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Disposable Glove Physical Chemical and Microbiological Hazards

Review

Potential for Glove Risk Amplification via Direct Physical, Chemical, and Microbiological Contamination

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Abstract

This review focuses on the potential direct physical, chemical, and microbiological contamination from disposable gloves when utilized in food environments, inclusive of the risks posed to food products as well as worker safety. Unrecognized problems endemic to glove manufacturing were magnified during the COVID-19 pandemic due to high demand, increased focus on PPE performance, availability, supply chain instability, and labor shortages. Multiple evidence-based reports of contamination, toxicity, illness, deaths, and related regulatory action linked to contaminated gloves in food and healthcare, have highlighted problems indicative of systemic glove industry shortcomings. The glove manufacturing process was diagramed with sources and pathways of contamination identified, indicating weak points with documented occurrences detailed. Numerous unsafe

ingredients can introduce chemical contaminants, potentially posing risks to food and to glove users. Microbial hazards present significant challenges to overall glove safety as contaminants appear to be introduced via polluted water sources or flawed glove manufacturing processes, resulting in increased risks within food and healthcare environments. Frank and opportunistic pathogens along with food spoilage organisms can be introduced to foods and wearers. When the sources and pathways of glove borne contamination were explored, it was found that physical failures play a pivotal role in release of sweat build-up, liquefaction of chemical residues and incubation of microbial contaminants from hands and gloves. Thus, with glove physical integrity issues, including punctures in new, unused gloves, that can develop into significant rips and tears, not only can direct physical food contamination occur, but chemical and microbiological contamination can find their way into food. Enhanced regulatory requirements for Acceptable Quality Limits of food grade gloves, and the establishment of appropriate bioburden standards would enhance safety in food applications. Based on information provided, together with a false sense of security associated with glove use, the unconditional belief in glove chemical and microbiological purity may be unfounded.

Highlights

1. COVID-19 demands exposed and amplified hazards related to disposable glove manufacturing.
2. Glove contamination at production is consequential for users, and food or healthcare endpoints.
3. Loosely regulated safety and quality standards are causative factors within the glove industry.
4. Glove physical failures are pivotal in release of sweat build-up and liquefaction of chemical residues.
5. Incubation of microbial contaminants from hands and gloves can represent an additional hazard.

Introduction

As identified by Lipcsei and team, and in earlier research, bare-hand contact by potentially infectious workers (food handlers and preparers) was among the top factors contributing to outbreaks in retail food service establishments (Lipcsei et al., 2019; Todd et al., 2010b). Studies have revealed that viruses occurring in feces and the upper respiratory tract at high density are spread via hands, with glove use being an effective tool to help reduce the spread (Hjelt, 1991; Hoover et al., 2020; Leclair et al., 1987). Gloves have become essential in both food and medical applications because hand hygiene is not fully effective at removing, killing, or inactivating all infectious material from cracks and crevices on skin surfaces (Anedda et al., 2020; B. Michaels et al., 2003, 2004).

In food environments, while reusable gloves first saw use around 40 years ago, food service enlistment of lightweight disposable gloves to replace bare-hand contact for handling ready-to-eat food is still in its infancy (Guzewich & Ross, 1999). After all, it was only in 2010 under the guidance of senior leadership at the IAFP that a definitive set of publications were able to document the importance of eliminating bare-hand contact in favor of the use of glove in critical food handling situations where there was no further processing step enabling pathogen control (Todd et al., 2010b). As such, we are still learning the intricacies involved in their safe and effective use, to help reduce foodborne disease transmission in commercial food handling situations. Even with the best 21st century glove knowledge, no better example of how microbes can still totally overcome our glove-based defenses is the global pandemic. This experience laid bare multiple weaknesses in the halo effect of glove use, setting the stage for the potential of risk amplification when it appeared we needed intelligent application of gloves more than ever in the history of their utilization.

Gloves and the COVID-19 pandemic. With the appearance of the SARS-CoV-2 virus in late 2019 (COVID-19) and its subsequent spread, the global pandemic impacted nearly every aspect of human society. Transmission of infectious viral particles was found to include direct, indirect, or close contact via saliva and respiratory secretions from infected persons (Szczuka et al., 2021). Since transmission of SARS-CoV-2 virus was found to be multimodal, this pandemic brought awareness that a range of PPE, in addition to social distancing, enhanced ventilation, and air filtration, would be needed to provide effective interventions (Forrest, 2006; Hosseini et al., 2022). Food companies identified increased hygiene of workers and equipment, followed by use of masks and gloves, as the most important food safety attributes related to operating under pandemic conditions (Prasetya et al., 2022). The ensuing excessive glove demand, by healthcare workers and non-healthcare workers alike, magnified pre-existing physical, chemical, and microbiological glove contamination issues and resulted in food handling glove shortages (Anedda et al., 2020; S. Ardagh, personal communication, August 2020; Australian Government Department of Health and Aged Care: Therapeutic Goods Administration, 2022; Bown, 2022; McLean et al., 2021; U.S. Federal Bureau of Investigation, 2020).

Glove supply was prioritized to prevent COVID-19 impacts on the global food supply chain (Prasetya et al., 2022). Depleted glove stocks raised multiple concerns with guidance issued by the Centers for Disease Control and Prevention (CDC) and the European Centre for Disease Prevention and Control (ECDC) (European Centre for Disease Prevention and Control, 2020; U.S. Centers for Disease Control and Prevention, 2019). With scarcity, global supply chain shortages, and rapidly increasing prices, longstanding safety issues in glove manufacturing and distribution became significant (Bown, 2022; European Centre for Disease Prevention and Control, 2020). Worldwide material shortages, factory closures, and gloves of unknown origin and composition were being traded, taking advantage of supply uncertainty for nefarious gains (Bown, 2022). By July 2021, a CNN investigation called nitrile gloves “the most dangerous commodity on Earth,” and uncovered “tens of millions of filthy, used medical gloves imported into the US” for the healthcare and food industries (McLean et al., 2021). This investigative report highlighted, at least for a time, “an industry riddled with fraud.” By 2022, further reports emerged of “counterfeit” gloves of unknown origin, safety, or composition being sold to unsuspecting healthcare systems (Australian Government Department of Health and Aged Care: Therapeutic Goods Administration, 2022; U.S. Federal Bureau of Investigation, 2020). During the pandemic, over a trillion gloves were used, based on a peak usage rate of 65 billion gloves per month (Prata et al., 2020). Available literature pre and post pandemic demonstrates, a host of direct physical, chemical, and microbiological glove contamination issues highlighting food, healthcare, and worker safety concerns needing some level of corrective scrutiny.

Glove risk reduction, amplification, and transferal. Michaels and scientific team (B. Michaels et al., 2004) introduced the idea that use of gloves in food applications can reduce, amplify, or transfer risks by many orders of magnitude depending on how and under what

circumstances they are utilized. The literature review and data provided in this report will present evidence of potential for risk amplification via direct physical, chemical, and microbial glove contamination. While risk reduction is the objective for glove use, and risk transferal is not of significance, in these instances gloves would appear to have no advantage over bare hands (additional cost with no benefit). It is risk amplification that is important to identify, monitor, and prevent within the context of food safety. Glove dermal compatibility and food handler skin health is significant in the scheme of managing safe food operations as hand hygiene quickly degrades (B. Michaels & Ayers, 1999, 2000).

This article also explores the potential for risk amplification of physical, chemical, and microbiological hazards involving food workers. With respect to the potential for chemical and microbiological hazards present in gloves, the potential for contamination can come to food and the food handler at the same simultaneously. One needs to remember that food and worker are separated by the same polymer membrane with innate chemical and microbiological properties. Thus, it turns out that food and worker can be exposed to the same hazards differing each by exposure durations, contact surface areas and outcomes.

Glove dermal compatibility and food handler safety (as well as factors that don't magnify existing hazards) is significant in the scheme of managing safe food operations. Food workers suffering from dermatitis are not efficient workers, carry out hand hygiene less often (B. Michaels & Ayers, 1999, 2000), and are prone to skin infections (Ford, 2012; Nørreslet et al., 2021). These skin infections can carry risks of being food pathogens (Ford, 2012; Nørreslet et al., 2021). These workers often missed work, required long recuperative periods, and required prolonged sick leave. Studies have found that after workers were diagnosed with occupational contact dermatitis (OCD), 35% had changed their occupation and 43% had lost their job because of OCD (Dietz et al., 2022). By raising

Figure 1

awareness of the glove-related risk factors for occupational skin disease among safety managers as well as food workers, it should lead to preventive measures aiming at reduction of exposure (Lampel & Powell, 2019).

In presenting evidence of potential for risk amplification via direct physical, chemical and microbiological contamination, it provides information on where and how those risks develop based on a variety of preventable shortcomings, and where more work is needed to mitigate those risks as well as what food businesses need to do to improve glove use outcomes. While food must meet high standards regarding food safety and quality, the same can't always be said for or are being required of gloves. Gloves are relatively inexpensive, consumable commodities falling under HACCP prerequisite programs. Identified glove manufacturing complexities and shortcomings have not been easily or openly available to the food industry.

Glove production cycle. The process of manufacturing dipped and heat-sealed plastic film gloves is presented in Figure 1. For dipped gloves, which make up the bulk of the

longer duration types (including reusable gloves) relied on in food and healthcare applications, production steps may sometimes contain over a dozen subprocesses, as shown in this figure, represented as: a generic diagram based on several sources (Lovato et al., 2023; Patrawoot et al., 2021; Poh et al., 2019; A. H. Tan, 2022; Wanlaso, 2012), the relevant processes vary by glove type and individual factory production boundaries. Figure 1 is provided in order that readers will gain a better understanding of the critical aspects of the production process that can result in direct chemical and microbiological contamination. The figure extends from production, to usage, and into the glove wastes, wastewater recycling, and potential for contamination of the environment and potentially the human food chain. Therefore, in presenting this production process, essentially from cradle to grave, it identifies the fact that not only do glove factories recycle vast quantities of water back into the natural waters that they draw from (Wanlaso, 2012), but the environmental breakdown processes and even incineration of leach tank residues comes back into the purview of overall disposable glove quality and safety.

The process of manufacturing heat-sealed plastic film gloves is more straightforward than that for making latex, vinyl, and nitrile gloves using the dipping process and, in part, accounts for the much lower cost of these lighter weight gloves. The limitations on functionality and durability restricts usage to short duration (Todd et al., 2010b). For polyethylene or thermoplastic elastomer (TPE) gloves, sheet stock is stamp cut and seam sealed together with heat to produce the glove, Fig. 1.

For dipped gloves, the raw materials needed to produce gloves consist of various polymer blends of latex, nitrile, vinyl, or polychloroprene, or mixtures thereof with the necessary process ingredients. The compounding chemicals utilized in the dipping process are additives included in formulations necessary to achieve the required physical characteristics, such as strength, performance integrity, color, and aging protection (Crepy, 2016). The chemical additives include plasticizers, fillers, antioxidants, stabilizers, vulcanizing agents, and processing aids (Yip & Cacioli, 2002).

As presented in Figure 1, at the start of the glove production cycle (step 1), the continuously reused hand-shaped glove formers are cleaned by acidic solutions, oxidizing agents, surfactants, or combinations, followed by neutralizers and soft water rinse. They are then dipped into a coagulant tank and dried (step 2) to ensure that the polymer mixture will adhesively stick to formers. Coagulants are often polyvalent metal salts, an organic acid, or acid salt, and sometimes contain calcium carbonate to prevent the elastomer from sticking to the formers. With step 3, the formers are dipped into a polymer compound tank. This is followed by baking in a drying oven <175°C to cause the polymer mixture to gel, developing the glove film (step 4). In step 5, pre-leaching takes place where the wet, gelled film is rinsed in water to remove the excess chemicals before being vulcanized. Following

this leaching step, the glove cuff edge is rolled at the rim (beading). Some chemicals are added during beading to prevent deterioration of polymer molecules subjected to environmental aging and to aid in vulcanization. Following pre-leaching, the glove films present on formers are vulcanized by being oven baked at 100°C to 300°C, depending on polymer type (step 6).

