Submission to the Inquiry into Biotoxin-related Illnesses in Australia

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Executive Summary

This submission provides information related to the Inquiry into Biotoxin-related Illness in Australia, obtained primarily through secondary research and analysis and industry-experience. All relevant research can be found in the appendices.

Results of the research and analysis demonstrates:

- Mycotoxins are a by-product of fungi and mould growth with larger exposure and consumption in humans from commonly-consumed foods rather than via mould contaminated structures such as water damaged buildings,
- Some current mould sampling has procedural flaws, inconsistent results and is implicated in the diagnosis of CIRS and mycotoxosis,
- The development of ERMI testing and its relevance to assessing a water damaged building (home) in Australia and overseas,
- There are no International or Australian standards for mould levels in a built environment, only guidelines created by individuals and organisations designed to be used by mould remediation professionals and these guidelines are not based upon academic research,
- There is a lack of evidence connecting fungal spores, water damaged buildings and exposure with certain health conditions,
- The medical effects of mycotoxosis and the history of the CIRS theory and how it can, promote unsafe, expensive and unwarranted treatment of CIRS, and
- Research on medical treatments of CIRS in both Australia and the United States of American through medical protocols.

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Introduction

This submission provides a brief overview of biotoxins and subsequent mycotoxins and their effects on humans when exposed in water damaged buildings and other settings along with an analysis and review of current and past sampling procedures used within the mould remediation and water damage restoration industries to evaluate the levels of mould within a built environment.

Outlined are the equipment and tools used for testing, procedures followed for collecting samples, analysis of the samples, applicable standards to measure samples tested and the relevance of the information within Australia.

It is important to understand that some testing procedures have either flaws or inconsistent findings, resulting in differing determinations by individuals and organisations who use them.

There are no Australian or international standards for mould levels in a built environment due to the lack of reliable methods to quantitate the airborne mould spores, only guidelines created by individuals and organisations designed to be used by mould remediation professionals.

Whilst many studies have been completed for mould related allergens, there is no direct link between toxins in moulds and a direct impact on a persons' health attributed from water damaged buildings.

Current legislation in Australia, The United States of American and the European union regarding mycotoxin exposure through the most common form, ingestion,

Also included is information on types of water damaged buildings and sources of moisture that are commonly found in Australia.

Health Effects of Mould and Mycotoxins

While mould itself is not toxic or poisonous, certain moulds are toxigenic, meaning they can produce toxins, specifically mycotoxins (Centres for Disease Control and Prevention, 2017, A). Exposure to mycotoxins is mostly through ingestion (Peraica, Padic, Lucic and Pavlovic, 1999). Mycotoxins can be found in everyday products such as wine, bread, coffee, soybeans, cereal, fruit, rice, corn and many other common dietary items. The Food and Drug Administration in the United States, as well as the European Union, have limits and regulations for several mycotoxins allowed in food (Ukwuru, MU., Ohaegbu, CG., and Muritala, 2017). The Australian New Zealand Food Standards Code currently have regulations for two mycotoxins, Aflatoxin and Phomopsin. (Australian Government, 2018).

Aflatoxins are a side-effect of Aspergillus fungus, and tend to flourish in warm, humid environments. Australia would likely be more prone to Aflatoxin contamination due drought-stressed harvest containing more than 100mg per kilogram of Aflatoxin, when the Code of Practice for Feed for Food Producing Animals sets levels at no more than 0.02mg per kilogram for dairy animals (Queensland Government, 2017). Production animals, such as cows and pigs, are likely to consume these pre-production crops, and can remain contaminated for up to 2 weeks, in which time they can be slaughtered or milked (Queensland Government, 2017). The Codex Alimentarius Commission, an international agency, has formulated maximum limits for contaminates and have outlined them in a Codex (Gong, Routledge, Kimanya, Musoke, Nelson, Sonoiya and Manyong (2015). The Codex identifies a limit of 15 micrograms per kilogram, 15 parts per billion, for Aflatoxins in a range of nuts needing processing, or 10 micrograms per kilogram for ready-to-consume nuts (Gong et al, 2015).

