Comments and Recommendations

BSI Flex 5555 *Community Face Coverings Specification*

Version 1: January 2021

Document Purpose: To provide input re: certain potential health, safety and environmental issues that impact community face coverings and may warrant a consumer advisory (product labeling)

Submitted To: Members of the British Standards Institution (BSI) Flex 5555 Review Panel

Submitted By: Richard L. Nicholas, Founder, TPA NETWORK *Research Consortium*

Date: January 18, 2021

Background / Context

My interest in face coverings is as a result of my work creating the ***Research Consortium***, an entity intended to evaluate new medical technologies/health innovations for US health plan sponsors and to support clinical trial participation in the US. Due to the emergence of the pandemic, face coverings became our first project. We studied COVID-19 and wrote the 70-page **COVID-19, ITS TRANSMISSION AND FACE MASK EFFICACY**. To support our research, we sought a face covering to endorse and promote. Unable to find one, we created a patent-pending face covering (available Q1 2021); ergo, our interest in face covering standards/regulation.

We studied each of the community face mask specifications of the leading international standards entities:

- AATCC M14-2020 Guidance and Considerations for General Purpose Textile Face Coverings (US)
- ASTM WK73471: New Specification for Barrier Face Coverings (US)
- CWA17553 Community Face Coverings: Guide to Minimum Requirements, Methods of Testing and Use
- AFNOR Specification S76-001: Masques Barrières (France)
- NEN-Spec 1-2:2020-11-09 Certification Scheme Community Face Masks (The Netherlands)
- NM ST 21.5.200/2020 Réglementation Relative aux Masques de Protection (Islamic Countries)
- TU 13.92.29-005-00302178-2020: Hygienic Face Masks (Russian Federation)
- Health Commission Policy Update: Community Use of Face Masks (African Union)

We also reviewed the specifications of dozens of countries that modified one of the documents above and the specifications of countries that developed their own guidelines from scratch.

Perspective / Approach

I am a forty-year veteran of the healthcare, employee benefits and healthplan administration industries. I submit my comments and recommendations from the perspective of an employer, union or health insurer purchaser looking to rely upon it to help evaluate face coverings for their employees, members or insureds.

My approach to evaluating standards would liken that of a business consumer looking for information, data and guidance to mitigate the widespread general confusion that exists relative to general-purpose community face coverings and their effectiveness, safety and impact on the environment. In my view, face mask standards have an obligation to identify (if not address) all known and suspected potential health risks, dangers and hazards related to their use. As such, a standard can only truly achieve its stated purpose if it includes language to this effect along with suitable end-user/consumer advisories and warnings.

Comments and Recommendations

BSI Flex 5555 - Version 1, though comprehensive, does not appear to address several potential health, safety and environmental risks that may be the rightful concern of face mask consumers. These risks relate to the use of 1) biocidal (antimicrobial) agents, 2) activated charcoal filters, 3) nanoparticles and 4) toxic fabrics and other materials, finishes, mechanisms and technologies (used to enhance a face covering's effectiveness, performance, safety or environmental impact), and the danger/risk of 5) bioburden build-up.

A face covering standard that is silent on these issues will not only fail to fulfill its intended purpose but also be negligent by not warning the public about potential risks and failing to extinguish pre-existing misconceptions. Although some of these issues are addressed in the standard (by reference to existing national requirements), it does not contain a labelling requirement for a specific consumer advisory or warning that is aimed at the face covering purchaser or end-user/consumer. This document details why it is important to public, private and individual consumers that these issues be addressed in the new standard.

Understanding that fully addressing each of these issues would be difficult given the current timeframe, we recommend changing the introductory language to reflect your recognition of the issues and intent to address them at a later date. Our proposed text changes are in *blue italics*:

Proposed Change to "Introduction" Text

The agile BSI Flex development process enables a specification to be rapidly developed, and on an iterative basis, in order to fulfil an immediate need in industry. *As such, this document is necessarily limited as to its scope and anticipates improvements, refinements and content expansion over time to address, by example, several aspects that relate to the material composition and design of community face coverings that may influence their safety, health, and environmental impact. These include the use biocidal materials; bioburden inhibitors; and potentially toxic finishes, mechanisms or inhalable substances, some of which may be subject to oversight by government agencies and warrant additional testing and regulatory oversight as to their efficacy and safety. Accordingly,* this BSI Flex can be considered for further development as a PAS, British Standard, or constitute part of the UK input into the development of a European or International Standard.

