Once all samples were back at the NAMSA laboratory, the swatches were removed from the garments and cultured for surviving organisms using a validated bioburden recovery method.
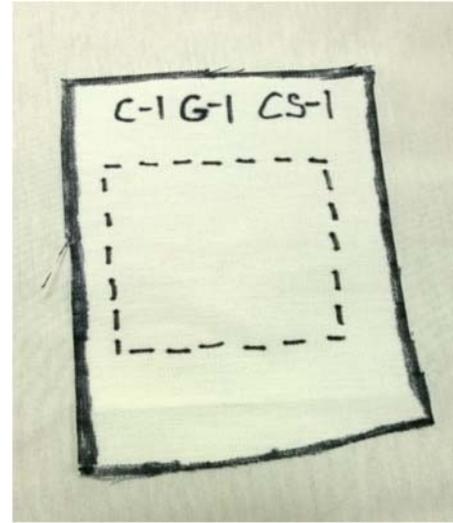

Figure 2

All methods were validated to demonstrate that repeatability, accuracy, precision, and robustness were consistent.

UniSafe® Process Testing Study Results

The testing process and subsequent lab results demonstrate that UniFirst UniSafe Service for food-related businesses reduces bacterial contamination levels on work garments by >99.9999%.

The results achieved with UniFirst UniSafe laundering process utilizing UniFirst's specialized formula detergent shows a greater than 99.9999% reduction of all three (3) critical organisms, when compared to the positive controls. The results achieved using the specialized laundering process are shown in Table 2 and Figure 3.

Table 2: UniSafe Wash Cycle Results

Challenge Organism	Initial Inoculum Challenge Without UniSafe Wash Cycle Process (Positive Controls)	Recovery Counts Post-UniSafe Wash Cycle Process	Microbial Percent Reduction of UniSafe Wash Cycle Process
Escherichia coli	3.0×10^7	1.8×10^1	>99.9999%
Staphylococcus aureus	2.3×10^8	6.7×10^0	>99.9999%
Candida albicans	1.8×10^8	2.8×10^1	>99.9999%