The Codex, however, has not been able to prepare internationally adequate limits for staples such as rice (Gong et al, 2015). As mycotoxins are natural, Stored Grain (2009), states that it is “difficult to set acceptable intake levels for long-term consumption”, and therefore only a small number of limits have been set for mycotoxins in consumables. According to Gong et al (2015), as the Codex does not outline standards for more basic, or common, foods, nations have developed their own maximum limits, increasing risk of Aflatoxin contamination between diverse agro-ecological regions. There are no Australian limits for Ochratoxin A because it is only produced by a very limited number of species in the genera Aspergillus and Penicillium (Pitt, J., 1998).

Exposure to mycotoxins is less likely through the inhalation of mould spores and dermal contact. A natural amount of mould spores exists everywhere in both the indoor and outdoor environment (Centres for Disease Control and Prevention, 2017, B). In the outdoor environment, the amount of mould spores in the air change with environmental factors and geographic locations. For example, it is likely to record higher particulates in air quality testing within a rain forest and lower at the beach. The levels of mould spores within the air within an indoor environment should fluctuate in correlation to the outdoor readings. These natural levels of mould spores contain mycotoxins which we breath in every day.

When mould grows in an indoor environment it increases the amount of mould spores into the air and can cause health problems. These can vary depending on how sensitive the person is to mould. Common side effects include nasal stuffiness, throat irritation, coughing or wheezing and eye irritation. Mould spores can vary in size of between three to forty microns, and increased levels in indoor air quality can cause these irritations (Fairey, P., Chandra, S. and Moyer, N., 2014).

People suffering from a pre-existing medical issue such as asthma may have an allergy towards mould spores as well as other biological particle matter such as pollen, animal dander and house dust mites. Allergy testing is available to confirm if this is an issue (National Center of Environmental Health, 2018).

Immune compromised people such as people with HIV infection, cancer patients taking chemotherapy, and people who have received an organ or stem cell transplant and people suffering from chronic lung illness may have a more allergic reaction or fungal infections (Centres for Disease Control and Prevention, 2017 C). People suffering from a pre-existing medical issue such as immune suppression or chronic lung illness should avoid environments with poor indoor air quality.

Biotoxins

Biotoxins are substances which are both toxic and have a biological origin.

They come in many forms and can be produced by nearly every type of living organism: there are mycotoxins (made by fungi), zootoxins (made by animals) and phytotoxins (made by plants).

Whilst some appear to have no advantage for the organism making them (they might be a waste product, for example), most are produced to help in two main activities – predation and defence against predation by other species, and so have very important roles in the life cycle of the organism (Omicsonline, 2018).

Many biotoxins can be further classified into what kind of effects they have on the body. Some of these groups include the following:

- **necrotoxins**, substances that cause tissue destruction via cell death and are carried in the bloodstream.
- **neurotoxins**, substances that affect the nervous system.
- **haemotoxins**, substances that are carried in the bloodstream and target red blood cells.
- **cyanotoxins**, produced by cyanobacteria.
- **cytotoxins**, substances toxic at the level of the cell (kills individual cells).
- **mycotoxins**, produced by fungi.
- **apitoxin**, honey bee venom, injected via the sting.

Mycotoxins

For a toxic effect to happen to an individual, three circumstances need to be achieved; a toxin must be present, there must be some form of exposure, and the individual must receive an ample dose (Bush et al, 2006). Mycotoxins are not progressive toxins, having half-lives, varying from hours to days, conditional to the mycotoxin (Bush et al, 2006). It is not known whether mycotoxins found in mould-affected environments represent a definite health risk via inhalation (Bloom, E., 2008). Due to current, westernised lifestyles, individuals can spend up to 90 percent of their time indoors, and according to Bloom (2008), these lifestyle changes can be associated with the considerable increase of allergic diseases. Brewer, Thrasher, Straus, Madison and Hopper (2013) discuss the detection of mycotoxins in patients with Chronic Fatigue Syndrome (CFS). The study they reference could not identify any one cause to explain in full CFS. Additionally, the study was only conducted over a 6-month period, and was carried out at one private facility, implying a lack of contrast and a possible insufficient time-line to develop a conclusion (Brewer et al, 2013).

Exposure to Biotoxins and Mycotoxins

The Centre for Disease Control and Prevention states that biotoxins are poisons that come from plants or animals, and include nicotine, ricin, algae, spider bites, bee stings, pollen and mould and fungi (CDC, 2016). For the purpose of the inquiry, this submission is focusing on mycotoxins and the effects on humans, referred to mycotoxicosis. Mycotoxins are "low-molecular-weight chemicals" constructed by moulds, however only particular mould species produce specific mycotoxins under certain circumstances (Bush, Portnoy, Saxon, Terr and Wood, 2006).