Proposed Product Labeling Requirement

Without labeling that calls attention to the health, safety and environmental issues above, a standard is not sufficient…as consumers are unlikely to read a standard (let alone its notes). Recognizing this, a generic consumer advisory along the lines of the text below is needed for the new standard to fulfil its purpose:

This standard does not purport to address all of the health, safety and environmental concerns, if any, associated with the use of community face coverings. It does not address the use of biocidal materials, finishes, or mechanisms that are subject to regulatory oversight as to their efficacy and safety by various governmental agencies. It also does not address the several aspects that relate to the design and material composition of community face coverings — including potentially toxic finishes, inhalable substances from materials, bioburden inhibitors, etc. — may warrant attention as to their health, safety and environmental impact. As such, it is important that face covering end users familiarize themselves with the specific special claims being made for products and to ask for support data and information to verify such claims."

Labelling that is silent on these issues does not address the consumer "confusion" as to products made with toxic materials and treatments that are claimed to provide more protection or greater effectiveness. Indeed, this may foster a false sense of security in the effectiveness of these face coverings. Further, acknowledging these issues with manufacturers within the standard's text, and not requiring similar notification to the consumer, makes no sense. Lastly, commercial and retail entities expect and appreciate a consumer advisory that eliminates or at least mitigates any implied liability as it relates to these issues.

Support Discussion

1. Biocidal (Antimicrobial) Agents – *Detailed Discussion*

Face coverings that feature an anti -bacterial, -microbial or -viral (collectively "antimicrobial") material, finish or mechanism have become increasingly popular. In part, this is likely because of the *commonsense* belief by the public that coverings treated with an antimicrobial offer an added degree of wearer protection.

Enjoying decades of success on textiles, even in healthcare settings, this belief is not unfounded. A face covering having an antimicrobial treatment should theoretically offer an added level of wearer protection versus one that does not if the antimicrobial is effective at fending off and inhibiting the growth and spread of pathogenic microbes on the covering's surface over time. Indeed, there is considerable evidence that (enveloped, gram-negative) coronaviruses are among the easiest pathogens for antimicrobials to inactivate.

Notwithstanding that a barrier face covering can be effective at blocking a certain percentage of undesirable particulates, a portion of those blocked infected viral can survive for a considerable period on the covering's surface and propagate. Fabric face coverings create an environment that is conducive to microbial growth given their extended close contact with the wearer's skin (and optimal nutrient, temperature and moisture conditions). And, while viruses are not living things, they do hijack healthy cells by attaching to and penetrating hosts; injecting them with noxious genetic material; building new viral proteins and finding new hosts to infect. Employing a variety of methods, antimicrobials are intended to ensure that pathogenic microbes do not attach to a fabric's surface and, if they do, to kill. Some are highly effective at doing so.

Face covering buyers are wise to research and scrutinize the often-exaggerated claims made by manufacturers and marketers as to the efficacy of the antimicrobial substances they employ. Metal-based antimicrobials are only marginally effective as they must come in direct contact with the virus to be effective. To do this, the metal would have to be incorporated into every single fabric fiber to fully live up to its potential. Antimicrobials that rely upon toxic poisoning have limited useful lives as their reservoir of toxins is finite and eventually runs out. Lastly, an antimicrobial's ability to remain fixed to fabric is a key determinant of its safe useful life. Most metal-based antimicrobials are added to fabric post-manufacture that wears off with each machine wash cycle and eventually degrades to an unreliable level over time.

In addition to effectiveness claims it is important to note that many antimicrobials pose potential health, safety and environmental risks. Heavy metals are used as antimicrobials due to their biocidal/poisonous qualities. The most common metal-based antimicrobials used on face covering fabrics are zinc, silver and copper. These antimicrobials work because of the metal's inherently toxic characteristics: these toxins are transferred to the infected host cell to chemically poison it. When metal-infused fabrics are used in face coverings this noxious "chemistry experiment" occurs a few centimeters from the wearer's mouth and nose.