Vulcanization is a thermochemical process that cures natural or synthetic rubber polymers by incorporating sulfur and/or other accelerators to irreversibly cross-link the polymer, producing a netlike structure that increases tensile strength; and provides greater elasticity and durability. Accuracy of cross-linking is temperature dependent, but also is a function, to some extent, of evaporation and thus introduces batch-to-batch variation (Cao et al., 2010; A. H. Tan, 2022). Post-cure leaching by hot water (step 7) removes chemicals from what is to becomes the inner glove surface. Here it should be noted that throughout the process chemical residues are only removed from inner, not what become the outer, food contact surfaces. Step 8 provides surface treatment by donning aids, powder slurry, chlorination and/or polymer solution treatment.

With step 9, the gloves are dried and stripped off the glove formers and, in the process, are turned inside out. This is where the inner surface in contact with the formers becomes the outer surface and up until now, the outer surface becomes the surface that will meet or contact the hands of wearers. All gloves will then be subjected to tumble drying at what is supposed to be high temperature (step 10), with cooling at temperatures of around 42°C. The final process step (11) consists of inspection and packaging where date codes are provided, setting indication for shelf-life designation. As with the initial steps, these last few steps may contain variations relative to the exact type of gloves and process being utilized at any manufacturing plant (Lovato et al., 2023; Patrawoot et al., 2021; Poh et al., 2019; Wanlaso, 2012).

The glove manufacturing process requires the consumption of a large amount of water during the washing or leaching process (Figure 1, steps 5, 7, & 8) (Wanlaso, 2012). For this reason, all glove plants are situated near natural waterways, while concurrently discharging into the same watercourses. Based on the clustered locations of glove manufacturing plants, these factories tend to be located on some of the most polluted waterways of Southeast Asia (Samsudin et al., 2018; To et al., 2020; Wang et al., 2015). It has been reported that typical wastewater treatment plants are hardly capable of treating

Figure 2

the quantities of wastewater produced, with <5,000 m^3 (1.3 million gallons) generated per day at large facilities (Wanlaso, 2012). This means that not only is the effluent capacity

limited, but influent for leaching tanks and glove leachates become burdened by dissolved organic matter (DOM), dissolved organic carbon (DOC), suspended solids (SS) and particulates (collectively known as leach tank coagulum). The cycle from clean hot leach water, build-up of highly contaminated leachate before leaching tanks are flushed takes place repeatedly with water temperature and chemical build-up cycles affecting levels of impurities or contaminants during glove manufacture (Cao et al., 2010; A. H. Tan, 2022).

Energy requirements for driving the process and specifically for heating the leach tank water can be significant (Patrawoot et al., 2021; Poh et al., 2019). The water and energy requirements enabling glove production puts these systems under stress, where leach tank water is often at suboptimal temperature and cleanliness levels, resulting in microbial and chemical loading adversely affecting both chemical and microbial contamination potential, as identified in further sections of this article.

Sources and Routes of Contamination. Presented in Figure 2 is an expansion of the center-top portion of Figure 1 that is titled, "Potential Direct Food and Human Exposures". Figure 2 provides a map of the main pathways of contamination incorporating the physical, chemical, and microbiological routes (Fig. 2, direct contamination pathways A, B, & C) as well as the pathway D that involves glove-food worker interactions. The latter pathway is generated as potential second or third order downstream consequences of food worker glove use can have food safety implications.

Figure 2 leads through the food processing or food service management, to the foods being handled, the food worker and glove usage along with applicable manufacturing considerations capable of impacting safety. With respect to setting the priorities for glove manufacturing as identified in GM-1 (Fig. 2) marketing and sales strategy is typically based on some combination of pricing versus quality. This will ultimately determine what the glove material type and formulary will consist of (Fig. 2, GM-2) based on the so-called price quality matrix. It will also determine to what extent the quality and safety specifications are being tested (Fig. 2, QS-1), to obtain and maintained that level of (Fig. 2, QS-2), of targets and tolerances (Fig. 2, QS-3). Thus, this sets the stage to determine if the specifications and standards will be strictly set to high standards and controlled for high quality gloves versus set for medium or low-quality gloves. Testing for achieving high physical, chemical microbiological standards are costly especially if it means frequent testing, record keeping and corrective measures to reduce factory rejects. If lower quality is acceptable across the board, without the necessity of testing and stringent monitoring, then low-quality, low-priced gloves can result. Based on key decisions made in GM-1 and GM-2, a further off-shoot is whether a high dermal compatibility claim (Fig. 2, GM-3) and additional testing will be required to support that claim within acceptable regulatory frameworks (U.S. Food and Drug Administration, 1999). Another significant price versus

quality decision involves polymer content and filler issues (GM-4) discussed in the next section.

From marketing and sales strategy of price and/or quality the quality/safety regime is set to follow the format provided in Figure 2 as an exploration of the three potential pathways involved in physical, chemical an microbiological contamination (Fig. 2, A, B, & C).

Potential for direct physical contamination of food. Physical contamination from ripped and torn glove pieces presents food safety issues, with the usual precursor being puncture. Punctures allow chemical and/or microbial transfer via sweat in a time-dependent, drop-by-drop manner (Hübner et al., 2013). The physical integrity continuum Fig. 2, P-1 through P-6 provides a listing of the causes of punctures, breaks, and tears. In the case of organisms trapped inside gloves either derived from hand surface normal or transient flora (Price, 1938), or from inherent glove contamination (described in the last section of this article) incubation will take place during the period of wear increasing microbial loads Fig. 2, CC-3. With the physical glove pieces shed into food, larger slugs of liquified soils amplify this hazard in a visible and hard to ignore fashion (B. Michaels, 2004a; B. Michaels et al., 2004; B. Michaels & Ayers, 1999, 2000; B. S. Michaels, 2002b), that will trigger recalls.

While glove pieces are dramatic, the incessant time-dependent, drop-by-drop result of a leak or many leaks from all food workers on shift can have significant consequences as a single puncture can represent liquid bridge to whatever is contacted. The extent of the liquid bridge that can emanate from a single hole a little larger than 1μm can be deduced from the observed flow of 1.8×10^4 CFU of *S. aureus* over a 20-min period initiated with the aid of the sweaty hand of the wearer (Todd et al., 2010b). This effect was observed in recent glove use experiments (Selvaraj et al., 2023). The driving force for the liquid bridge is glove occlusion (sealing off) (Fig. 2, GU-3). With the rise of skin temperature by perhaps greater than 5° C, skin hydration increases significantly as does exposure of the skin to chemicals within gloves (Fig. 2, CB-3), while at the same time evaporation of sweat and other volatile materials are prohibited (Groce, 2003).

The magnitude of sweat build-up within a disposable glove related to the thermoregulatory role of eccrine sweat glands can be considerable. Whilst the average human has some 2.03 million functional glands spread across body skin surfaces, the highest density can be found on the volar surfaces of the fingers (530 glands per cm^2) (Taylor & Machado-Moreira, 2013). Under the thermal stress of glove occlusion, the very high density of sweat glands found on the hands are capable of generating up to 160 grams of sweat per hour (Taylor & Machado-Moreira, 2013). At Figure 2, center we have termed the combined effects sweat build-up, punctures and leaks as the "Sweat-Leak-Nexus". Within this nexus, chemical and microbiological glove hazards can be amplified as per Fig. 2 CB-3 and CC-3, respectively.

Glove polymer surface failure (rips and tears) is often directly related to raw material formulation shortcomings and filler use (Lovato et al., 2023) (Fig 2, GM-4). Fillers are inexpensive powdered solids added to glove polymers that at low concentrations can improve physical properties, but at high concentrations are often used to lower cost and increase thickness, to the detriment of durability (Lovato et al., 2023). According to the FDA Current Good Manufacturing Practice (CGMP) Regulations, food-compliant gloves must be both sanitary and impermeable; however, some glove types structurally fail either right out of the box or within the first few minutes of use (Phalen & Wong, 2011; Rego & Roley, 1999; Selvaraj et al., 2023). Failure rates for vinyl and polyethylene gloves out of the box have been reported to be as high as 41% and 61% respectively (Selvaraj et al., 2023). In the evaluation of new, unused nitrile medical/food grade gloves, failure rates are more on the order of 0-3% (Phalen & Wong, 2011; Rego & Roley, 1999). While the failure rates reported either when new or when in use are under laboratory testing, it should be kept in mind that studies have estimated that 50% to 90% of all glove perforations during use go unnoticed or undetected by wearers (Hübner et al., 2013; Timler et al., 2015; Todd et al., 2010b).

As indicated in Figure 2., "GM-4., glove stretch, strength, thickness, breathability, heat build-up and dexterity are all impacted by filler and polymer content ratios. It is not uncommon for gloves to contain over 30% fillers. While above 15% in formulation concentration can reduce costs, overuse of filler may become detrimental to glove performance and quality (Marzec & Zaborski, 2012; Wijesinghe et al., 2016). Conversely, low fill, low modulus (low ratio of stress to applied strain; stretches with less resistance) nitrile gloves have a lower percentage of leaks following simulated movement when compared to higher fill, higher modulus equivalents (Phalen & Wong, 2011). The ratio of acrylonitrile and butadiene groups, called the ACN content, is crucial to nitrile gloves' physical properties (Phalen et al., 2020; K. Y. Tan et al., 2018). The higher the ACN content, the better polymer resistance to non-polar solvents. Most applications requiring both solvent resistance and low temperature flexibility require an ACN content of around 33%. Reducing costs with high fill and lowered ACN levels increases glove breakdown rates and decreases durability when exposed to fats, oily solvents or animal proteins (Fig. 2, P-5), allowing liquid penetration through glove tears and cracking (Ardagh, 2017). In summation, lower cost, high-fill, low ACN content gloves can rip and tear, leading to not just physical, but also chemical, and microbiological contamination during food manufacturing.

Ripped glove pieces in food are reported regularly (Flynn, 2012; U.S. Department of Agriculture FSIS, 2021; Yedroudj & Kershaw, 2019) and can also cause customer complaints, recalls, or withdrawals, with cost and safety implications when glove pieces contaminate food products via large scale batching processes (B. Michaels & Ayers, 1999,

2000). Physical contamination occurs frequently with poor quality gloves, prompting the availability of metal detectable gloves claiming to reduce costs associated with accidental contaminations in food processing or pharmaceutical industries (Lupo, 2017). This somewhat flawed strategy, switching from poor quality gloves to a variant with metal detecting capability, is a trade-off addressing the symptom not the cause, whereas gloves with low rip/tear potential address the cause.

Various authors have recommended utilization of highly visible, colored gloves to enable in-plant traceability, with colors assigned to functional work tasks, work areas, or food types, that assist in identifying responsible individuals or areas, should contamination (visible or detected) occur (King & Michaels, 2019). Color coding of gloves within processing or preparation environments provides a visual cue, when wearing the raw color/indicator gloves, to remove the gloves before touching other surfaces or food.

Management, procurement, or supplier failure to recognize the importance of bright colors and higher quality gloves can have significant consequences, as gloves found in soup during a recent recall were low-visibility gray, a significant contributory factor in the lack of early detection (U.S. Department of Agriculture FSIS, 2021). Third-party audits and HACCP-based self-assessment systems can monitor compliance with zone glove color coding (King, 2013; King & Michaels, 2019; U.S. Food and Drug Administration, 2006). With the FDA Food Code (U.S. Food and Drug Administration, 2023) referencing gloves as "utensils," these can be defined as a Zone 1 Food Contact Surface, requiring proven barrier effectiveness.

Food processing/service glove period of wear. A significant contributing factor of glove punctures and breaks is gloves worn for excessive periods (Fig. 2, P-3). Determination of the proper glove wear duration period (Fig. 2, GU-2a) is difficult without actual glove trials as it is influenced by the role played by the food worker within a facility, integrity of the gloves being utilized, and the exact type of work being performed. Ultimately this should be determined by testing under in use conditions and ensconced into facilities glove standard operating procedures (G-SOPs) (Fig. 2., GU-1).