While there is a central focus on water-damaged buildings and their effect on occupants, as a consequence of being exposed to mycotoxins, there needs to be an emphasis on individuals also being exposed to mycotoxins through the ingestion of contaminated foods (Page and Burr, 2016). Moulds that can produce mycotoxins can grow on various foodstuffs such as cereals, dried fruits, nuts and spices (WHO, 2018). One type of mycotoxin, Ochratoxins which is produced by Aspergillus and Penicillium, commonly contaminates wheat, pork, coffee and cocoa (Page and Burr, 2016).

Ochratoxin A (OTA), the most common Ochratoxin found in food, has previously been detected in 100 percent of blood and urine samples in selected studies (Page and Burr, 2016). Tricothecene, another mycotoxin, has similarly been identified in the urine of 98.7 percent of 300 generally healthy people, however that number was reduced once the subjects' cereal grain intake was limited (Page and Burr, 2016). Furthermore, some of the greatest exposures to microbes can be found upon farms and dairies, animal confinement and waste compost, with points up to 1 billion spores per cubic metre of air, and between 320,000 and 130 million spores per cubic meter polluting swine and poultry and corn and mushroom farms (Page and Burr, 2016).

The American Academy of Allergy, Asthma and Immunology has stated that occurrences of mould related toxicity and mycotoxicosis from exposure to inhaled mycotoxins in a non-occupational setting is not supported by the current data and its occurrence is improbable and that exposure to mould and their products such as mycotoxins does not induce a state of immune dysregulation (Bush et al, 2006). It is concluded that the practice of performing large-scale, nonspecific immune based tests as an indication of mould exposure, or mould related illness, is not evidence-based, and should be discourages, nor should testing for antibodies to mycotoxins be relied upon, as it is not scientifically validated (Bush et al, 2006).

Following Hurricane Katrina in New Orleans, U.S.A, the largest scale study was completed on the relationship between mould exposure and allergic response with 2008 participants (Rabito, Perry, Davis, Yau and Levetin, 2010). Despite extensive exposure and multiple measurements of exposure there was no relationship found between mould, exposure and sensitivity to mould allergens with those people living with damp/mould homes (Rabito et al, 2010).

Sampling Methods

Bio-Tape

Bio-Tape Testing is conducted as a way of determining mould growth within a building. A plastic container is obtained from a laboratory, which contains a hard, flat piece of plastic with a piece of standard size Bio-Tape on top. The hygienist, mould specialist or home owner is then instructed to wear gloves, and peel off the tape and place it over an affected area. The tape should then be removed and placed back onto the plastic. A description of the affected area should be recorded, placed back into the container and sent to a laboratory for analysis. As the Bio-Tape comes in a standard slide, the surface area that is sampled is controlled, and the only restriction is that the surface area needs to be flat.

The results of a swab test only provide analysis based on the mould growth from the specific surface area that was tested (EMSL Analytical, Inc., 2018 A). Most commercial operators, such as mould specialists and hygienists, will take the samples on the visible mould growth present within a room. This procedure suggests that the results are exaggerated and presented to the occupants as an indication of the mould growth throughout the entire property. Mould and fungi does not grow in a uniform, consistent pattern across all surfaces (EMSL Analytical, Inc., 2018 A). This suggests that results cannot be used to make a judgement of indoor environment quality or mould growth. Gromicko and Ward (2018) concur with this by listing a disadvantage of tape testing as being unable to straightforwardly detect light-coloured and highly airborne groups, for example Aspergillus and Penicillium. Furthermore, tape samples are not guaranteed to correctly identify smaller airborne mould spores, with these spores less likely to settle onto a flat surface (Gromicko & Ward, 2018).

The Bio-Tape test method of mould sampling is simply a visual analysis of the particulates that were collected under a microscope. Other particulates such as dust and debris affect the

accuracy of the tape counts and can contribute to human error in the visual identification process (Gromicko & Ward, 2018).