While each of these metals has some inherent medicinal quality that makes it beneficial to human health when used in a certain way, these same properties cause heavy metal poisoning and other toxicity issues.

- The Mayo Clinic advises against zinc nasal sprays, as many people suffer a loss of smell afterward.
- While not a carcinogenic, mutagenic or reproductive toxicant in low doses, copper can cause serious health problems if it accumulates at high levels in the liver and other organs. Breathing high levels of copper can cause nose/throat irritation; exposure to copper fumes can cause chronic copper poisoning.
- Silver has many toxicity issues. Though normal silver concentrations in human tissues are low, with overexposure it can accumulate in the skin, liver, kidneys, eyes, etc. with serious health consequences. It poses a risk of neurotoxicity; it may interact with skin flora to weaken the skin's defense barrier; and more. Inhaling silver compounds/dust/fumes can cause/contribute to respiratory tract irritation, bronchitis, emphysema and lower pulmonary volume. Some silver nanoparticle strains are very toxic.

The US EPA and FDA are charged with regulating antimicrobial agents based on their intended application. In general, agents used on inanimate objects are regulated by the EPA as antimicrobial pesticides under FIFRA; and agents used in or on living animals or humans are regulated by the FDA under FFDCA.

The EPA has strict rules regarding marketing claims made about the capabilities of antimicrobials. Among them are prohibitions against making claims beyond that of the "treated article" itself. Without specific EPA approval, claims cannot be made about an antimicrobial's protection against or prevention from specific organisms infectious to humans (e.g., COVID-19) or that of the treated fabric. These prohibitions cover the product's packaging, advertising and communications.

As it relates to face coverings, unless authorized by the EPA, any claim as to an antimicrobial's ability must be limited to the face covering itself; be specific and not unqualified; refrain from referencing health-related microbes and from denoting personal (e.g., "for skin, wound, or respiratory") protection. Graphic representations of the covering's antimicrobial protections cannot include or imply protection of public health significance or take prominence above other normal product claims.

Claims are made by US manufacturers about an antimicrobial's perceived ability to kill the COVID-19 virus, although no US entity can justly make such a claim as, to date, there has been no approval, or any form of government-sanctioned testing performed to prove the effectiveness of any antimicrobial agent against COVID-19. *Despite this, many US and international face covering manufacturers circumvent these prohibitions by maintaining that the intended purpose of their antimicrobial is solely for odor control.*

My understanding is that in Europe the oversight and regulation of biocidal (antimicrobial) agents is largely the domain of the REACH system; inclusive of the REACH (EC 1907/2006) Regulation as interpreted and administered by the European Chemicals Agency (ECHA). For the specific purposes of this document, it is assumed that the general intent, approach, structure and methods employed by both US and EU regulatory agencies are similar as they relate to the limitations and restrictions of using (and promoting the use of) biocidal (antimicrobial) agents on face coverings, and that no distinction in this regard is necessary.

Recommendations Re: Biocidal (Antimicrobial) Agents

Given that there exist many misconceptions on the part of the public about antimicrobials, their safety and effectiveness, any community face covering standard would be remiss without addressing this topic, in one way, shape of form…both at the manufacturer level as well at the consumer / end user level.

A standard focused on community face coverings may not be the ideal venue to address the issue of biocidals, however it would be a disservice to the standard's intended beneficiary to be silent on the topic. It is likely that consumers / end users may read the standard and get the impression that biocidal materials, finishes, or mechanisms must either not be particularly significant, or they must be effective and safe, because they are not addressed in the standard. This is a false impression that should not be allowed to stand. At the very least, face covering consumers should be made aware of the need to research and become familiar with the effectiveness, and safety and environmental impact of biocidals.

I believe that BSI Flex 5555 - Version 1 would be greatly improved if it were amended to include the proposed text noted earlier with the accompanying consumer advisory labelling requirement.