Common statements of change frequency when performing the same task, usually with clear safe use caveats are, "after two hours of continuous use" (Hanson, 2022; Leblond, 2018) or "the gloves must be changed at least every four hours" (Daniel, 2023; Guthmiller, 2019; Molen, 2016; Strohbehn et al., 2011). Reasons for citing specific levels include, that the period is long enough for pathogens to multiply to dangerous levels, or to guard against possible unseen punctures, both reasons for scheduled changes in healthcare applications. It should be noted that in these recommendations there are essentially no distinctions being made between single-use or the heavier repeated-use (reusable) gloves more commonly employed in produce handling and some types of food processing. Reusable

gloves are intended to be used for longer times than disposable gloves but data on actual documented practice is limited (Zhao et al., 2021). While it is assumed that USDA Extension Service scientist intend that the guidelines apply to repeated-use gloves, it would still appear that four (4) hour wear periods on a single task is extreme in respect to skin health risks alone. The long duration glove usage recommendations made across the board without distinguishing between glove types, give license to the kinds of abuse most often cited as food safety hazards posed by gloves that include not changing when soiled, punctured, or compromised due to having clear cross-contamination potential (Guzewich & Ross, 1999; B. Michaels, 2001a; B. Michaels et al., 2004; B. Michaels & Ayers, 2000; B. Michaels & Griffith, 2017; B. S. Michaels, 2002b; Todd et al., 2010b).

Studies clearly indicate that the risk of micro-perforations and, as a consequence, the loss of protection for wearer, food or patient in healthcare, increases with wear duration (Hübner et al., 2010). With respect to setting a shortened change period, the shortest mandated in some jurisdictions is 30 minutes. This is the equivalent duration as skin health guidelines for good hand care to help prevent occupational hand dermatitis in food handlers and kitchen staff wearing gloves (Ford, 2012) and coincides with some food service company hand washing frequency requirements and practice in monitored quick-service and casual restaurants (Manuel et al., 2023; Strohbehn et al., 2011).

Potential for direct chemical contamination of food. Natural and synthetic gloves have been identified as sources of potentially toxic, poisonous, and deleterious chemicals that can be introduced into food, and cause dermal problems via solubilization of glove chemicals within gloves via sweat, as demonstrated in food simulating solvent testing (L. Edwards et al., 2022; Feng & McLellan, 2019; B. Michaels, 2004a, 2004b; B. S. Michaels, 2002b; Pinprayoon & Mae, 2019) and in reports of dermal exposure (see Table 2, Table 3, Fig. 2, CB-2, CB-3, CB-4).

Table 1 contains a list of chemical contaminants having the potential for food contact safety issues reported in the literature. Here can be found numerous reports describing chemical contaminants released from gloves through various extraction or monitoring procedures at both low levels, (Forrest, 2006; Ling et al., 2017; Oishi et al., 2013; Reichel, 2012; Sidwell & Forrest, 2000) and those sparking concern (Olson et al., 2019; Poitou et al., 2021). In viewing the listing in Table 1, for the potential of glove risk amplification, several significant caveats must be kept in mind:-1) this is a diverse listing with each chemical or individual chemical within the grouping of chemicals listed having their own toxicity profile; 2) in most cases, a full risk assessment and important toxicity assessments have not been completed; 3) and further in the vast majority of cases, there is yet insufficient data available in published peer reviewed literature concerning the risks that might be posed to humans via food contact with the gloves in question;-4) in the few cases where some

scientific experts feel strongly that all previous caveats have been satisfied, there exists current scientific debate with unsettled science;-and finally, 5) this has left many regulatory bodies unable to reach consensus on courses of action to limit potential human exposures to the most concerning of these chemicals (Landrigan et al., 2023; L. Edwards et al., 2022; Cao et al., 2010; Geens et al., 2012).

Before briefly going through the listing in Table 1, and providing available details specific to each chemical or chemical group, the recent pandemic experience, has offered challenges with ingredient declarations, and issues specific to each of the main disposable glove types worth relating. With COVID-19 related shortages, the US Federal Bureau of Investigation (FBI), FDA, and the Australian Therapeutic Goods Administration confirmed the counterfeiting of nitrile gloves having unknown composition, mislabeled/misbranded, and in violation of regulations (Australian Government Department of Health and Aged Care: Therapeutic Goods Administration, 2022; U.S. Federal Bureau of Investigation, 2020). This represented a multitude of unknown hazards, with possible violations of all international standards for performance and safe chemical ingredient requirements.

While the violations identified during the pandemic are extreme, there are instances where investigations into adverse events related to glove use revealed chemical additives not listed in manufacturing statements (Dahlin et al., 2014; Hansson et al., 2014). The lack of detailed certificates of analysis (COAs) and knowledge of chemical ingredients is particularly important when it comes to user safety, as seen in the next section. A complaint registered by clinicians investigating dermal complications associated with glove use is that, unlike numerous product types, there is a lack of regulations requiring that glove chemicals be listed as ingredients on products (Cao et al., 2010; Santarossa & Larese Filon, 2018).

Glove type related hazards. While this is an article covering various types of disposable gloves used mainly in food but also in healthcare environments, it is assumed that readers will already be aware of the types available and what their characteristics are. Choosing the right glove for a particular food establishment in terms of current technology, involving conditions of use, material type, thickness, size, performance, and propensity for puncture (new and under use conditions) is complex and beyond the perview of this article. Instead, this article is devoted to the hazards posed by the types that are currently in use by food operations and are associated with one or more of the hazards discussed in this article.

Latex gloves. The average prevalence of latex allergy globally for the general population is estimated at 4.3% (Wu et al., 2016), with reports of latex allergic reactions caused by

food contaminated by workers wearing latex gloves (Bernardini et al., 2002; González-Díaz et al., 2022). As of this writing, eight US states have banned latex gloves for food manufacturing and restaurant use due to food safety precautions, consumer complaints by susceptible individuals, and workers' compensation claims from latex-related allergies (Bernstein, 2007).

Nitrile gloves. Nitrile gloves are manufactured from a synthetic polymer (acrylonitrile, butadiene, and carboxylic acids) along with zinc oxide, sulfur, and process accelerators, providing the latex-like characteristics upon vulcanization. With excellent abrasion resistance, they provide credible barrier protection against chemical solutions and some commonly encountered fats, oils, and greases. However, they can degrade with prolonged exposure to solvents (Lovato et al., 2023). Nitrile gloves are made using a copolymer of acrylonitrile and butadiene. Acrylonitrile is poisonous by inhalation, ingestion, or skin contact, and once introduced into the body will result in cyanide release. It is also considered potentially carcinogenic (Lenzner et al., 2018). Acrylonitrile has been detected in nitrile gloves (Wakui et al., 2001), and has limits set by FDA and internationally in food contact regulations.

Vinyl gloves. A 2019 survey determined two-thirds of quick service restaurants utilized vinyl gloves (Olson et al., 2019). PVC for vinyl gloves is produced by the free radical polymerization of vinyl chloride monomer (Poitou et al., 2021). Plasticizers are small molecules, not covalently bound to the vinyl polymer matrix, making up to 41% of the glove's weight, and are widely used in plastic manufacturing, imparting the needed flexibility to PVC resins to make gloves (Poitou et al., 2021; Tsumura et al., 2001). Under conditions of use, these phthalate plasticizers can be released either into food or into the hand glove environment. When worn, some of these chemicals can become a dermal exposure source for food workers, as described in the next section (Poitou et al., 2021).

In testing, Poitou and team found the presence of the plasticizer DEHP at what were termed concerning levels in ten different glove samples recently studied.

Polyethylene Gloves (PE). While PE gloves are seldom named a source of harmful chemical exposures an early report identified Butylhydroxytoluene (BHT) or butylated hydroxynisole (BHA) functioning as antioxidants (Sugiura et al., 2002).

Chemicals with heightened food exposure concerns. While not going into detail on every chemical listed in Table 1, there are a few noteworthy chemicals or groups of chemicals where significant information is available regarding potential exposures.

Phthalates. Because of their lipophilic characteristics, phthalates are known to contaminate fats, meats, and dairy products, attributing to causing health effects such as neurotoxicity, endocrine system disruption (Kühne et al., 2021; Poitou et al., 2021; Varshavsky et al., 2018), carcinogenicity, fertility impairment (early puberty, lower sperm count), metabolic disorders, and diabetes (Landrigan et al., 2023; Poitou et al., 2021). Several commonly used phthalates are now classified as toxicants by the EU (European Community, 2008), though for the most part they have not seen stricter regulations in the US (Engel et al., 2021; Poitou et al., 2021). Human exposure to these compounds can occur through ingestion, inhalation, and parenteral routes, and to glove users through dermal absorption (European Chemicals Bureau et al., 2008; Tsai et al., 2019; Wormuth et al., 2006). Even though gloves are found to be manufactured with phthalates (Olson et al., 2019; Poitou et al., 2021), current legislation directed toward limiting plasticizers in food contact articles has thus far been limited. Therefore, glove manufacturers' decisions to reduce or eliminate these chemicals are largely voluntary.

While there are a number of exposure sources for most phthalates contaminating food, data suggests that a significant role is played by packaging, processing, and handling foods via gloves (Cao et al., 2010; Petersen & Jensen, 2016; Rudel et al., 2011). The public health cost associated with endocrine-disrupting compounds in vinyl gloves used in quick service food preparation can be considerable and estimated by combining available data. In the US alone, the overall annual healthcare cost of endocrine-disrupting compounds is estimated to be $340 billion (more than 2% of the gross domestic product) (Attina et al., 2016), with 14% of vinyl gloves recently testing positive for phthalates (Olson et al., 2019). When phthalates were banned in Japan, a 33% drop in endocrine-disrupting compound exposures was noted (Tsumura et al., 2003). While the Japanese experience does not document a benefit to public health, there are indications that the continued usage of phthalates in vinyl gloves may amount to several billion dollars in the US. With phthalates found in food production and diet samples because of gloves and other food contact materials, Japan and Nordic countries, along with the state of Maine (Olson et al., 2019), have banned DEHP and other phthalates from vinyl gloves (Tsumura et al., 2003).

Bisphenol A (BPA). BPA is used as an antioxidant and an inhibitor of end polymerization in PVC plastic products. It is found in food packaging and epoxy linings of canned foods and utilized for the elimination of excess hydrochloric acid during PVC production, including being commonly found in vinyl gloves (Norman et al., 2023). Having been found to have carcinogenic properties (Seachrist et al., 2016), BPA has caused allergic contact dermatitis in individuals in multiple industries, all exposed via vinyl gloves (Cao et al., 2010). Phthalates and BPA pose food safety concerns to children, by means of impaired neurodevelopment, toxicity promoting obesity ("obesogens"), and to both males and females as a result of endocrine disruption, with reproductive and immune system

impairment (Cao et al., 2010; Geens et al., 2012). With BPA and phthalates in particular levels have been demonstrated to be present at levels triggering concern (Friedman, 2024; Olson et al., 2019).

N-nitrosamines. Known to be produced at the vulcanization step in the glove production cycle (Fig. 1, Step 6) (Pensabene et al., 1995). Possible risks due to N-nitrosamines migrating to foods from handling by gloves or exposure of workers wearing those gloves has been examined in several research studies. Both latex and nitrile gloves have been tested with food-simulating solvents and artificial sweat (Feng & McLellan, 2019; Pensabene et al., 1995; Pinprayoon & Mae, 2019). The results of those studies when compared to daily intake of N-nitrosamines from food indicate that under extreme conditions, it could lead to exceeding dietary intake guidelines (Pinprayoon & Mae, 2019).

Heavy Metals. Some glove materials have been identified as potential heavy metal food contamination sources, with some food simulants having the potential to alter or disintegrate elastomeric materials (Kühne et al., 2021). Metals can be introduced into the glove manufacturing process as cross-linking agents that speed up sulfur vulcanization steps (Fig. 1, step 6). This often involves ions of zinc, magnesium, zirconium, chromium, iron, and aluminum (Yew et al., 2019, 2020). Garçon and team (Garçon et al., 2017) found that metals could be leached from vinyl, nitrile, latex, and neoprene gloves including cadmium, mercury, lead, and arsenic. Similar results were reported in earlier research conducted with 4% acetic acid extracts of vinyl, polyethylene, latex, and nitrile gloves, where aluminum, copper, lead, and cadmium were found (Wakui et al., 2001). Concern for the potential for heavy metal entry into drug products from glove elastomers prompted much of this testing, and while contaminating elements were found below designated safety thresholds, it was determined that more information was needed to enable cumulative level calculation for food or drug exposure assessment (Paskiet et al., 2019). Heavy metal, however, can become a human exposure concern when considering environmental fate, as illustrated in Fig. 1 “Environmental & Natural Resources”. It is also noteworthy that with glove wastewater and treatment processes, factories typically employ release of wastewater into water sources used to feed the “Fig. 1, Water System,” and that, along with energy inputs, are critical in driving the glove production cycle.