Swab

Swab testing is carried out as a way of determining mould growth within a building, especially in hard to reach or on uneven surfaces, in which Bio-Tape is unsuitable (MouldLab (NSJ EnviroSciences Pty. Ltd., 2018 A). A sterile swab is obtained from a laboratory supplier. The hygienist, mould specialist or home owner is then instructed to wear gloves and roll the swab over an affected area. A description of the affected area should be recorded, and the swab should then be placed back into the tube and sent to a laboratory for analysis.
As there is no standard sample surface area in which the process should be performed, results can vary and be inconsistent with the number of particulates attracted to the swab; rendering the results being unable to be standardised. Along with Bio-Tape Testing, the results of swab tests only indicate mould growth in the specific area tested.

There are two different types of mould swab sampling, which include culture swabs, that are incubated to grow a certain species of mould, which are then visually counted by a lab technician. This will provide an indication of viable mould spores collected only within the species in which the agar medium is designed to grow. Only 10 percent of mould species will grow on culture whatsoever, indicating that 90 percent of species cannot be identified using this method of testing (InspectAPedia, 2018). Additionally, a culture that allows only some mould species to cultivate can be deemed as misleading, even hazardous, when relied upon to probe “building-related illnesses” (InspectAPedia, 2018).

The second type of swab testing is simply analysing the collected particulates under a microscope. Again, like Bio-Tape analysis, dust and debris can affect the accuracy of the swab counts, and the visual identification process can increase the risk of human error. This form of testing cannot be referenced against mould levels and growth in the natural environment surrounding the premises in question. There is no scientific protocol for conducing laboratory testing for either of these two methods.

ERMI

Environmental Relative Mouldiness Index (ERMI) was developed by the U.S. Environmental Protection Authority (EPA) and is based on DNA analysis of mould extracted from carpet dust (Rosen, 2015). It was developed to index indoor mould levels in premises from a dust sample and relies on a U.S. database of approximately 1,096 homes combined of both affected and un-affected properties (Rosen, 2015). According to Parkhurst (2009), the ERMI can identify moulds with 99.99 percent accuracy, however only applies to 36 moulds that the EPA identified.

The procedure is based on using mould-specific quantitative polymerase chain reaction (MSQPCR) to count the 36 moulds and calculate an index number, to compare with the homes on the database (EMLab P&K, 2018). A high index indicates that there is, or was, water damage, which resulted in elevated levels of water indicator moulds, and therefore a low index suggests that there has been so such issue (Rosen, 2015). According to Rosen (2015), the relative mouldiness of carpet dust is based on a comparison of 26 known water damage indicator moulds, known as Group 1, to 10 moulds typically found outdoors, known as Group 2. The higher ERMI value, Group 1 versus Group 2, the more mould-affected and water damaged the home.

Conducting an ERMI test can be carried out through two methods, Vacuum Collection Method or Swiffer Cloth Collection Method (Parkhurst, 2009). To carry out the testing via vacuum collection, a nozzle containing a dust collection filter must be obtained, and the hygienist, mould specialist or home owner is then instructed to wear gloves and tape an area of 900 millimetres by 1800 millimetres in two sections of the home, by Australian lab requirements. U.S. laboratories require a taped-off section of 914 millimetres by 1029 millimetres, however others will accept two square metres. The top and bottom caps of the dust collection nozzle is removed, to allow air to pass through the device, and then fitted to any vacuum cleaner, and

the taped off section is vacuumed. It is suggested by some laboratories that the chosen area is vacuumed for 5 minutes or until 30 to 100 milligrams of dust is collected.

Once the sample has been taken, the caps are placed back on the top and bottom of the dust collection canister, and a description of the affected area should be recorded, along with the serial number of the individual canister and sent to a laboratory for analysis.

The Swiffer Cloth method involves sampling a hard surface, and there is no need to set a chosen area as there is no suggested area size to be sampled. The hygienist, mould specialist or home owner is then instructed to wear gloves and wipe the cloth in one direction across a surface. While avoiding a scrubbing action, the individual carrying out the test, needs to attempt to rotate to a fresh area of the cloth for each area sampled. Once the sample(s) have been taken, the cloth is placed in a secure, snap-lock bag, and a description of the affected area should be recorded and sent to a laboratory for analysis.

ERMI testing was developed for a way to relate carpet dust and water damage to the development of asthma in children, and not to determine if current conditions are problematic or not (Rosen, 2015). The U.S. EPA, as of January 2013, had 10 functioning licenses of the MSQPCR technology, however it was found that some licensee's advertising had the probability to deceive the public into believing the MSQPCR and ERMI research tools were EPA-approved procedures for assessing indoor mould (Rosen, 2015). The Inspector General went on to say that the ERMI "has not been peer reviewed or validated for public use" and that there is the "potential for firms … to overstate the implications of the ERMI tool … to persuade [others] to undertake more costly remediation" (Rosen, 2015).