2. Activated Charcoal Filters – *Detailed Discussion*

Many face coverings feature built-in or removable and replaceable filtration mechanisms that include non-woven melt-blown layers, activated carbon/charcoal* filters and HEPA filters. The popularity of these types of face coverings is growing and products with integrated / removable filters account for a large share of the world face covering market. The recent TIME Magazine *List of 100 Best Inventions of 2020* features three face coverings, each with a changeable filter, some boasting of filtration rates of up to "99.6%... of airborne particles, down to 0.1 micron". Putting filtration claims aside, there are potential; health, safety and environmental issues related to the use of activated charcoal filters in face coverings.

The activated charcoal filtration process is not entirely efficient, effective or safe. It is formed from powder-sized carbon particles that have been treated to be extremely absorbent through "activation", which refers to the injection of hot air, CO^2 or steam into the carbon. This process, *enhanced by chemicals*, create a mesh of tiny pores to increase overall surface area and filtration. Highly absorbent, activated charcoal media is effective at attracting and removing organic compounds, chemicals and gasses from the air. Contaminated air passes through the filter and is ***ad***sorbed (bonded to the carbon surface) to prevent their inhalation. Often, the carbon media is given a positive charge to attract negatively charged microbes.

Activated charcoal filters are not good at removing chemicals that are not attracted to carbon (e.g., sodium, nitrates, heavy metals, fluoride, etc.) nor are they effective against most pathogenic bacteria or viruses. As such, activated charcoal filters are often paired with other filters (e.g., HEPA) to address the entire range contaminants. Activated charcoal filters *should not* be promoted as a means of filtering pathogenic viruses.

Note that activated charcoal filters ***ad***sorb rather than ***ab***sorb contaminants: nothing is brought *inside* anything; instead, pathogenic microbes that are attracted to carbon stick or bond to the outside of the carbon structure (and ***ad***sorbed). This adsorption of the contaminated microbes creates a" bioburden build-up" over time, eventually saturating the filter to the point where it will lose its ability to trap and retain contaminants. Ultimately, these contaminants are released back into the environment, defeating the purpose of the filter.

Beyond effectiveness and efficiency, activated carbon filters can also present significant health risks. While activated charcoal has been reported to be an inert substance, mounting evidence suggests that inhaling charcoal is associated with acute respiratory distress syndrome and pulmonary compromise. Many epidemiologists suspect that breathing in charcoal fragments, particles and dust is not good for your lungs; may cause mild irritation to the upper respiratory tract and infection; and can produce skin, nose and eye irritation. Impurities found in carbons (e.g., iodine) can be toxic. Persons with impaired respiratory function, airway diseases, emphysema or chronic bronchitis are likely to be more severely impacted by inhaling such particulates. All of this is important as it is very possible that carbon particles (and other related toxins and harmful impurities) may be inhaled from a face covering having an activated charcoal filter. Lastly, when wet, activated carbon removes oxygen from the air: not a good face covering feature.

Recommendations Re: Activated Charcoal Filters

BSI Flex 5555 - Version 1 is silent about activated charcoal filters although many face coverings feature them. Because the effectiveness, safety and environmental impact of these filters is a matter of legitimate concern to many (e.g., those with certain health issues), face covering consumers should be advised to become familiar with activated charcoal filter technology and to research and carefully assess all claims related to performance, safety and environmental impact. ***BSI Flex 5555 - Version 1 would be greatly improved I believe if it were amended to include the proposed text noted earlier with the accompanying consumer advisory labelling requirement.***

- Although different, "carbon" and "charcoal" are used interchangeably as both are the product of incomplete combustion.

3. Nanoparticles – *Detailed Discussion*

Nanoparticles are pieces of matter between 1 and 100 nanometers (nm) in diameter. Nanotechnology is essentially the push toward microminiaturization and the expansion of science into the nanoscale. The characteristics that make nanoparticles attractive for applications in industry, medicine and technology are not just their miniature size but also the way that their surfaces are assembled or modified with chemical treatments to increase their stability and the ease with which they can interact with biological systems.