Potential for chemical contamination with dermal concerns. Protective gloves, employed as risk reduction measures, are sometimes responsible for increasing risks in several forms. Gloves are the most important personal protective measures in the prevention of occupational skin disease (OSD) in all public sectors, but they must be utilized correctly, should be changed when punctured to prevent entry of allergens from food or facility cleaning compounds, (see Fig. 2., “A-1 Food Allergens” and “A-2 Facility Detergents…” respectively) (Wright et al., 2023) not contain glove-related allergens themselves, (see Table 3 & Fig. 2. A-3) and the occlusive effects should be mitigated (Wilke et al., 2018). Occupational skin diseases in food handlers, cooks, and bakers are frequent causes of illness in the food industry. OSD in the food industry is around double the average

found in other industries (Ford, 2012) and represents a cluster of different types of dermatitis, each of which can have links to glove usage. Fifty-five percent of all skin problems in the industry is caused by wet-work (Ford, 2012).

Wet-Work. Wet-work (Fig. 2, "CD-fwG-1) is defined as unprotected exposure to humid environments/water >2 hours per shift with exposures to detergents and disinfectants (Fig. 2, (A-2); high frequencies of hand washing, >20 times per shift (Fig. 2, GU-2b); or prolonged glove occlusion, >2 hours per shift (Fig. 2, GU-3)(Behroozy & Keegel, 2014). In considering wet-work equivalence by definition of glove use for two hours versus 20 hand washes per shift and unprotected hand exposure to wet conditions, while it is true that a great deal of sweat can be generated per hand (Taylor & Machado-Moreira, 2013), evidence suggests that glove use is not totally at fault. In a single cross-sectional study, it was demonstrated that prolonged glove wearing (e.g. occlusion for 6 h per shift in clean-room workers) did not appear to affect the skin negatively (Weistenhöfer et al., 2015). But in this instance, there was not exposure to additional hazardous substances as would occur in food or healthcare environments. This is supported by experimental evidence that not only did 6 hours per day of glove occlusion not cause negative skin changes, but that occlusion of skin previously treated with sodium lauryl sulfate, a commonly used anionic detergent emulsifier found in soaps and cleaning products, leads to an increased susceptibility to the irritant, with an aggravation of the irritant reaction (Ramsing & Agner, 1996).

Skin damage can also carry increased risk of pathogen harborage on hands. The irritation caused on the skin by frequent washing and/or wearing of occlusive gloves is associated with changes in hand microbial flora, and their potential negative endpoints (Fig. 2, CD-fwG-5). Bacterial counts from the hands of healthcare professionals with damaged hands were higher than those with healthy hands, and those with damaged skin presented higher frequency of *Staphylococcus aureus*, 16.7% versus 10%; gram-negative bacteria, 20% versus 6.7%; and yeast, 26.7% versus 20%, respectively, as well as the sum of these microorganisms. The presence of *Staphylococcus haemolyticus* was seen only in nurses with damaged hands. The presence of antimicrobial-resistant *S. aureus* and gram-negative bacteria was also greater among damaged hands (Rocha et al., 2009). Recent research has shown that in healthcare, cleaning, and catering professions, where occlusive gloves are often required, around half of all patients with hand eczema are colonized with potentially harmful *S. aureus* (Nørreslet et al., 2021). With wet-work skin damage, workers are prone to yeast infections by *Candida albicans* (as well as related spp.), and bacterial infections from colonizing bacteria and further associated with injuries from burns and knife cuts (Fig. 2, NO-3) (Ford, 2012).

Table 2 is provided as an aid in understanding the various occupational skin disease types affecting food workers, and involving gloves as described in this section, and appearing in the literature on the subject. Further, presented in Table 3, is a listing of chemicals with the potential for causing user safety issues to glove wearers. For the most part, glove wearers need to be aware of the risks of chemicals or food allergens entering gloves (via punctures, rips, tears or gauntlet entry) that can cause internal contamination, resulting in negative

exposure consequences such as chemical burns and/or food allergies (Rawson et al., 2005). While these types of events are commonplace and should be prevented, chemicals introduced into gloves during manufacture have a similar ability to elicit allergic reactions, or potentially result in systemic absorption through the skin. With potential food exposures to glove chemicals, full risk assessments are needed to understand the risks posed to workers potentially exposed to these chemicals.

Dermatitis caused by polymeric gloves can be caused by the glove polymer, additives to the polymer, or by donning aids such as powder or moisturizers (Li et al., 2020). While every glove type poses dermal safety issues, natural rubber latex (latex) gloves leads the list. Vinyl and nitrile are known for problems related to plasticizers and accelerators respectively. Irritant contact dermatitis (ICD) is defined as the physical injury to superficial layers of the skin because of repeated exposure to water and/or harsh chemicals (Kersh et al., 2018; Li et al., 2020). Allergic contact dermatitis (ACD) and contact urticaria (CU) are markedly different as symptoms relate to immune-mediated hypersensitivity reactions to specific chemical triggers (Kersh et al., 2018; Li et al., 2020). Contact urticaria is common in food handling and cleaning trades (Giménez-Arnau et al., 2022). While CU is an immediate Type I hypersensitivity resulting from immunoglobulin E antibodies, which at times can be severe, it is more often a pronounced irritant reaction (Li et al., 2020; Siegel et al., 2010). ACD, however, is a delayed Type IV hypersensitivity reaction where an allergen attached to a protein carrier (hapten), termed a hapten-carrier-complex, can elicit a T-cell-mediated immune response. Once sensitization occurs, cutaneous re-exposure at minimal dose will produce symptoms that include erythema, vesicles, pruritus and/or scaling, often resulting in disability (Kersh et al., 2018). It is therefore critical to identify the allergen inciting symptoms to be able to avoid further exposures (Johnston et al., 2017).

Latex allergies attributed to latex gloves were reported at high frequency during the pandemic (Alluhayyan et al., 2020; Hu et al., 2020). Latex, derived from the sap of the commercial rubber tree, *Hevea brasiliensis*, is a complex protein, lipid, and phospholipid mixture having more than 35 proteins capable of initiating an allergic reaction. While healthcare workers have been most impacted by latex allergies, there is a risk of allergic contact dermatitis in food workers as well, with latex also cross-reacting to food-induced allergies (Caballero & Quirce, 2015; Pastor-Nieto & Giménez-Arnau, 2018), especially in fresh produce packing facilities where use of latex gloves is common (C. Chaidez, personal communication, June 1, 2023).

A debilitating skin condition encountered among wet-work glove wearers is occupational hand dermatitis. It is provoked by wet-work and glove use, bringing about skin barrier dysfunction (Karagounis & Cohen, 2023). Multifactorial in causes and presentation, it can result in multiple types of dermatitis occurring simultaneously. Skin damage symptoms are characterized as involvement of erythema (redness & inflammation), skin fissures or erosions, skin maceration, vesicles, and bullae (blisters), pruritus (itching), and pain with

variable swelling, being provoked by wet-work and glove use bringing about skin barrier dysfunction (Jacobsen et al., 2022; Kersh et al., 2018). Contributing factors in its development are frequent hand washing, the wearing of occlusive gloves for a prolonged duration, and exposure to detergents, alkalis, or organic solvents. Occurring with regularity in food and healthcare workers, it was identified during the COVID-19 pandemic in studies focused on PPE-related dermatoses. In a systematic review of occupational dermatoses caused by personal protective equipment (PPE) during the COVID-19 pandemic, Keng and team (Keng et al., 2021) identified these symptoms with regularity among 3958 participants in 16 studies, with the most widely implicated circumstances involving the increased frequency of hand hygiene and glove use for extended periods.

As presented in Table 3, a leading cause of glove-related allergic contact dermatitis (delayed-type hypersensitivity) and hand eczema (dermatitis) are accelerators used to cross-link or polymerize synthetic or natural rubber, speeding up the typically slow process of vulcanization. The issue of glove allergen appearance has been described as a self-perpetuating cycle whereby elimination of one type or set of polymerization accelerators prompts an increase in new novel allergens to appear in succession. Thus the listing found in Table 3 (Kersh et al., 2018). Because of frequent allergic contact dermatitis and occupational skin disease from glove related accelerators, accelerator-free gloves are recommended and effective for those with suspected or confirmed hand allergic contact dermatitis (Crepy et al., 2018; Smylie et al., 2021).

Latex and synthetic gloves deteriorate relatively easily, with oxidation caused by the atmospheric oxygen and ozone. Thus, antidegradants increase glove shelf life. Antioxidants such as UV-stabilizers and antiozonants have triggered allergies (Hamann et al., 2014; Kruger et al., 2005; Suuronen et al., 2013). And antimicrobials isolated from all glove types have both irritating and sensitizing properties (Aalto-Korte et al., 2007; André et al., 2022; Dejonckheere et al., 2019). In addition to food migration issues represented by plasticizers, workers have been sensitized by a variety of plasticizers and additives found in various glove types, but vinyl gloves are a major contributor to this type of complaint (Li et al., 2020). A recent study of 20 different vinyl exam glove brands found all contained compounds listed in Table 3 as potential sensitizers (Norman et al., 2023).

Glove powder. Cornstarch and calcium carbonate have been the dusting powders commonly employed as donning aids. All types of powdered gloves have been associated with adverse events, including airway inflammation (Grunewald et al., 2003), wound complications, infection promotion (Suding et al., 2010), and postsurgical adhesions, resulting in FDA and international bans on powdered medical gloves (Patrawoot et al., 2021; U.S. Food and Drug Administration, 2016). To manufacture powder-free gloves, manufacturers must rely on two different methods to reduce surface stickiness, either

chlorination and/or polymer coating (Yip & Cacioli, 2002). Chlorination involves multiple washings with a solution of hypochlorite and hydrochloric acid, to oxidize the rubber film, decreasing friction of the surface. Polymer coatings (e.g., acrylic polyurethane and silicone polymers) are used to coat the inner surface of the gloves (Patrawoot et al., 2021).

Bacterial Endotoxin. Identified in Fig. 2, CC-2, bacterial endotoxins can represent a toxic insult complicating dermal health endpoints for glove wearers. Gram-negative bacteria are enclosed in protective outer membrane composed largely of lipopolysaccharide (LPS), that when these bacteria are killed, disrupt the membrane release the LPS within a toxic complex containing protein and phospholipid refered to as endotoxin. These endotoxins are pyrogens (fever-inducing) that can trigger immune system response and cannot be eliminated by standard sterilization processes (Kramer & Assadian, 2016). A study that compared eight types of examination glove, endotoxin contamination of unused gloves ranged almost four thousand-fold (from below 1.5 to 5810 endotoxin units) (Thorne et al., 2005)and a recent study from four manufacturers found endotoxin to be present on three types of glove with gloves from one manufacturer, levels exceeded 300 EU (Takahashi et al., 2020). While surgical applications require liminting endotoxin levels (the limit is 0.5 EU/ml or 20 EU/device) in order to prevent adverse effects to patients, wearers of gloves could also on occasion suffer from skin reactions. Endotoxin sources are inadequate washing during manufacture, or use of contaminated cleaning or leaching water (Takahashi et al. 2020). Use of gloves by food workers containing high levels of endotoxin, could further aggravate symptoms of already scratched, cut, irritated, or allergen triggered hands as measured with stimulation of host immune response in vivo (Takahashi et al., 2020). It should be noted that as reported in the next section, several glove samples tested were found to contain gram-negative bacterial species capable of increasing endotoxin levels on gloves.