Figure 3: Inoculated Food Service Garments Exposed to UniSafe Wash Cycle
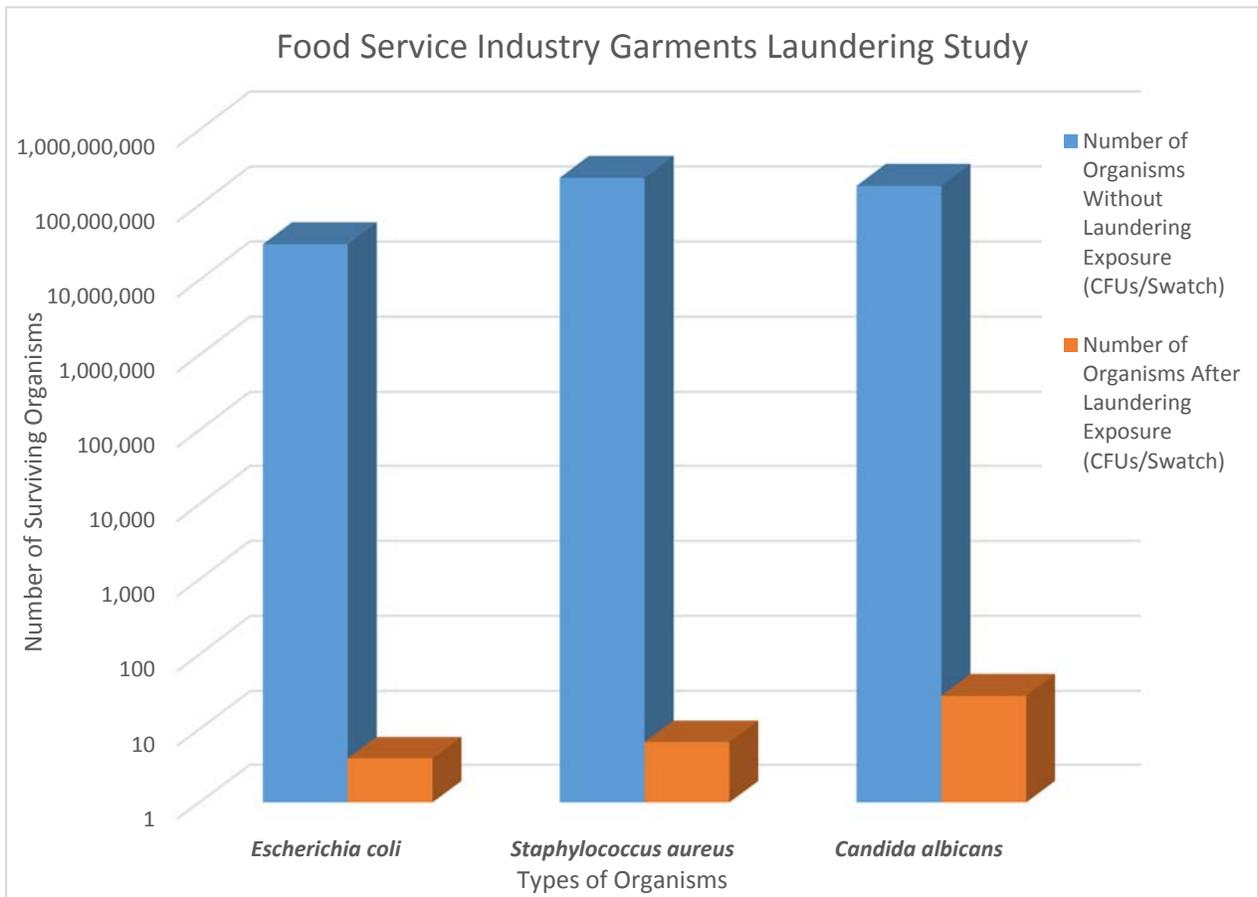
The results achieved with the steam tunnel testing, utilizing high temperature exposure, were a greater than 99.9999% reduction of all three (3) critical organisms, when compared to the positive controls. The results of the steam tunnel process are shown in Table 3 and Figure 4.

Each of the laundering and steam tunnel steps in the Product Protection Process demonstrated it is effective in killing over 100 million organisms.

Table 3: UniSafe Steam Tunnel Process Results

Challenge Organism	Initial Inoculum Challenge Without UniSafe Steam Tunnel Process (positive controls)	Recovery Counts Post-UniSafe Steam Tunnel Process	Microbial Percent Reduction of UniSafe Steam Tunnel Process
Escherichia coli	8.1×10^6	4.0×10^0	>99.9999%
Staphylococcus aureus	7.0×10^6	1.5×10^2	>99.9999%
Candida albicans	6.8×10^7	1.8×10^1	>99.9999%