Nanotechnology is used to make materials stronger, lighter, cleaner, water- and residue-repellent, anti-reflective, self-cleaning, resistant to UVA and IR, scratch-resistant, more reactive, more sieve-like, better electrical conductors, etc. It has helped revolutionize many products, processes, industry sectors and technologies as nanoscale materials are used in hundreds of household products (from paint to sunscreens to eyeglasses), enable *smart fabrics* with nanoscale sensors, and facilitate the delivery of drugs, heat, light, genes, etc. to specific types of cells. Some antimicrobial agents now feature (metallic) nanoparticles.

Despite the many benefits that nanotechnology affords, great concern exists that the use of nanomaterials may be harmful and even unsafe in certain applications. Indeed, the dangers associated with contact with nanoparticles is not just speculation. Indeed, as more research is conducted, concern increases. It is now believed that the very properties that make nanoparticles appealing (size and chemical surface modification for biologic purposes) are the same properties that pose potential danger for humans and the environment.

- Nanosized particulates can be deposited throughout the human respiratory tract when inhaled, with a consequential number reaching the lungs. They move easily and depending upon exposure time, material amounts can travel from the lungs to the liver, spleen, brain and possibly even a fetus.
- Nanoparticles can also be brought into the body through the olfactory nerve (that conveys smell) through the nose's mucous membrane. It is the shortest route from the nasal passage to the brain.
- Exposure via skin contact can result in nanoparticles entering the body. Further, they may *ad*sorb onto the surface of larger molecules they encounter as they enter the tissues and fluids of the body.
- Studies have also demonstrated the passage of inhaled nanoparticles into the bloodstream.

In general, the most prominent effects of inhaled nanoparticles are lung inflammation and heart problems. However, another reason why the use of nanoparticles in certain applications is suspect is that the properties of certain nanoparticles often differ markedly from those of larger particles of the same substance. As such, materials which by themselves are not very harmful can be toxic if they are inhaled in nanoparticle form.

The rapid, more expansive and widespread use of nanomaterials has caused concern among many as the long-term effects of chronic exposure to them on humans are not well known. *This raises legitimate health concerns related to the wisdom of using nanoscale materials (e.g., nanosilver) as the antimicrobial agent base for treatments used on face coverings specifically intended to be worn for extended periods of time.*

Nanosilver is an example of how nanoparticles can be unsafe, unhealthy and environmentally unfriendly.

The medicinal benefits of silver are well documented and large doses of silver can be safely tolerated. What is of concern to physicians, scientists and environmental watchdogs is the manipulation of nanoparticles and their use for applications where silver has never been used. Consumer products companies have been adding nanosilver particles for antibacterial purposes to an ever-expanding array of items as diverse as cutting boards, underwear, yoga mats, running shirts, gloves, socks, toothbrushes. With the emergence of the pandemic, many popular face coverings now feature nanosilver as an antimicrobial. Worse yet, in addition to its inherent toxicity, nanosilver is often added to face covering fabric at the finishing stage. This can inhibit its bonding to the fabric, allowing it to be easily removed by normal use / laundering over time.

Environmentalists and public health officials fear the negative impact the disposal of various silver treated medical and consumer products has when they end up in sewage treatment systems and, ultimately, in the environment. This is because there are presently no effective ways to filter silver nanoparticles. Many scientists believe that the large-scale contact with, or release of nanosilver particles into the atmosphere, may lead to not only disturbances of the microbiological ecosystem but also our bacterial resistance to silver. Researchers at the U. S. Geological Survey warn against the overuse of silver and have expressed their fear of the explosion of its use on products where we do not know it to be effective; noting that it is important to evaluate the risk of using silver before putting it into the environment. Recognizing that there may be adverse long-term effects from the consumption of, or exposure to, silver many believe that the use of nanosilver products should be avoided unless justified (e.g., for needed medical interventions).