Potential for direct microbial contamination of food. Microbial loads (bioburden) on unused, disposable, protective gloves have been studied because of hospital-associated outbreaks (Berthelot et al., 2006; Stock et al., 2012), contamination of clinical specimens (Roux & Raoult, 2004; Sáez-Nieto et al., 2017; Sorio et al., 2023; York, 1990), and to answer questions about the safety of DPGs (Creamer et al., 2012; Ferreira et al., 2011). When comparing bacterial loads, statistically significant differences have been found on disposable protective gloves versus sterile gloves, describing "low count" ranges (range, 0-44 CFUs/glove) (Creamer et al., 2012). While the clinical significance of these microbial findings has failed to raise critical awareness of glove contamination risks (Creamer et al., 2012; Hughes et al., 2013), subsequent work has shown gloves are commonly contaminated during manufacture even when classed as “low count” (B. Michaels et al., 2019, 2021, 2022).

In addition to contamination levels, the identity of contaminating species, as well as the presence of potential pathogens, appropriate bioburden standards for both healthcare and food gloves need to be addressed (Kramer & Assadian, 2016; National Sanitation Foundation (NSF), 2005). The NSF P-155 method for food grade gloves bioburden determination includes stomacher treatment with around 25 mL of eluting fluid (sterile deionized water plus 1% Tween 80) per glove (National Sanitation Foundation (NSF), 2005). Acceptable bioburden for food grade gloves, as per NSF P-155 total aerobic bacterial and yeast and mold counts combined, must be less than (<) 65 CFU/30 cm^2. Based on glove surface areas, this is ~1,000-2,000 CFU/glove, without distinction as to microbial identities. A limit of <100 CFU/mL of glove rinse fluid has been suggested by Kramer and Assadian (Kramer & Assadian, 2016), representing a standard of <1,500 CFU/glove (for 15 mL rinse) for glove outer surfaces. This proposed standard for disposable, non-sterile exam gloves states the detection of *E. coli* or *S. aureus* would disqualify the gloves for healthcare use (Kramer & Assadian, 2016).

Documented outbreaks have occurred in healthcare settings (Berthelot et al., 2006; Stock et al., 2012) by direct transfer from gloves connected to microbiomes of the glove manufacturing environment. With global glove manufacturing in over 100 factories, mainly in Southeast Asia, during the pandemic the US Customs and Border Protection banned several glove manufacturers due to inadequate glove worker health standards, and what has been termed modern slavery (U.S. Customs and Border Protection, 2021). This represents a threatening microbial contamination issue associated with filthy living conditions that could lead to disease transmission from infected factory workers to gloves used in food or healthcare facilities (BMA (British Medical Association), 2016; Lee, 2020; SwedWatch, 2010). To mitigate the risk of adulteration due to poor quality gloves containing holes and punctures, the FDA ordered the impoundment of specific lots and brands of gloves having extremely high defect rates (U.S. Food and Drug Administration, 2022a). Of significance is the longstanding identification of the dual problems of child/forced labor living under poor health conditions in glove factories, along with high puncture rates of gloves (BMA (British Medical Association), 2016; SwedWatch, 2010).

While working under slave labor conditions is not a food safety issue in and of itself, it is a symptom of a workplace culture that puts profits ahead of all else. Single-use gloves are a prerequisite program component under HACCP and this negative aspect is a strong alarm and warning sign of potential other failures by management. It is estimated that approximately 50% of cases of foodborne illness are due to failures in the “culture” of the organizations responsible for the safety of products (Jespersen et al., 2018). A company’s safety culture is the shared attitudes, values, and beliefs relating to the importance of product safety (Smith, 2022). Since the safety culture of an organization is a critical aspect of their ability to manage the challenges implicit in producing safe and effective products,

obvious breakdowns signal compromised values. Safety culture really starts with the team's well-being (Glave & Stuber, 2022).

A wide variety of spore-forming and non-spore-forming bacteria and fungi have been recovered from new, unused disposable protective gloves, including *Bacillus cereus, Clostridium perfringens, Paenibacillus* spp., and *Staphylococcus* spp. (Berthelot et al., 2006; Ferreira et al., 2011; Hughes et al., 2013; Roux & Raoult, 2004; Sáez-Nieto et al., 2017). Hospital-associated outbreaks have often been traced to direct contamination from gloves and latex finger stalls from a range of frank and opportunistic pathogens. During the *Bacillus cereus* outbreak investigation, where this organism was identified from isolates taken from eyes, throat, and stool samples in a neonatal intensive care unit, this bacterium was isolated in opened boxes of nonsterile gloves (Berthelot et al., 2006). A few months later, a cluster of digestive colonization and infection cases with *Clostridium perfringens* was recorded in the same unit. Being unable to find this bacterium in the hospital environment, a bacteriological examination of unopened boxes of disposable protective gloves made of latex, nitrile, and vinyl was undertaken. Findings revealed that when considering glove contamination by spore forming bacteria, all glove types were contaminated mainly with *Bacillus subtilis* and other aerobic bacteria (notably *B. cereus*). By contrast, anaerobic spore-forming bacteria (*Clostridium acetobutylicum* and *C. perfringens*) were only recovered in two glove boxes.

York (York, 1990) reported five instances of nonpathogenic *Bacillus* isolates identified from blood cultures that when clinically evaluated, found the *Bacillus* spp. isolates were identical to those from the same lot of disposable protective gloves worn by phlebotomists. Roux and Raoult (Roux & Raoult, 2004) also identified similar glove contaminants, *Paenibacillus massiliensis*, *P. sanguinis,* and *P. timonensis*, isolated from blood cultures. Sáez-Nieto et al. (Sáez-Nieto et al., 2017) identified nine species of the *Paenibacillus* genus in isolates from clinical specimens, discovering the common problem being contamination of laboratory worker gloves. Similarly, Sorio et al. (Sorio et al., 2023) reported a hospital-wide outbreak of pseudo-bacteremia by *Paenibacillus* spp. affecting 139 patients that presented with at least one positive blood culture during a 13-month period. Microbiological experiments indicated that contaminated gloves were associated with false indications of systemic blood infection (bacteremia) episodes that came with high patient safety concerns and unnecessary treatments, all at considerable expense. This outbreak of pseudo-bacteremia is considered a pseudo-outbreak (a real clustering of false infections). In this instance it was attributed to failures in the specimen collection, caused by contaminated gloves.

There are other instances where investigative teams isolated a variety of bacterial species from open boxes in patient rooms, assuming the source was linked to healthcare workers hand contamination, though some of these species were indicative of glove production

origin (Diaz et al., 2008; Hughes et al., 2013). The various characterizations of glove contamination, with identification of a variety of microbial species by investigative teams (Berthelot et al., 2006; Diaz et al., 2008; Ferreira et al., 2011; Hughes et al., 2013; Sáez-Nieto et al., 2017; Sorio et al., 2023; Stock et al., 2012; York, 1990), is mirrored by and enlarged upon by findings from recent work by Michaels et al. (B. Michaels et al., n.d., 2019, 2021, 2022) and described here. As part of a hazard analysis of the glove manufacturing process, samples from 26 brands consisting of gloves from new, unused, and unopened boxes were analyzed in pools of 25 to 50 gloves from each glove brand. In total, over 2,800 gloves were sampled, with 5.5 X 10^5 microorganisms counted, incorporating various enrichment broths and incubation conditions prior to 16S amplicon and shotgun metagenomic sequencing. See Supplementary Material section for microbial methods accessed via article link.

Frank and opportunistic pathogens were identified on tested gloves, including recognized fecal indicators, enterotoxigenic strains of *Bacillus cereus* and *B. anthracis* along with the presence of *Listeria monocytogenes*, *Clostridoides difficile*, *Staphylococcus aureus*, *Pseudomonas aeruginosa,* and *Streptococcus pneumoniae* (B. Michaels et al., n.d., 2022). In total, 44 genera of bacteria and a wide assortment of fungi genera were identified (B. Michaels et al., n.d., 2021, 2022), with many genera and species being previously associated with glove contamination (Berthelot et al., 2006; Diaz et al., 2008; Hughes et al., 2013; Roux & Raoult, 2004; Sáez-Nieto et al., 2017; Sorio et al., 2023). Based on both 16S amplicon and shotgun sequencing, around 50% of samples contained fecal indicator organisms (B. Michaels et al., n.d.). In terms of microbial counts of single-use non-sterile exam gloves with food contact capability, limited testing in published studies has shown numbers from 0 to 9.6 x 10^3 cfu/glove (Berthelot et al., 2006; Creamer et al., 2012; Ferreira et al., 2011; Hughes et al., 2013). Statistical analysis was performed employing Box-Cox transformation plot of glove count data from 26 brands of disposable gloves representing approximately 25% of the estimated 100 Southeast Asian glove factories. Confirming earlier work of sometimes high background counts of up to 10^5 CFU/glove (Berthelot et al., 2006; Ferreira et al., 2011; Hughes et al., 2013), this statistical analysis indicates with some degree of confidence that 10^5 to 10^6 per 100 glove boxes could be possible.

Edwards (J. Edwards, 1994) identified heavy fungal contamination of gloves, with isolation of *Aspergillus fumigatus* from gloves and glove packaging suggesting storage concerns. It is noteworthy that while wetting of packaging or storage areas of high relative humidity in healthcare may be limited, in food venues this may be a more frequent issue. Singer et al. (Singer et al., 1998) reported an outbreak of systemic aspergillosis in a neonatal intensive care unit was caused by *A. fumigatus,* with the infection source being contaminated latex finger stalls. Four pre-term neonates developed cutaneous aspergillosis, three of whom unfortunately died (Singer et al., 1998). Culturing additional finger cots revealed not only *A. fumigatus* but also *A. flavus* and *A. niger* (Singer et al., 1998). Besides the wide range of bacteria reported by Berthelot (Berthelot et al., 2006), his team identified the fungi

Aspergillus versicolor from unused gloves, posing an infectious hazard to neonates (Berthelot et al., 2006). Stock (Stock et al., 2012) identified a fatal fungal case caused by gloves contaminated by *A. fumigatus,* the exposed neonate having died due to multi-organ failure. Testing of four glove boxes from three lots of the same supplier revealed *A. fumigatus, A. niger, and A. versicolor* (Stock et al., 2012). This investigation revealed inadequate process control, leading to nonconforming products, where patient exam gloves were insufficiently dried, packaged, or distributed in a moist condition. Subsequent lot testing found both *Aspergillus* spp. and *Fusarium* spp. molds. With FDA involvement, these gloves were recalled from the market before other infections could occur (Stock et al., 2012). In the current testing, we report detecting a variety of fungi from the 26 glove brands, utilizing ITS1 fungal amplicon and shotgun metagenomic sequencing of m-Green yeast and fungi enrichment broths. Besides various club fungi (Basidiomycota), there were Ascomycetes filamentous fungi, including 13 species of *Penicillium,* five species of *Cladosporium,* and *Aspergillus* spp*.* It should be noted that glove sampling methodology utilized in this work (B. Michaels et al., n.d., 2019, 2021, 2022) was designed to minimize possible contamination from glove cardboard packaging (B. Michaels et al., 2019).

Potential for microbial contamination with dermal concerns. By examining microbial counts and diversity for both insides and outsides of gloves independently in various individual studies, it was demonstrated that at times high counts and diversity could be found on one side or the other. With resulting diversity measures for each side of the individual gloves brands sampled, bacterial populations were demonstrated to be distinctly different when the multivariate statistical method of principal coordinates analysis (PcoA) was employed. The sidedness of bacterial populations result from glove mold contact for the outside of the glove versus the inside of the glove that is first to be leach tank exposed (Figure 1, steps 5 through 8). Based on the identity of microbial species detected on or in gloves, skin health problems described for food and healthcare workers (occupational skin disease & barrier function disruption), it could be expected that colonization of the skin by species found in gloves could occur. This now represents a future area for study with potentially significant implications for food and healthcare workers.