Figure 4: Inoculated Food Services Garments Exposed to UniSafe Steam Tunnel
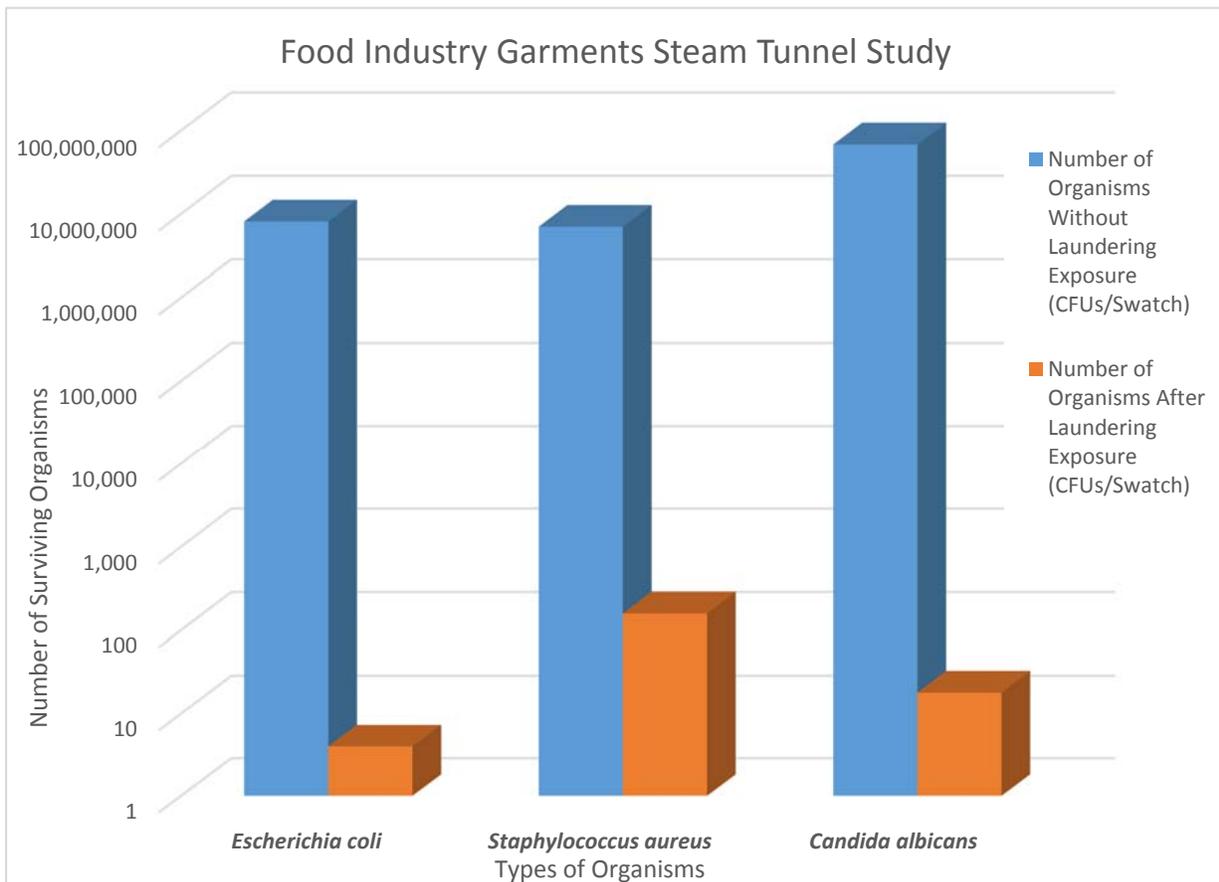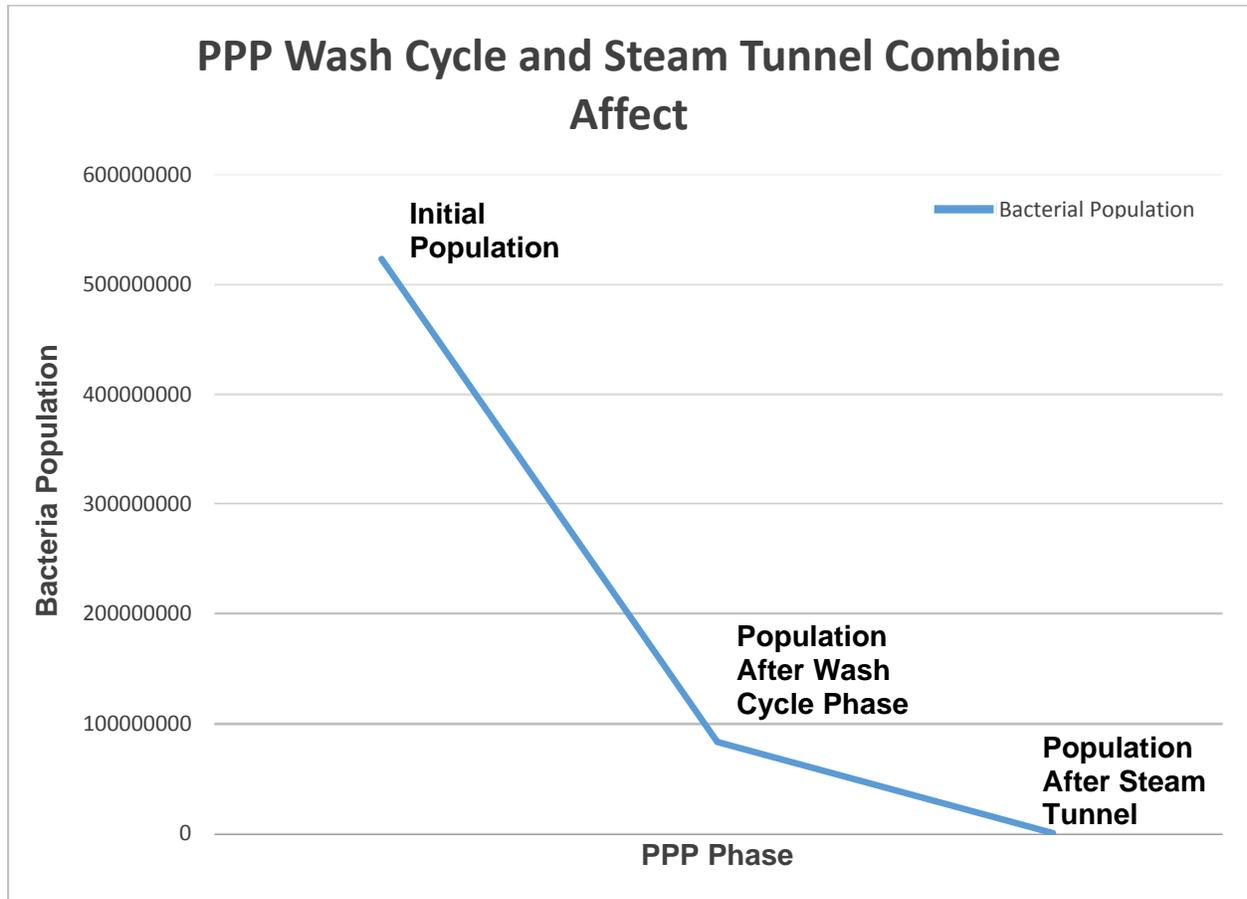
Figure 5: UniSafe PPP Wash Cycle Service and Steam Tunnel Combined Effect