Graphene, a nanoparticle, also poses potential risks. Still in its infancy as it relates to real world applications, graphene is a nanomaterial comprised of sheets of carbon atoms in a honeycomb pattern. It is essentially graphite oxide (GO) in one layer. Graphene is the world's first *two*-dimensional material and the thinnest and lightest object ever made: it is 300 times stronger than steel. Flexible, transparent and a better conductor than copper many scientists believe that graphene could one day enhance, or replace, metals and plastics in our daily lives as a one-atom-thick sheet of it can be applied to many materials in many ways

Given this, it is not surprising that engineers and scientist began to explore the use of graphene and GO for use in the fight against COVID-19. Some are focused on the potential to create a graphene (oxide)-based antibacterial as graphene is reported to exhibit strong anti-bacterial activity. This, it is hoped, could help make face coverings repel bacteria (and, presumably, viruses). By applying a graphene coating to the covering's outer layer, private researchers claim to have created a bacteria-resistant graphene coated surface that repels, reduces or otherwise inactivates ≥ 90% of various bacteria, even after multiple washings.

For some, graphene may not be ready-for-primetime as it relates to it use on face coverings. In large part, this is because of the many issues inherent to the material and its limited use in textiles. It is still a reasonably high-cost material fraught with uniformity, transport and handling challenges and it is not subject to the standards that are customary in most industries. Further, like other nanoparticles, it poses potential health, safety and environmental problems: the (June 2018) American Society for Microbiology's *Journal of Antimicrobial Agents and Chemotherapy* publish that "…their possible ecological effect must be properly evaluated before their widespread use". Studies of graphene have indicated that it could be toxic to the liver, kidneys and lungs like other nanoparticles. Given the other proven alternative ways to safely imbue fabrics used in face coverings with antimicrobial properties, prudence dictates that the use of graphene should be delayed until further evidence of its effectiveness and safety are better understood.

Recommendations Re: Nanoparticles

In the US, nanosilver manufacturers must register their products with the EPA citing the risk they pose. Both the US OSHA and NIOSH agencies have warned against the potential hazards of exposure to nanoparticles through inhalation, skin contact and ingestion. The Commission adopted Commission Regulation (EU) 2018/1881 to modify REACH Annexes I, III and VI-XII, introducing nano-specific clarifications and new provisions in the chemical safety assessment (Annex I), registration information requirements (Annex III and VI-XI) and downstream user obligations (Annex XII). Clearly this topic is one that warrants attention at the consumer / end user level yet *BSI Flex 5555 - Version 1* is silent on nanoparticles and, left as is, readers who are unfamiliar with the potential dangers posed by the use of nanoparticles on face coverings will remain uninformed.

I believe that BSI Flex 5555 - Version 1 would be greatly improved if it were amended to include the proposed text noted earlier with the accompanying consumer advisory labelling requirement.

4. Bioburden Build-Up – *Detailed Discussion*

Even when used properly, ordinary paper surgical masks and fabric face coverings create large populations of viable microorganisms that scientists call a "bioburden". Bioburden build-up develops as a result of

- the wearer breathing and coughing germs and viruses into the face covering,
- the face covering collecting pathogenic particles that have been transmitted by others, and
- the face covering's surface being allowed to host microbial build-up over time.

COVID-19 is a deadly virus making bioburden build-up of this virus a particularly dangerous. This makes putting on, taking off, storing and laundering face coverings critical tasks that must be mastered to ensure that both the self-contamination and transmission risk is not needlessly amplified.

Today, we know to what extent microbes like COVID-19 can survive on various surfaces. A study in the *Journal of Clinical Microbiology* (February 2000) on the transfer and survivability of micro-organisms concluded that bacteria survive longer on polyester vs. cotton and can become a vector for the spread of microorganisms, creating serious infection control implications. A study in *The Lancet* (April 2020) noted that "a detectable level of infectious virus could still be present on the outer layer of a surgical mask on day seven" of a study. Infectious disease researchers and doctors at Johns Hopkins University/Health System found that COVID-19 survives better on less porous *artificial fibers* like polyester (and spandex) vs. cotton. Understanding this, with respect to the dangerous bioburden build-up of COVID-19 microbes, the evidence is clear that polyester is not a wise fabric choice for face coverings. This is because one of the intended purposes of face coverings is to act as barrier against virus-infected droplets and aerosols understanding that some of those particles will remain on the face covering and accumulate over time. Knowing this, the fabric used on face coverings should inhibit the possibility of bioburden build-up, not enhance it.