Vesper, McKinstry, Cox and Dewalt (2009) outline that the ERMI results have previously only agreed with visual inspection 48 percent of the time. Additionally, Vesper et al (2009) record that 7 percent of the lowest ERMI quartile homes overestimated the mould problem, indicating

an inaccuracy in the findings. The inaccuracy of the findings can also be contributed to the variations to the ERMI testing methods, such as the age of the sample carpet, the frequency in which it is cleaned, either privately or professionally, and the type and efficiency of vacuum used for testing. Additionally, ERMI testing utilises non-calibrated devices ranging from household vacuums through to commercial grade vacuums to collect dust. These devices can extract varied samples, with some vacuums having a stronger flow rate, being able to reach deep into the carpet pile, and others having a poor flow rate, only collecting the sample from the upper layer of the carpet pile. Without calibrated devices using the same flow rate, such as the bio pump used for air-o-cell cassettes, or a particle counter, sample consistency can vary. While there is no doubt that these samples can identify mould spore count to a degree, it cannot be used to correlate indoor air quality, nor does analysing mould in flooring dust indicate the cause, location or extent of any current problems.

Such as the Vacuum Collection Method, the Swiffer Cloth Method has faults, with some licensed laboratories encouraging clients to collect samples via a dust collection cloth, but not stressing the importance of recording the locations that were sampled (Pinto, M.A., 2014). Additionally, despite the neglect of the U.S. EPA recommendations for the sample collection process, the findings are analysed and clarified as if it were an unquestionable ERMI sample (Pinto, 2014). Furthermore, it was stated by the U.S. EPA that if the samples were not "collected in accordance with the sampling procedure used to develop the ERMI, the results would be of questionable value" (Pinto, 2014).

The U.S. EPA declares that the ERMI should only be used for research, and that it has "not been validated for routine public use in homes, schools, or other buildings" (EPA, 2017). This statement can also relate to the use of ERMI in countries outside of the U.S., with Taubel, Karvonen, Reponen, Hyvarinen, Vesper and Pekkanen (2015) concluding that the ERMI was not an appropriate comparison for the conditions found in Finland, where Taubel et al (2015)

conducted their study. With the findings in the Finland ERMI scale, it should be noted that the American-based research tool does not account for the Australian region variables such as construction materials and architecture, climate and mould species. Roofing methods in Australia commonly use either tiles or metal sheeting, whereas American homes commonly use asphalt and wood shingles, and basements are far more common in the U.S. compared to Australia. These slight differences impact on the average moisture and humidity levels in the home, both which can contribute to an ideal environment for mould growth. Solar radiation, air mass influences, location of global high and low-pressure zones, heat exchange from ocean currents and distribution of mountain barriers all influence local climatic conditions, demonstrating that there is no one country that can implement testing methods for others.

HERTSMI-2

HERTSMI-2 is an acronym for Health Effects Roster of Type of specific Formers of Mycotoxdins and Inflammagens - 2nd Version. HERTSMI-2 is a mould identification process derived from the ERMI sampling method and results are added into a scorecard system developed by Dr Richie Shoemaker.

Rather than looking at 36 mould species, like ERMI, the HERTSMI-2 analysis only identifies 5 moulds. MouldLab (2018, C) identifies the 5 mould types as:

1. Aspergilus Penicilloides
2. Aspergillus Versicolor
3. Chaetomium Globosum
4. Stachybotrys Chartarum
5. Wallemia Sebi

The result collected are used to complete a scorecard which is designed to help patients who were previously sickened by water damaged buildings understand if a building is safe for them to occupy (Surviving Mold, 2018).

There HERTSMI-2 systems dependency on ERMI means it encounters the same controversies and limitations including:

1. ERMI identification and quantification has a precise method using the vacuum dust collection method and all the EPA comparison values are based on this process. Therefore, use of the Swiffer Cloth method as promoted by some laboratories is a complete abandonment of the EPA sample collection method. The EPA Office of Inspector General was restrained in their assessment of this problem when their report noted, “If mold samples are not collected in accordance with the sampling procedures used to develop the ERMI, the results would be of questionable value” (Pinto, 2014).