The testing challenged inherent intrinsic parameters of UniFirst UniSafe Service and garment processing to demonstrate quantifiable microbial contamination reduction in the wash process and steam tunnel/garment press finishing. Each critical process has a significant impact on reducing bacteria from worn garments. In fact, **Figure 5 demonstrates the combined effect and the clear advantage that UniSafe Service provides**. UniSafe Service provides redundant microbial lethality that results in hygienic cleanliness of garments soiled with the tested microorganisms. This formal study shows UniFirst and its customers the proven methodologies based on GMP that indicate definitive pathogen reduction from garment processing, and highlights the microbicidal effectiveness of this system for effectively processing food-related garments.

The study results show the reduction of microbial contamination in the processing of food-related garments. The microorganisms are reduced in very significant quantities by the laundering and steam tunnel operations as depicted in the CCPs and the entire PPP of UniSafe Service. The microbial lethality of UniFirst's PPP is exhibited across various types of microorganisms from bacteria to yeasts. Various contaminants, whether human pathogens or contamination from meat, dairy, beverage, bakery, or other products, will be effectively eradicated.

In Figure 5, the lethality efficiency of UniSafe Service is further exhibited on the individual challenge organisms. The initial challenge levels were between 7 million and 230 million organisms. The recovery after UniSafe laundering processing was between 4 and 28 CFU. The steam tunnel had a similar effect on the challenge organisms. The population of organisms on garments going into the steam tunnel was between 7 million and 68 million organisms. The population recovered after the steam tunnel process was between 4 and 158 CFU. The combination of the two processes used together effectively eliminates approximately 300 million organisms. This demonstrates that UniSafe Service effectively eradicates a broad spectrum of bacteria and yeasts that represent the majority of food-borne pathogens.