Certain antimicrobials and electrostatic air filters provide proven, safe means by which to inhibit and defeat bioburden build-up. Both approaches rely upon continuously inactivating/killing viral microbes rather than just blocking them and allowing them to build-up into a bioburden that can infect the face covering wearer and be transported to infect others. Unlike simple barrier filtration, antimicrobial and electrostatic methods address all sized particles. Because they kill infected microbes, a face covering's fit is not quite as critical a matter for it to be effective in use; there is less risk of face hand-to-face bioburden transmission when removed; and, relative to ordinary face coverings, it is safer to transport and store (as it is not covered with active microbes). This is critically important as each time the wearer touches, adjusts or discards a covering, the potential to infect the wearer, and infect others, increases the dangerous impact of bioburden build-up.

Recommendations Re: Bioburden Build-Up

Bioburden build-up is a known risk associated with wearing a face covering. *BSI Flex 5555 - Version 1* is silent on the issue and face covering users who are unfamiliar with the contamination and transmission danger it poses will remain uninformed if it remains as is. It does not appear that the REACH Regulation specifically addresses the topic about claims made as to the performance of bioburden inhibitors used on community face coverings. At the very least, I believe that consumers of face coverings should be advised to become familiar with bioburden build-up risk and how to mitigate it; evaluate face covering fabric's propensity to enhance or inhibit bioburden build-up; and to research and carefully assess all claims made of materials, finishes or mechanisms represented to mitigate bioburden build-up.

In the absence of an expansive advisory along the lines note above, BSI Flex 5555 - Version 1 would be greatly improved if it were amended to include the more limited proposed text (noted earlier for the Introduction) with the accompanying consumer advisory labelling requirement.

5. Toxic Fabrics – *Detailed Discussion*

Community face coverings are typically made of cotton, a man-made/synthetic fiber (e.g., polyester), or a blend. Synthetic fibers often carry with them health, safety and environmental concerns that may not be known to consumers who may not regularly purchase clothing articles. In fact, it is unlikely that most face covering consumers are familiar with the toxicity and environmental characteristics of various fabrics.

Fibers like polyester are fraught with issues that make them noxious materials that many people believe are inappropriate for use in face coverings. A type of plastic, polyester is a synthetic material that contains embedded toxic chemicals and is made with antimony, a known carcinogen, and other noxious chemicals (e.g., thermoplastic) that outgas toxic plastic molecules when heated in the clothes dryer. Prolonged contact with polyester can cause chronic and severe respiratory infection and excessive wearing of it can cause skin problems and lung, heart and other cancers. Polyester is neither sustainable nor bio-degradable, is dangerous to the environment and causes eco-friendly consumers to frown on its use. Its production disposes toxins into the water and emits lots of air pollutants. It is hard to recycle and, when it is, it uses more energy than producing cotton from scratch. Indeed, it takes two to ten times more energy to produce polyester vs. cotton.

Recommendations Re: Toxic Fabrics

Harmful chemicals, as identified by the European Chemical Agency (ECHA), are known as Substances of Very High Concern (SVHC) and many SVHC's found in textile products are considered harmful and therefore restricted from use by the REACH Regulation. The ECHA substance infocards on polyester and polyester resin (by example) identify these substances as subject to regulation however no consumer warning label requirements are noted as it relates to potential toxicity re: use in community face masks.

Most face mask buyers are unfamiliar with the relative toxicity of fabrics or their environmental impact. *BSI Flex 5555 - Version 1* is essentially silent on the topic of toxic fabrics and readers who are unfamiliar with their potential danger will remain uninformed. At the very least, I believe that consumers of face coverings should be advised to become familiar with the potential toxicity of the fabric used in a face covering (that may be worn daily, for months, for several hours per day) and to research and carefully assess the potential toxicity of the fabrics used in such products.

I believe that BSI Flex 5555 - Version 1 would be greatly improved if it were amended to include the proposed text noted earlier with the accompanying consumer advisory labelling requirement.