Discussion

With the pandemic bringing attention to personal protective equipment and its importance (European Centre for Disease Prevention and Control, 2020), safety issues that have long been endemic to the glove manufacturing/distribution supply chain were magnified, with negative consequences detailed. As a consumable item utilized in the food industry, gloves have long been known for providing a false sense of security when in use (B. Michaels, 2004a; B. Michaels et al., 2004; B. Michaels & Ayers, 1999, 2000; B. S. Michaels, 2002b;

Todd et al., 2010b, p. 8). To this pitfall should be added the unfounded belief that gloves are uniformly intact, durable, and free from chemical or microbial adulteration potential (a false sense of purity, durability, and cleanliness).

Basic to the performance of disposable gloves is physical integrity. Vinyl and polyethylene are commonly utilized in food service because of their lower cost and ability to fit a variety of hand sizes with loose fit. Typical of puncture standards for gloves used in healthcare are ISO EN 455-1:2000 and ATSM 6319 (Racer, 2001). These standards only require impermeability and tear resistance without repetitive pressure and shear strain reflective of actual use. Gloves having the propensity for rapid puncture with use, put glove wearers and food products at risk due to leakage either into or out of gloves (B. Michaels, 2004b). Ease of puncture with only short duration use represents both microbial and chemical hazards that can also cause skin problems and risk of infections to wearers, as well as having the potential for contamination of food products (B. Michaels & Ayers, 1999, 2000). Despite puncture standards for gloves used in healthcare (as in the example above), no such acceptable quality level (AQL) exists for gloves having food contact status, even though failure rates from 30% to 50% are not uncommon for gloves that can see dual use in healthcare and food service (Phalen & Wong, 2011; Rego & Roley, 1999).

With their treatment as simple consumable commodities by food industry procurement staff, there is a lack of validation or verification of safe and acceptable performance that should be pre-requisite program elements in adherence to HACCP and FSMA principles (B. Michaels, 2004b; Micheloni & Baruffini, 2008; Olson et al., 2019). Without accurate and detailed performance test data there is no way to access the hazards that are presented by a specific glove product. The FDA regulates Medical Exam Gloves and sets Acceptable Quality Limit at 2.5 (AQL 2.5) defects or less in a batch of 100 gloves to pass, with the facility where manufactured authorized by the US Food and Drug Administration with a 510K License Agreement (see FDA 1999 in reference listing as an example of FDA authority) (U.S. Food and Drug Administration, 1999). There is a stringent auditing process performed periodically by FDA for license retention. Within industrial workplaces where tasks such as janitorial, automotive, manufacturing, assembly, agricultural applications, food processing (meat, poultry, dairy etc.) or food service the gloves available for use might be medical exam glove grade (and labeled as such) or labeled for “industrial use only.” They may also be marked “food grade”.

Whether exam gloves or industrial gloves are used for food contact, FDA or other regulatory authority food contact status is required and may be specified with applicable testing. While the FDA, for example, requires that the AQL for an industrial disposable glove be 4.0 or less for defects, this is seldom enforced, and the wear (simulated movement) cycle defect rate has not been standardized (Phalen & Wong, 2011). Another

variation in the AQL designation is how complete the testing is, whether it is 100 gloves or simply a representative sample from each batch (batch tested). With both food contact and healthcare applications, an AQL of 1.5 translates into a higher level of quality and protection enhancing the safety of food, patients, and glove users. Examples of very high defect rates of new, unused gloves have been documented for vinyl and polyethylene gloves as high as 41% and 61% respectively (Selvaraj et al., 2023). These leak specifications, or lack thereof, represent measures of the potential for microbiological contamination from hands or inside of gloves to contaminate food handled and should be considered in standard operating procedures, required tech sheet specifications and in procurement (Jamal & Wilkinson, 2003).

Risk is extremes driven use (B. Michaels et al., 2004) and no better example is the importance of glove physical integrity when sweat is capable of generating a significant liquid bridge of contamination. Sweat glands can be found on the fingers at concentrations of up to 530 glands per cm^2 (Taylor & Machado-Moreira, 2013). Under conditions of thermal stress within a glove, hands are capable of generating up to 160 grams of sweat per hour (Taylor & Machado-Moreira, 2013). This sweat liquifies chemical residues and incubates microbial contamination present inside gloves and on hands driving risk. Long duration use of gloves, having high sweat rate characteristics, and extreme puncture rates when new and unused, creates a perfect storm of conditions that can lead to food contamination of all types described in this article.

Potential chemical contamination of food and beverages can occur from chemicals and food contact articles (FCAs), like gloves, used in all phases of production and packaging (Muncke et al., 2020, 2023). The Code of Federal Regulations Title 21 CFR Part 177 states that gloves must be composed of a material "generally recognized as safe for use in food and food packaging." In practice, most glove suppliers use the requirements stipulated by the FDA, or comparable regulations, as a guide to choosing acceptable raw materials, though multiple problems present for food contact articles in general. Food contact chemicals (FCCs) existing in glove products remain insufficiently evaluated due to inherent technical and methodological difficulties in safety assessment, significant knowledge gaps, and questionable regulatory compliance (Muncke et al., 2020; Olson et al., 2019). Testing food contact materials for food contact chemicals found almost 12,000 distinct chemicals used in food contact material manufacturing, many inadequately tested for toxicity or falling into the category of non-intentionally added substances (Geueke et al., 2022). Critical gaps exist with high chemical complexity, lax regulations, and both a lack of scientific progress and transparency by manufacturers being identified as contributory causes (Muncke et al., 2020, 2023).

Regulations for food contact items like gloves primarily cover rubber articles intended for repeated use (reusable gloves), with requirements for use of approved ingredients and limitations set forth. The regulations however fail to consider compounds that emerge during production. As a result, many chemicals in food packaging and food contact items remain untested, especially the interactions with non-intentionally added substances (NIAS) where these chemicals are relevant for human exposure.

Chemicals to which food, food workers, or healthcare workers are exposed include known existing chemical hazards as well as those that are unknown, unregulated, or uncharacterized causes (Muncke et al., 2020, 2023). Over the issue of phthalates found in vinyl gloves used in quick service restaurants in the US, Olson and team (et al., 2019) assert that more than forty years ago, FDA permitted about 5,000 industrial chemicals to be used in food contact materials. Olson and team argue that these chemicals were never reassessed based and that factor, the FDA fails to assess cumulative risk to health, as required by law, with the loopholes that allow industry to self-certify food contact chemical safety (Olson et al., 2019).

US 21 CFR Part 177 and EU directives define acceptable migration limits for food contact materials (FCMs). Migration tests typically involve immersing the material in solvents or food simulants and measuring leachable extractive levels over given times and temperatures. Provided in 21 CFR are permitted materials, including specific limitations, such as plasticizers, vulcanizing agents, and accelerators used in glove manufacturing. Both FDA and EU legislation require that food contact materials shall not adulterate food.

Choosing gloves which meet FDA requirements or EU directives (Regulation 10/2011) is a start; however, these are essentially one-off tests with no expiration date, and glove manufacturers need only to declare to be operating "in accordance with the rules" (Ardagh & Ronaldson, 2018; Micheloni & Baruffini, 2008). Similar regulations are included in other international jurisdictions, but compliance can be merely a repetitive paperwork exercise with little or no proof of veracity, policing or enforcement (Olson et al., 2019). Within the US and internationally, medical gloves are regulated as PPE used to protect the wearer and/or patient from the spread of microorganisms that may potentially cause infection or illness during medical procedures and examinations (U.S. Food and Drug Administration, 2022b). Within the landscape of food safety, regulatory bodies such as the FDA with expanding duties, appear not to see food grade disposable gloves as requiring a high level of regulatory oversight. As seen with the pandemic, priority instead goes to products suspected to be adulterated, fraudulent, or otherwise in violation of the law (Evich, 2022). Medical grade gloves undergo periodic review and have seen numerous enforcement actions based on failures to adhere to safety regulations covering physical leak failure rates, chemical composition, and microbiological contamination (Australian Government

Department of Health and Aged Care: Therapeutic Goods Administration, 2022; U.S. Federal Bureau of Investigation, 2020). Food grade gloves have only seen recalls based on detection of glove pieces found in food (U.S. Department of Agriculture FSIS, 2021).

More than 13 million Americans (and similar numbers for the EU) have occupational skin disease (Diepgen et al., 2013; Haughtigan et al., 2017). Allergic contact dermatitis represents 90% of all occupational skin disease cases, with annual US treatment costs exceeding $1 billion (Haughtigan et al., 2017) and total EU socioeconomic impacts for occupational skin disease estimated at €5 billion annually (Ring, 2017). Nearly 80% of occupational skin disease occurs in only seven occupational groups, including healthcare workers, food workers, and cleaners (Brans, 2023; Diepgen et al., 2013). Occupational skin disease caused by glove-induced dermatitis, involving both contact urticaria and allergic contact dermatitis (ACD), while most common in healthcare workers (Cao et al., 2010), also affects food workers (Mahler, 2020; B. Michaels & Ayers, 1999, 2000). A risk factor in developing glove-induced dermatitis is damage to the skin barrier (B. Michaels & Ayers, 1999, 2000; Nettis et al., 2002). Initiated by frequent irritant detergent washing, sometimes with hot water (B. Michaels et al., 2002), this causes increased transepidermal water loss. When this is followed by glove occlusion, the rise in skin temperature subsequently increases sweating and hyperhydration of the stratum corneum (skin outer layer) with the skin barrier properties can be further compromised (Graves et al., 1995; B. Michaels & Ayers, 1999, 2000), breakdown of skin integrity occurs (Hamnerius et al., 2018). Under the described conditions, increased duration of glove usage has been associated with hand dermatitis (Hamnerius et al., 2018; Nettis et al., 2002). This entire succession is presented in Fig. 2, for food worker exposures, leading to occupational skin disease (OSD). In susceptible trades, as occurs in the food and healthcare industries, glove-related dermatitis is often multifactorial, with irritant and allergic contact dermatitis, creating a mixed set of symptoms in combination (Kersh et al., 2018). Worker skin health issues can be expensive for food companies, as a single case of dermatitis can cost more than $10,000 in employer-paid expenses (OSHA (Occupational Safety & Health Administration), 2017).

With infectious disease experts already investigating which virus might cause the next pandemic (Neumann & Kawaoka, 2023), we would do well to improve our understanding of glove use and assumptions made related to chemical and microbial integrity. As COVID-19 wanes, we need to consider how gloves fit into our infection control toolbox and where they could be improved upon, whether in manufacturing, specification setting, or knowledgeable application of procurement. What are the lessons learned and what do food and healthcare personnel need to know to help improve preventive controls and reduce problems for glove wearers?

The presentation of information on direct contamination routes associated with disposable gloves should provide insights for interested parties, but there is still a great deal of unknowns. Not enough has been done to understand the full toxic profile represented by chemicals detected on glove surfaces, with risk analysis lacking for some of the compounds at or near safety cutoff limits (nitrosamines, etc.). Additional research is also needed to understand the hazards represented in the viable microorganisms that come to contaminate gloves during the production process.

Here we report enterotoxigenic strains of *Bacillus cereus* and *B. anthracis,* along with the presence of *Listeria monocytogenes*, *Clostridoides difficile*, *Staphylococcus aureus*, *Pseudomonas aeruginosa,* and *Streptococcus pneumoniae,* isolated from unused, disposable gloves. The NSF P-155 (National Sanitation Foundation (NSF), 2005) protocol for bioburden qualification from gloves was executed alongside the methods reported on here. The NSF protocol would accept counts of around 1000 CFU per glove, disregarding microbial identity. Based on the findings reported, the NSF standard would seem to be of limited value as a safety screening approach. While the Kramer & Assadian (Kramer & Assadian, 2016) proposed healthcare standard uses two disqualifying species *E. coli* or *S. aureus*, setting the CFU count cut-off at a slightly higher acceptance level, it would still also appear to be lacking. In a limited comparison between microbial counts on hands and gloves, Paul and team claimed microbial counts between the two were comparable (Paul et al., 2021). This is incorrect based on known counts of clean and dirty hands and fingernail regions (Lin et al., 2003; B. Michaels et al., 2004; Price, 1938). With glove microbial counts and identities of organisms found on gloves reported here, the safety margin between hands and gloves is reduced and becomes problematic, when approximately half of glove samples tested contained fecal indicators.