The charts and graphs of this study depict the overall effectiveness of UniSafe Service in killing bacteria. It provides a visual assessment of the removal of microorganisms from soiled food garments. These garments are worn in proximity to food preparation activities "from farm to table." Therefore, providing protective garments that are hygienically clean is an important control point. In the end, UniFirst UniSafe Service was shown to consistently reduce harmful bacteria levels on soiled food service garments.

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The results of the additional poly-wrap garment protection testing are shown in Figure 6. The testing showed an 84% decrease in organisms found on garments transported using poly-wrap bags when compared with those without poly-wrap protection, demonstrating that shipping garments with optional poly-wrap garment protection bags maintains a high level of hygienic cleanliness.

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Test results demonstrate that soiled/contaminated food preparation garments can be laundered, serviced, and returned to clients hygienically clean and virtually pathogen-free as a result of the inherent microbicidal properties of the UniSafe Service.

Poly-Wrap Garment Bag Effectiveness Testing and Results

The efficaciousness of the poly-wrap garment protection bags was tested by taking 20 food service industry garments and dividing them into two (2) test groups: one (1) group of 10 was processed though UniFirst UniSafe Service, placed in a poly-wrap garment protection bag, and transported to the lab for testing; the other group of 10 was processed through UniFirst UniSafe Service and transported to the lab for testing without the use of poly-wrap garment protection bags. Once at the lab, both groups were individually tested for bacterial contamination.
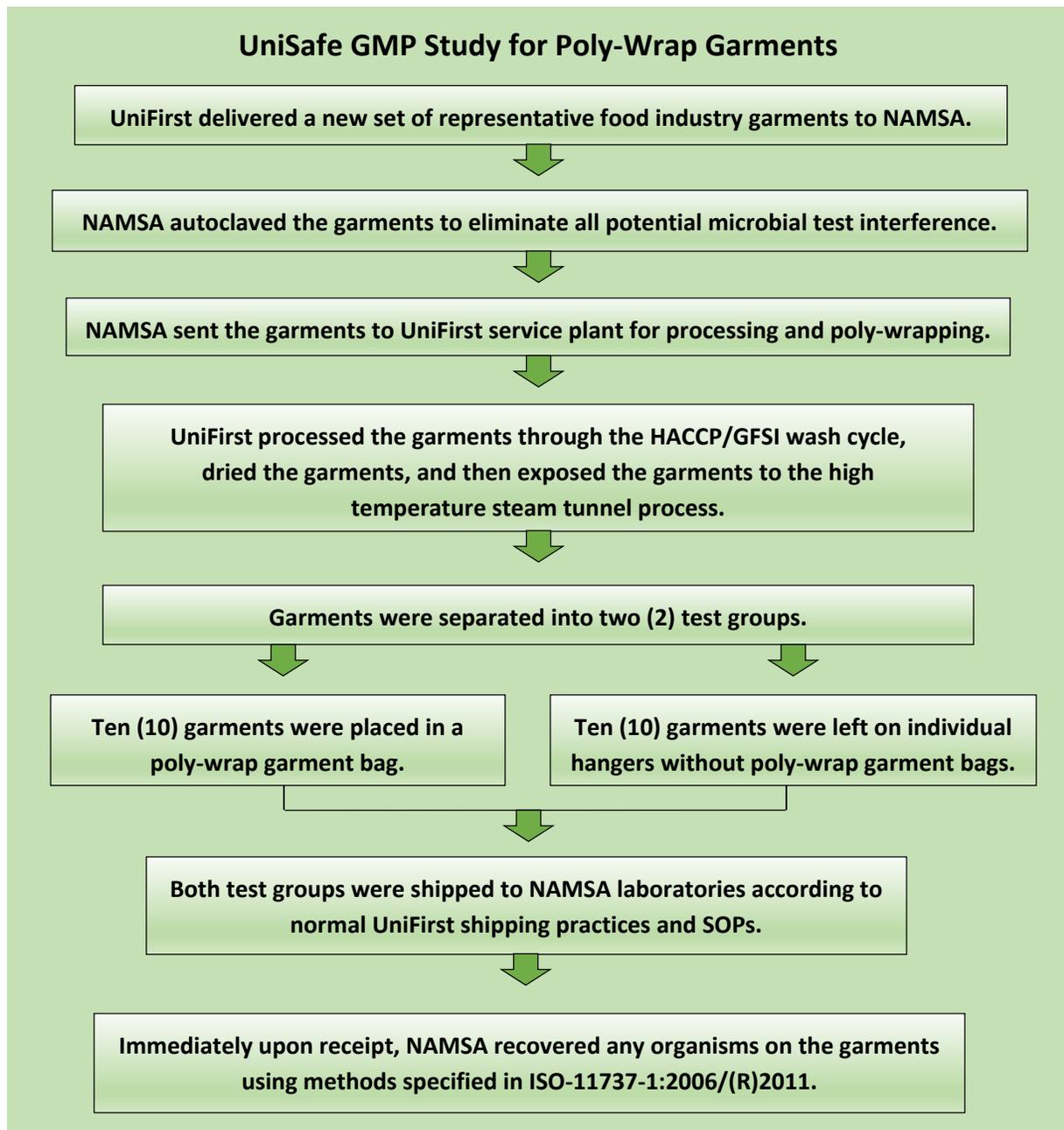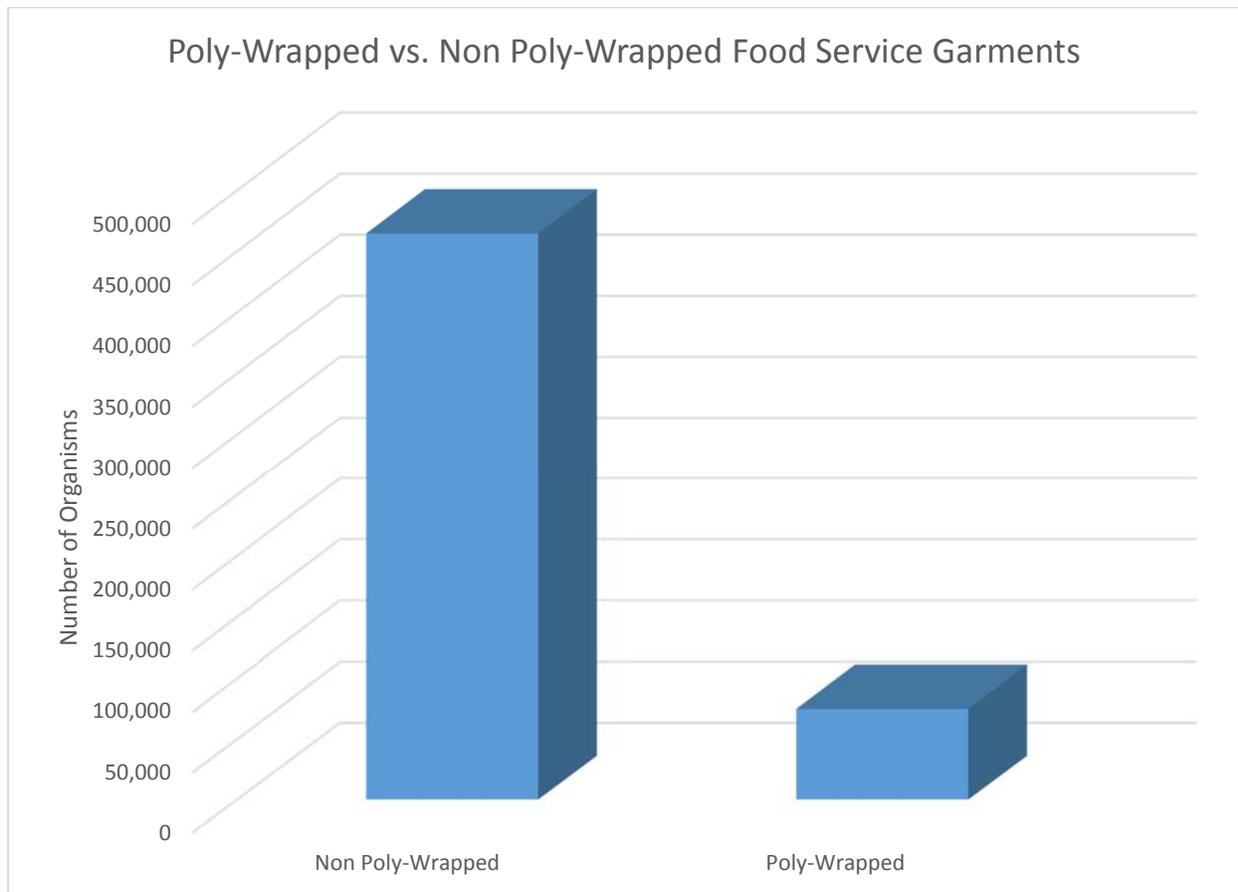
UniSafe GMP Study for Poly-Wrap Garments