2. ERMI was developed for use in homes and not offices or commercial buildings, as they were not included in the original EPA study. The misapplication of ERMI by the public had to be called out by the EPA Inspector General's office as a critique of ERMI and its validation process (Pinto, 2014).
3. Whilst the ERMI system has a very specific protocol for collecting samples via the vacuum dust collection method there are laboratories promoting a Swiffer Cloth collection method (Pinto, 2014).

According to Paradigm Change (2014), Dr. Ritchie Shoemaker established this test by examining the ERMI scores of thousands of individuals with apparent mould illness and concluding which species of mould appeared to be most problematic for them. Dr. Shoemaker recommends that this test be used to assess prospective residences by those suspect that mould is a problem for them, rather than to determine whether a suspect building is unsafe in general (Paradigm Change, 2014). This test has yet to have any papers published about it and is not yet in widespread use, but some mould doctors and patients suggest that it has been helpful to them.

While some doctors and patients put forward that this test has been helpful to them, the test has yet to have any publications and is not prevalent (Paradigm Change, 2014).

Air-O-Cell

Air-O-Cell Testing is carried out as a way of determining air borne mould spores and fungal fragments within a premise and comparing the results with an outdoor sample. A plastic cassette is obtained from a laboratory, which contains a small circular with inflow entry and an exit hole, for air to pass through the device. The hygienist, mould specialist or home owner is instructed to wear gloves and peel off the stickers at each end of the cassette and place it on a calibrated air pump. The air pump is then set with a time and pumps 15 litres of air through the cassette and some of the mould spores, fungal fragments, pollen, dust and skin cells settle on a small glass medium. Once the sample has been taken, the stickers are placed back over the entry and exit holes. A description of the affected area should be recorded, along with the serial number of the individual cassette and sent to a laboratory for analysis.

Once in the laboratory, the slides are removed from the cassette and undergo direct microscopic analysis (MouldLab, 2018 B). While Mould Lab (2018 B) suggests that Air-O-Cell testing allows for the sample to be compared to a wide range of particulates, EMSL (2018 B) states that "fungi cannot be fully speciated with this method", indicating it is an unreliable method due to similar species being reported together due to their alikeness. Kleinheinz, G.T., Langolf, B.M., and Englebert, E. (2006) report that this is an unreliable source of testing as well, stating that two common species, Aspergillus and Penicillium, are commonly grouped together as it is generally difficult to separate them morphologically.

The Environmental Protection Agency (EPA, U.S., 2012) states that there have not been any limits set for mould and mould spores, and therefore any form of sampling cannot be used to check a premises' compliance with relevant standards.

Particle Counting

Particle Count Testing is conducted as a way of determining air borne contaminates within a building and comparing the results with an outdoor sample. A Particle Counter machine, which is calibrated to an international standard ISO 21501 (Pandolfi and Kochevar, 2016), is used to take a sample of standard sample of air which passes through a laser beam thus scattering the light energy, and the electronics inside the sensor convert this light energy into a voltage. The voltage is proportionate to the size of the particle or the amount of light the particle scatters. The electronic circuitry picks up the voltage signal from the photo detector (which converted the light energy into the voltage signal). Digital threshold circuitry then sizes and counts the particles (Beckman Coulter, 2017).

The particle counter then displays in real time the airborne particulate counts in the sizes between .3 microns and 10 microns. These airborne particulates include biotoxin's such as pollen, dust and mould to give a true reading of Indoor Air Quality. Samples can also be taken from outside the test site to compare results and difference's in normal outside air quality and indoor Air Quality to see if there is an issue within a premise. The Particle Counter cannot distinguish between mould particles or pollen particles but can give an overall picture of properties indoor air quality in real time. Particle counters have been used in cleanroom environments for many decades to assess the effectiveness of heap filtration and decontamination procedures.

There is an international standard ISO 14644-1 for cleanroom standards to measure airborne contaminates and Indoor Air Quality (ISO, 2017).

Particulate Matter

Particulate matter is a term for a combination of solid particles and liquid beads observed in the air (EPA, 2016). Whilst some particles can be seen with the naked eye such as dirt, soot or smoke, smaller particles can only be detected using an electron microscope (EPA, 2016). The Environmental Protection Agency (2016) puts forward that particles less than 10 micrometers in diameter present the utmost problem, as the particles can enter the lungs, and possibly the bloodstream.