The glove manufacturing process requires the consumption of large quantities of water during the washing and leaching processes used to remove residual chemicals and reaction byproducts (Poh et al., 2019; Wanlaso, 2012). For this reason, all glove plants are situated on natural waterways shared by a wide range of industries. These waterways tend to be heavily polluted by industrial, urban, and agricultural wastes (Samsudin et al., 2018; To et al., 2020; Wang et al., 2015). It has been reported that typical glove wastewater treatment plants are hardly capable of treating the quantities of wastewater produced, with <5,000 m^3 (1.3 million gallons) generated per day at large facilities (Wanlaso, 2012). This means that influent for washing and leaching tanks tends to be somewhat limited and potentially contaminated, accounting for sources of microbial and chemical impurities.

Conclusion

Evidence provided shows that gloves of poor quality can result in potential for direct physical, chemical, and microbiological contamination. As presented, significant safety

issues related to direct contamination are relevant to foods, patients, and wearers of gloves. As a result of low-cost formulations using high filler content, tear strength can suffer, leading to direct physical contamination, with ruptures releasing glove pieces, chemicals, and microbial contents into food. While it is the glove pieces causing initiation of recalls, the result is to limit all three components of direct contamination.

Glove chemicals causing issues with respect to food/drug safety and human dermal compatibility, fall into several categories according to glove material type including plasticizers, accelerators, antioxidants/antiozonants, antimicrobials, and various processing aids. Direct chemical contamination can contribute to a range of potential human health effects including carcinogenicity, endocrine disruption, fertility impairment, metabolic disorders, diabetes, occupational skin disease, and allergic contact dermatitis. Direct chemical contaminants of concern include known allergens, phthalates, bisphenol A, Per- and polyfluoroalkyl substances, and uncharacterized food contact chemicals present in gloves which may have evaded safety testing (Geueke et al., 2022). Current extractives testing is inadequate, lacking requirements for fixed frequency and chemical characterization of extractives to ensure safety status and compliance with food contact chemical regulations.

While gloves are considered a critical tool in preventing occupational skin disease, they can become problems for the wearer resulting in allergic contact dermatitis due to glove chemical allergen exposures (B. Michaels & Ayers, 1999, 2000). Sweat within gloves can alter the physical properties of gloves inducing swelling, releasing chemical constituents, and deteriorating surfaces in contact with skin (Vinches et al., 2017). Release of those glove chemicals and absorption through the skin can lead to systemic effects in a similar way as can occur with introduction of facility cleaning chemicals (Rawson et al., 2005). When worn for long periods, occupational skin disease can result, either from glove allergens and irritants via chemical migration during sweat accumulation, or from internal contamination with food or facility cleaning chemicals introduced into gloves by holes, rips, or tears. These are common problems in occupations such as food handling, healthcare, and the cleaning professions (Diepgen et al., 2013). When human health effects from the migration of chemicals to both food and skin surfaces of wearers are considered, significant economic consequences are at stake (Attina et al., 2016; Fonacier et al., 2015).

Microbial contamination of new, unused, disposable gloves has been demonstrated to be responsible for hospital-associated pseudo outbreaks (clinical sample contamination events without infections) and actual outbreaks involving frank and opportunistic pathogens (Berthelot et al., 2006; Diaz et al., 2008; Ferreira et al., 2011; Hughes et al., 2013; Sáez-Nieto et al., 2017; Sorio et al., 2023; Stock et al., 2012; York, 1990). Work described here expands on these earlier investigations, with a wide range of bacteria and fungi having

been identified as associated with new unused gloves. Through application of 16S amplicon and shotgun sequencing, organisms of concern with respect to food safety, healthcare-associated infections, and the skin health of wearers were revealed. The presence of microorganisms identified on gloves, along with fecal indicator organisms, is suggestive of polluted water sources being utilized during manufacture. Based on the microbial contamination potential described previously, proposed bioburden standards for both healthcare and food gloves (Kramer & Assadian, 2016; National Sanitation Foundation (NSF), 2005) need to be revisited.

The summary of findings highlights significant direct contamination risks associated with gloves employed in both food and healthcare venues. Current glove manufacturing standards, as well as regulations and testing requirements, appear to be inadequate with respect to direct contamination challenges and put into question fidelity to HACCP and FSMA principles if assumptions of safety are not validated. There are several unanswered questions regarding chemical and microbial hazards that require further research. HACCP programs under FSMA regulations insist on improved preventive controls and demand proactive approaches to risk reduction. The full potential of glove use as a risk reduction strategy is only emergent when as a prerequisite, fully qualified gloves, without direct contamination threat, are utilized in prescribed manners, avoiding multiple pitfalls of use including that of cross-contamination.

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Table 1 Potential Chemical Contamination of Food Linked to Glove Usage

Chemical Food Exposures				
Compound Type	**Glove-type [a]**	**Specific Chemical**	**Comment**	**References**
Food Allergens	L, H	Latex & cross-reactivity to specific food allergens causing food consumer allergic reactions	4.3% of global population	(Bernardini et al., 2002; Bernstein, 2007; Girouard, 2007; González-Díaz et al., 2022; Wu et al., 2016)
Toxic Chemicals	N	Acrylonitrile	Potentially carcinogenic w/ limits set by FDA in food contact regulations	(Wakui et al., 2001)
Phthalates	V, (N, L)	Most toxic Phthalate plasticizer diethylhexyl phthalate (DEHP)	Potentially carcinogenic & banned from gloves in Japan, Nordic countries & Maine	(Olson et al., 2019; Tsumura et al., 2001, 2003)
	V, (N, L)	Phthalate plasticizers: dimethyl phthalate (DMP), diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), & DEHP	Endocrine disruption, carcinogenic, fertility impairment, metabolic disorders, and diabetes	(Jędruchniewicz et al., 2021; Kopf, 2021; Kühne et al., 2021; Landrigan et al., 2023; Poitou et al., 2021; Varshavsky et al., 2018)

	V, (L, N)	Vinyl glove (w/ phthalate plasticizers) contact exposure via packaging, processing & handling	Unsuitable for contact with infant & fatty foods	(Cao et al., 2010; Petersen & Jensen, 2016; Rudel et al., 2011)
Bisphenol A (BPA)	V	Stabilizer, antioxidant & plasticizer causing impaired neuro development, toxicity promoting obesity "obesogens"	Potentially carcinogenic properties to (exposure concerns for children & adults)	(Cao et al., 2010; Geens et al., 2012; Seachrist et al., 2016)
N-Nitrosamines	L, N	Levels extracted in food simulating solvents may exceed acceptable dietary intake limits	Vulcanization byproduct potentially carcinogenic but exist from many sources	(Feng & McLellan, 2019; Pensabene et al., 1995; Pinprayoon & Mae, 2019)
Antimicrobials	N	o-Phenylphenol	Fungicide transferred to cannabis (drug) product	(Laudani, 2021; WSLCB (Washington state's Liquor and Cannabis Control Board), 2019)
Heavy metals	All	Arsenic (Ar), cadmium (Cd), chromium (Cr), mercury (Hg), lead (Pb), having human health risks		(Garçon et al., 2017; Yew et al., 2019, 2020)

[a] All=all glove types; H=Hybrid containing multiple polymer types possibly including latex; I=Isoprene, polyisoprene (neoprene); L=Latex; N=Nitrile; V=Vinyl; PE=Polyethylene, (L,N)=significantly less often in these types (Poitou et al., 2021).

Table 2. Occupational Skin Diseases (OSDs) Affecting Food Workers Where Glove Usage or Chemicals Identified in Gloves can Represent a Contributory Factor

Clinical Term	Characteristics	Etiology	References
Hand Eczema (HE) or Hand Dermatitis (HD)	The clinical features of eczema may include itching, redness, scaling, clustered papulovesicles, hyperkeratosis, or fissuring.	HE/HD is the most frequently recognized industrial injury and nonspecifically consist of both irritant contact dermatitis (ICD) (~70% of cases) and allergic contact dermatitis (ACD) (30% of cases).	(Hamnerius et al., 2019; Jacobsen et al., 2022)
Irritant contact dermatitis (ICD)	Most commonly occurring when physical and/or chemical damage exceeds the skin's ability to repair damaged barrier function	Wet-work (working under wet conditions, frequent hand washing, glove use, & at work chemical exposures (detergents, organic solvents, alkaline substances)	(Jacobsen et al., 2022; Kersh et al., 2018; Li et al., 2020)
Contact urticaria (CU)	Following contact largely confined to the hands with causative agent the skin releases histamine, causing localized itchy swelling (wheals) at contact site typically fading away minutes to hours later (immediate-onset non-immunological in nature).	Glove-related urticaria may occur with immediate reaction to various glove types and related to combined shearing forces and physical pressure combined with chemical triggers. Looser-fitting gloves may relieve symptoms. May progress to immunological (ACD)	(Giménez-Arnau et al., 2022; Kersh et al., 2018; Li et al., 2020; Siegel et al., 2010; Sugiura et al., 2002)
Allergic contact dermatitis (ACD)	While the appearance can be the same as ICD, this is an immunological response to a specific allergen. The allergen may have been tolerated for years without reaction, but once sensitized, may be triggered by minimal exposure.	Food handler contact allergens include rubber accelerators and other chemical ingredients in gloves, food preservatives, and naturally occurring chemicals in foods (fruits, garlic, onions, and many plants).	(Baeck et al., 2013; Chu, 2001; Dejonckheere et al., 2019; Kersh et al., 2018; Li et al., 2020; Ueno et al., 2007; Vanden Broecke et al., 2014; Weimann et al., 2010) (Caballero & Quirce, 2015; Crepy et al., 2018; Pastor-Nieto & Giménez-Arnau, 2018; Smylie et al., 2021)

Protein contact dermatitis (PCD)	PCD refers to an allergic reaction to proteins of animal or plant origin and is a chronic or recurrent dermatitis, occasionally with vesicular flare-up that can become noticeable just minutes after contact	Exposure to animal and vegetable (fruits/vegetables/spices/plants) protein including natural rubber latex gloves. It often presents as a combination of both immediate-onset CU and delayed ACD and is relatively common in fish processing plants and abattoirs.	(Alluhayyan et al., 2020; Caballero & Quirce, 2015; Crepy et al., 2018; Hu et al., 2020; Pastor-Nieto & Giménez-Arnau, 2018; Smylie et al., 2021)
Occupational hand dermatitis (OHD)	Work-related skin disorders of with erythema (redness & inflammation), skin fissures or erosions, skin maceration, vesicles, and bullae (blisters), with variable swelling.	Skin barrier dysfunction contact with fluids, use of occlusive gloves for prolonged periods, and high frequency of hand washing represented high risk occupational wet-work exposures. May result in more than one type of dermatitis displayed (ICD, ACD, PCD, CU) simultaneously.	(Diepgen et al., 2013; Karagounis & Cohen, 2023; Nørreslet et al., 2021)

Table 3. Dermal Exposure to Glove Chemicals Potentially Impacting Glove User Safety

Dermal Exposures				
Compound Type	**Glove-type(s)[a]**	**Specific Chemical**	**Comment**	**References**
Allergens: Based on Glove Type	L, H	Latex & cross-reactivity to specific food allergens	Long term disability & rehab, worker compensation	(Bernstein, 2007)[b]
	V, (N, L)	Bisphenol A (BPA) (Vinyl Stabilizer, antioxidant & plasticizer)	Allergic contact dermatitis (ACD), contact urticaria (CU) or dermal absorption	(Cao et al., 2010; Norman et al., 2023)
	V, (N, L)	Di-(n-octyl)-tin-bis(2-ethylhexylmaleate) &/or polyadipic acid propylene glycol (Vinyl Plasticizers)	ACD or CU	(Boran & Terzi, 2017; Norman et al., 2023; Ueno et al., 2007)
	V	Tricresyl phosphate (Vinyl Plasticizer)	ACD or CU	(Crepy et al., 2018; Norman et al., 2023)
	N	Acrylonitrile a small molecule compound recognized as a potent toxin & sensitizer	Potentially carcinogenic w/ limits set by FDA in food contact regulations	(Chu, 2001; Wakui et al., 2001)
Allergens: Glove Polymer Accelerators[c]	L, N	Thiurams, dithiocarbamates, guanidines, thioureas, and thiazoles	ACD or CU	(Goodier et al., 2018; Kadivar & Belsito, 2015)