UniFirst delivered a new set of representative food industry garments to NAMSA.

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NAMSA autoclaved the garments to eliminate all potential microbial test interference.

↓

NAMSA sent the garments to UniFirst service plant for processing and poly-wrapping.

↓

UniFirst processed the garments through the HACCP/GFSI wash cycle, dried the garments, and then exposed the garments to the high temperature steam tunnel process.

↓

Garments were separated into two (2) test groups.

↓   ↓

Ten (10) garments were placed in a poly-wrap garment bag.   Ten (10) garments were left on individual hangers without poly-wrap garment bags.

↓

Both test groups were shipped to NAMSA laboratories according to normal UniFirst shipping practices and SOPs.

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Immediately upon receipt, NAMSA recovered any organisms on the garments using methods specified in ISO-11737-1:2006/(R)2011.

Figure 6: Poly-Wrap Garment Production Bag Effectiveness

The results of the study conducted to evaluate the microbial contamination reduction potential of the poly-wrap garment protection bag determined that using the poly-wrap garment protection bag resulted in **83.8% fewer microorganisms** than the garments without the poly-wrapped protection. Figure 6 shows the comparison in the number of organisms recovered on garments that were shipped with no protection (464,662 CFU) versus the number of organisms recovered on garments that were shipped inside the poly-wrap garment protection bags (75,131 CFU). This study demonstrates a clear microbial contamination level advantage by using UniFirst poly-wrap garment protection bags in the transportation process of the cleaned garments.

Conclusions

Laboratory tests indicate that UniFirst UniSafe Service® and Product Protection Process (PPP) for food-related businesses reduces bacterial contamination levels on workwear by >99.9999%.

(Comprehensive test results are available.)

The UniFirst UniSafe Service program is a systematic, preventive approach to controlling potential microbiological hazards in food supply safety and works effectively to reduce microbiological contamination by decreasing bacterial levels on workwear by >99.9999%.

This study measured, monitored, and documented the effectiveness of the specialized service program, and demonstrated that it is a consistent pathogen reduction methodology for laundering and processing soiled food-related work garments. It was proven that UniFirst UniSafe Service and Product Protection Process provides for effective garment disinfection consistent with the safety goals of those in food-related industries.

UniFirst UniSafe Service is available from UniFirst Corporation: 800.225.3364 / unifirst.com.

Endnote

The testing and results documented in this paper reflect UniFirst's Standard Operating Procedures (SOPs) in place at the time the study was conducted. Wash formula and processing innovations in the textile services industry may result in UniFirst varying these SOPs. However, any such variations are expected to yield comparable levels of hygienically clean results consistent with HACCP/GFSI principles.

About NAMSA®

NAMSA is the global medical research organization providing comprehensive services to advise clients and evaluate the safety and efficacy of medical devices, IVDs, and combination products. For nearly 50 years, NAMSA clients have utilized its consulting, testing, and clinical services to bring safe and effective therapies to market.