Exposure via inhalation can affect both your lungs and heart with scientific studies linking particle pollution to problems including:

1. early death in people with heart or lung disease
2. heart attacks
3. abnormal heartbeat
4. exacerbated asthma
5. decreased lung function
6. increased respiratory symptoms, such as irritation of the airways, coughing or difficulty breathing (EPA, 2018).

The Environmental Protection Agency (2018, B) states that particle matter can be made up of several different components such as “acids (such as sulphuric acid), inorganic compounds (such as ammonium sulphate, ammonium nitrate, and sodium chloride), organic chemicals, soot, metals, soil or dust particles, and biological materials (such as pollen and mould spores)”.

The health effects, deposition and retention in the respiratory system, sources and structure are the elements that differ fine and coarse particles (EPA, 2017 B). Although it is often theorised that particular elements or sources may be the cause of particle pollution -related illness and

death, there is no sufficient, readily-available evidence allowing the differentiation of those components that are strictly related to health outcomes (EPA, 2017 B).

Particle pollution occurs throughout the year and can be the reason for air-quality problems across entire nations. Some particle matter can linger in the air for weekly period, and are able to cover immense distances, and impact air-quality in areas far from the original location (EPA, 2017 B). Demonstrating this, was a severe case of thunderstorm asthma in Victoria in November 2016, in which 10 people died, because of rye grass pollen sweeping across the state. The pollen burst into fine particles and sparked asthma-like symptoms in thousands of people.

From adequate research, it is suggested that thunderstorm asthma is typically brought on by an unusual type of storm, which causes pollen grains to be carried into the clouds, as the storm forms (Asthma Australia, 2017). When the grains absorb moisture, they open and distribute sizeable amounts of smaller allergen particles, sometimes up to 700 particles (Asthma Australia, 2017). As these particles are blown to the ground, they are inhaled deeply into the lungs, which in some individuals, can cause irritation, swelling and mucus production, bringing on the asthma symptoms (Asthma Australia, 2017).

Water Damaged Buildings

The World Health Organisation estimates that in Australia dampness is a problem in 10 - 50% of buildings (WHO, 2009). When people think of water damaged buildings they usually think of issues caused by natural events or plumbing related flooding. Buildings can be water damaged from events extending from natural disasters such as flooding, storms and cyclones through to faulty appliances, plumbing or drainage. However, water vapour leading to condensation can also be a significant contributor. Activities such as cooking, laundering, or showering, which leads to the water vapour condensing on colder surfaces and items like walls, windows or furniture, are a common influencer of water damage (Andersen, Frisvad, Rasmussen and Larsen, 2011).

Condensation is reported as a common issue in households by various people across South-East Australia and this can be a large contributor to mould growth, especially during colder months. This condensation can form for various reasons however wet rooms can also lead to a property having a moisture related problem as they generate substantial amounts of water vapour. Use of bathroom ventilation systems can assist but, in some cases, they are not enough to prevent the issue. Wet rooms can also have water pooling in the flooring around shower basins, sinks and troughs. Grout, the commonly used fluid to reinforce tiles, is of a porous nature, and as wet rooms are generally tiled, the area becomes highly susceptible to microscopic growth (EPA, 2012).

Methods of construction can be another contributor to buildings becoming water affected. Homes built prior to 1940, including heritage-listed homes, are an example of this, with lime or sandstone being a common material for foundations and walls (NSW Heritage Office, 2004). These properties are particularly vulnerable to rising damp and water damage, as the foundations and walls are incredibly porous and can draw moisture upwards from the ground. This moisture can continue to rise, unless prevented by a damp course. A damp course is a

barrier through a structure, such as a wall or flooring, designed to prevent moisture rising by capillary action (NSW Heritage Office, 2004). The use of damp course is a common practice in new buildings, however prior to 1900, it was not commonly incorporated in building design (NSW Heritage Office, 2004). Therefore, properties built during this era are renowned for having rising damp issues. These properties are commonly found in older regions of Australia, including Sydney's Inner-West and Eastern suburbs and Melbourne's Inner-City suburbs.

It has been reported in many publications that occupants of properties with damp problems and fungal growth are at an increased risk of respiratory problems, respiratory infections and the exacerbation of asthma. Whilst a connection between fungal exposure and development of Type I Allergy has been evident, the clinical confirmation between fungal spores, hyphal fragments and/or metabolites to certain health complaints is lacking (Andersen et al, 2011).