	L, N	Mixed dialkyl thioureas and 1,3-diphenylguanidineare	ACD or CU	(Dejonckheere et al., 2019; Hamnerius et al., 2019; Warshaw et al., 2013)
	N	Triphenylguanidine	ACD or CU	(Dahlin et al., 2014)
	N	Zinc diethyldithiocarbamate (ZDEC), zinc dibutyldithiocarbamate (ZDBC) and diphenylguanidine (DPG)	ACD or CU	(Cao et al., 2010; Hansson et al., 2014; Siegel et al., 2010)
	I, V	2-Mercapto-benzothiazole (MBT), benzisothiazolin, methylisothiazolinone	Anti-microbial w/ plasticizer properties	(Aalto-Korte et al., 2007; André et al., 2022; Cao et al., 2010; Norman et al., 2023)
Allergens: Donning Aids & Release Agents	All	Cornstarch, calcium carbonate	Airborne carrier of allergens	(Grunewald et al., 2003; Patrawoot et al., 2021; U.S. Food and Drug Administration, 2016)
	All	Methyl hydroxystearate (MHS) (Plant-based moisturizers)	MHS an Allergen derived from castor oil	(Crepy et al., 2018; Vanden Broecke et al., 2014)
Allergens & Irritants: Antioxidants/Antiozonants & Antimicrobials	L, N	Phenylenediamine (Antiozonants)	ACD or CU	(Kruger et al., 2005)

	V	Triphenyl phosphite (Antioxidant)	ACD or CU	(Norman et al., 2023; Suuronen et al., 2013)
	PE	Butylhydroxytoluene (BHT) or butylated hydroxynisole (BHA) (Antioxidants)	ACD or CU	(Sugiura et al., 2002)
	All	Bacterial Endotoxins (Pyrogens)	ACD or CU	xxx(Takahashi et al., 2020; Thorne et al., 2005; Kramer & Assadian, 2016)
Allergens: Colorant Chemicals	N, V	CI Pigment Blue 15 (phthalocyanine), CI Pigment Orange 34	ACD or CU	(Kanerva et al., 2000; Reckling et al., 2016; Weimann et al., 2010)
Allergens: Other Agents Employed in Polymer Synthesis	L, N	Cyclohexylthiophthalimide, diaminodiphenylmethane, dithiodimorpholine, and hexamethylenetetramine	ACD or CU	(Baeck et al., 2013; Warburton et al., 2015)
Chemicals of Concern for Dermal Absorption	V, (N, L)	Phthalate plasticizers: dimethyl phthalate (DMP), diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), & diethylhexyl phthalate (DEHP)	Dermal absorption effects	(European Chemicals Bureau et al., 2008; Poitou et al., 2021; Tsai et al., 2019; Wormuth et al., 2006)
	L, N	N-Nitrosamine Levels identified extracted from gloves in artificial sweat may exceed acceptable dietary intake limits	Vulcanization byproduct potentially carcinogenic but exist from many sources	(Feng & McLellan, 2019; Pensabene et al., 1995; Pinprayoon & Mae, 2019)

[a] Key to glove type abbreviations: All=all glove types; H=Hybrid containing multiple polymer types possibly including latex; I=Isoprene, polyisoprene (neoprene); L=Latex; N=Nitrile; V=Vinyl; PE=Polyethylene, (L,N)=significantly less often in these types (Poitou et al., 2021).

[b] Recommendation of synthetic gloves (Rosenstock & et al, 1997)

[c] Recommendation of accelerator-free gloves (Cao et al., 2010; Crepy et al., 2018; Smylie et al., 2021)

Figure 1. Schematic view of the glove production cycle and how that and the environmental breakdown process fit into glove usage and direct contamination potential, the subject of this report as well as an issue not covered, that of cross-contamination.

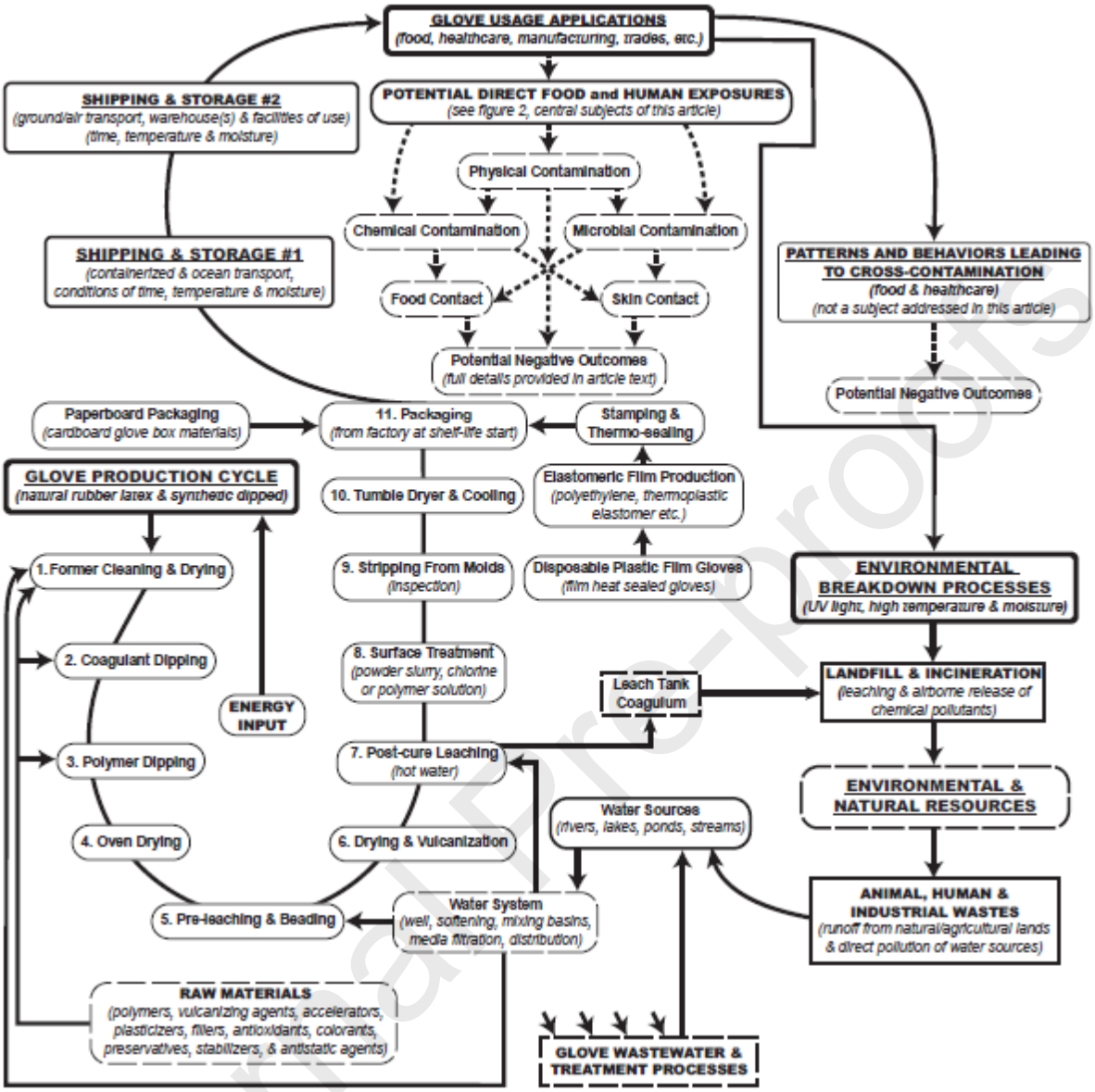
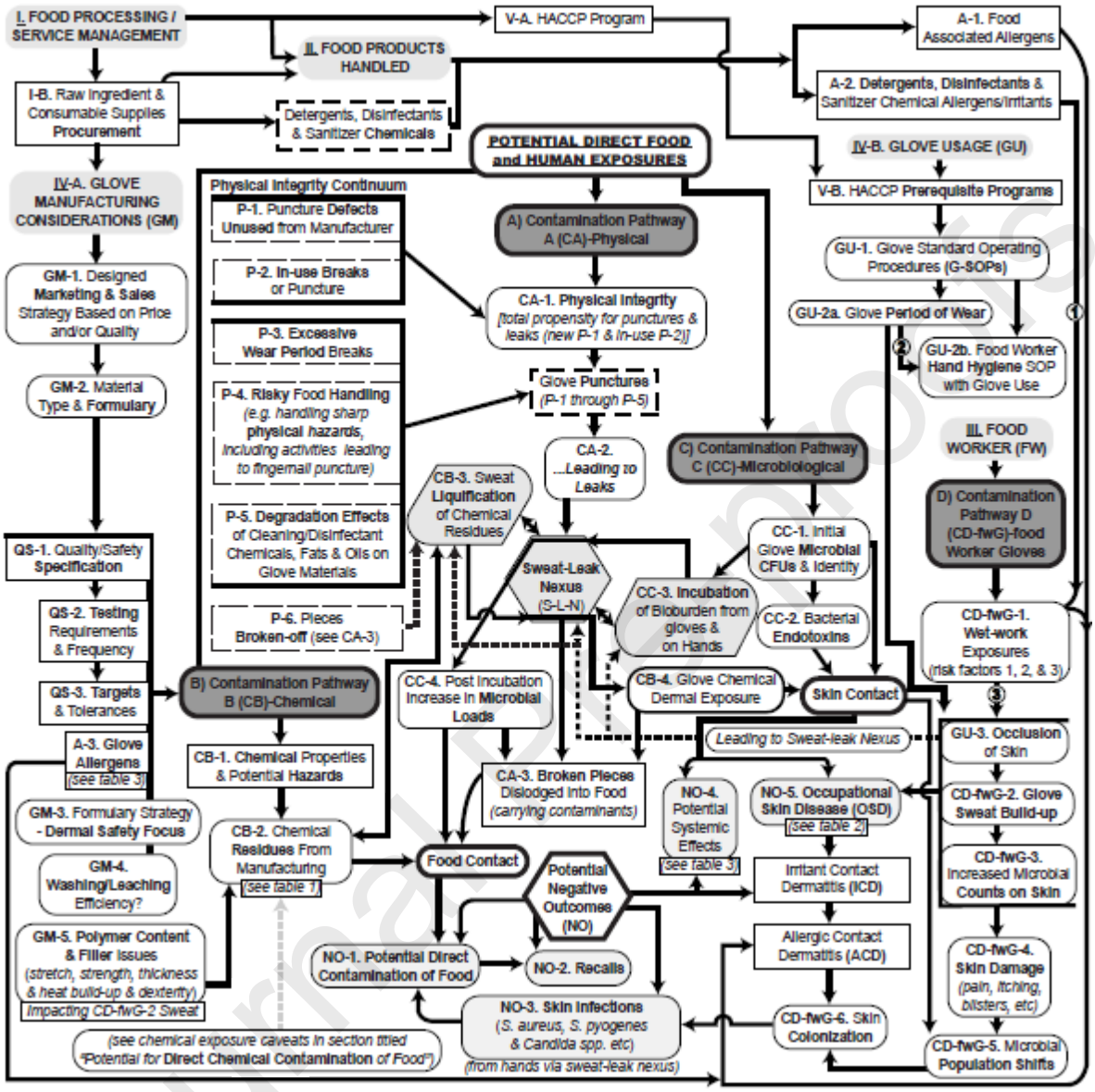


Figure 2. Map of the components of disposable glove use in food environments tracking pathways, contributing factors and interactions leading to potential direct physical, chemical and microbiological contamination, posing chances for negative outcomes relevant to food safety objectives.



Highlights

6. COVID-19 demands exposed and amplified hazards related to disposable glove manufacturing.

7. Glove contamination at production is consequential for users, and food or healthcare endpoints.

8. Loosely regulated safety and quality standards are causative factors within the glove industry.

9. Glove physical failures are pivotal in release of sweat build-up and liquefaction of chemical residues.

10. Incubation of microbial contaminants from hands and gloves can represent an additional hazard.