Definitions

Critical Control Points (CCPs) – Critical Control Points are crucial points, steps, or procedures within a process for controlling cross contamination where controls can be applied so food safety hazards can be prevented, eliminated, or reduced to acceptable (critical) levels. The most common CCP is cooking of food.

FDA – The Food and Drug Administration is an agency of the United States Department of Health and Human Services, a U.S. federal executive department. The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceuticals/medications, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), veterinary products, and cosmetics.

FSMA – The Food Safety Modernization Act was enacted to increase the regulatory power of the FDA to ensure a safer food supply chain and to enhance the power of the FDA to monitor and prevent food-borne illness outbreaks. Goals are met through four (4) main points of the bill (according to care2.com).
- Test for dangerous pathogens
- Trace outbreaks back to their sources
- Provide the FDA with mandatory food recall authority
- Subject foods from overseas to the same standards as those foods produced in the U.S.

HACCP – Hazard Analysis & Critical Control Points is a systematic method for the identification, assessment, and control of safety hazards. It is a series of tools used to assess and establish control systems that focus on prevention rather than relying on corrective action based on end-product testing. The methodology provides a quantitative approach to risk factor rating and focuses on controlling the risk of microbial contamination.

GFSI – The Global Food Safety Initiative is a worldwide business-driven initiative for the continuous improvement of food safety management systems to ensure confidence in the delivery of safe food to consumers. GFSI provides a platform for collaboration among some of the world's leading food safety experts from retail, manufacturing, food service, and other service providers associated with the food supply chain, international organizations, academia, and government.

GMP – Good Manufacturing Practices are practices and the systems required to be adapted in pharmaceutical manufacturing, quality control, and quality system covering the manufacture and testing of pharmaceuticals or drugs, including active pharmaceutical ingredients, diagnostics, foods, pharmaceutical products, and medical devices. GMPs provide guidance that outlines the aspects of production and testing that can impact the quality of a product.

ISO – International Organization for Standardization is an international standard-setting body composed of representatives from various national standards organizations. Founded in 1947, the organization promulgates worldwide proprietary, industrial, and commercial standards.
- ISO 22000 – The family of International Standards that addresses food safety management.

Microbiology Terminology

- <u>Bacterium</u> – Prokaryotic microorganisms typically a few micrometers in length that exhibit two (2) shapes ranging from spheres to rods. Bacteria are present in most habitats, growing in almost all types of environments. There are typically 40 million bacterial cells in a gram of soil and a million bacterial cells in a milliliter of fresh water. In all, there are approximately five nonillion (5×10^{30}) bacteria on Earth, forming a biomass that exceeds that of all plants and animals.

- <u>CFU</u> – A colony forming unit is the microbiological term to quantify a single organism. Study levels for pathogen challenges were greater than 1 million organisms or CFU.

- <u>Fungus</u> – A member of a large group of eukaryotic organisms that includes microorganisms, such as yeasts and molds. These organisms are classified separate from plants, animals, and bacteria.

- <u>Pathogen</u> (aka, infectious agent or germ) – A microbe, microorganism such as a virus, bacterium, prion, or fungus that causes disease in its animal or plant host. There are several substrates, including pathways whereby pathogens can invade a host. The principal pathways have different episodic time frames, but soil contamination has the longest or most persistent potential for harboring a pathogen.

- <u>Virus</u> – A small infectious agent that can replicate only inside the living cells of organisms. Viruses infect all types of organisms, from animals and plants to bacteria.

Product Protection Process (PPP) – The Product Protection Process is UniFirst's portal-to-portal servicing procedure specifically designed to prevent cross-contamination threats from being carried on uniforms and other worker garments. PPP begins at the customer's facility and extends throughout all handling, laundering, and finishing to safely deliver hygienically clean garments on a regular schedule.

UniSafe® Service – UniFirst's specialized uniform food safety program specifically designed to limit potential bacterial contaminants that could be associated with employee workwear. The program is based on the food safety guidelines set forth in the HACCP (Hazard Analysis & Critical Control Points) and GFSI (Global Food Safety Initiative) programs.