Chronic Inflammatory Response Syndrome (CIRS)

Chronic Inflammatory Response Syndrome (CIRS) is defined by Richie Shoemaker as an "acute and chronic, systematic inflammatory response syndrome, acquired following exposure to the interior environment of a water-damaged building with resident toxigenic organisms, including, but not limited to fungi, bacteria, actinomycetes and mycobacteria, as well as inflammagens such as endotoxins, beta glucans, hemolysins, proteinases, mannans and possibly spirocyclic drimanes; as well as volatile organic compounds (Surviving Mold, 2018 B).

CIRS is a term coined by Shoemaker over the last decade, which encompasses everything from Lymes disease, insect bites, parasites, bacteria and mould, and their possible effects on individuals that present with varying symptoms. Shoemaker states that CIRS beings once "a person is exposed to a biotoxin. In most people, the biotoxin is 'tagged' and identified by the body's immune system and is broken down and removed from the blood by the liver" (Surviving Mold, 2018 C). He has developed a business focused on the diagnosis, training and sales in support of his historical works. Those that engage in services from Shoemaker are generally self-selected, that is they have identified themselves as suffering from health problems because of having been exposed to mould and have sought treatment from Shoemaker after reading his website or other literature.

Diagnosis and Treatment of CIRS

Chronic Inflammatory Response Syndrome (CIRS) has a difficult diagnosis process, and there are a number of steps to diagnose and treat CIRS.

Step One

Step One includes the completion of tasks that include:

- Answering questions of symptoms that are being experienced,
- Identifying a water damaged building that the person has been occupying,
- Discussing concerns with a Shoemaker Protocol certified technician,
- Completing blood tests, and
- Completing an online VCS test

A Visual Contrast Sensitivity (VCS) test, is an eye test, which measures the capability to see details at a low contrast and is regularly used as a non-specific test of neural function (VCS, 2018). The VCS testing site (VCS, 2018) itself states that online VCS testing is not a diagnostic tool for any one condition, and a patient is still recommended to see a health practitioner. Thomas, Burton, Mueller and Page (2010) all contributed to a paper outlining that further studies are needed to determine what aspects could be responsible for the VCS findings, and whether they have any quantifiable implications for those affected.

Step Two

Step Two is inclusive of carrying out ERMI testing within the building that the affected individual occupies, and the results are then compared with a persons' Alpha-Melanocyte Stimulating Hormone and C4A levels (Surviving Mold, 2018 D). According to Shoemaker's theory, "ERMI testing [is performed] to ensure there is no exposure to a building with an ERMI greater than 2 if the patient's MSH is less than 35 and C4A is less than 20,000; or no exposure

to ERMI greater than negative 1 if MSH is less than 35 and C4A is greater than 20,000" (Surviving Mold, 2018 D).

ERMI testing has been identified in a separate section of this submission, so the focus below is on the MSH and C4A levels and factors that can contribute to their differences.

MSH is a family of peptide hormones and neuropeptides. It should be noted that there are many external factors which increase a persons' MSH levels, such as sunlight, nicotine, leptin, insultin, stress, eating, and endotoxins and cytokines (Self Hacked, 2018). Factors that decrease a persons' MSH levels can include fasting, melatonin, dopamine, and conditions such as anorexia, alcoholism, multiple sclerosis and acute brain injury (Self Hacked, 2018). Shoemaker states that normal MSH levels are between 35-81 pg/ml (Surviving Mold, 2018 E). However, there are studies completed which contradict his range, as the study shows in the 30 people studied, the average MSH level was 14.5 pg/ml, and not one individual had a level over 35 pg/ml (Shishioh-Ikejima, Ogawa, Yamaguti, Watanabe, Kurastune and Kiyama (2010). Shoemaker then goes on to say that normal ranges of C4A are between 0 – 2830pg/ml (Suriving Mold, 2018 E), however there are studies demonstrating increased levels of C4A can be linked to AIDS, Lymes disease and Systemic Lupus Erythematosus (Stricker, Savely, Motanya, and Giclas, 2008).

Step Three

Step three is carried out via removing the individual from the water damaged building, ensuring they are no longer exposed to the elements.

Step Four

Step four is the process of correcting the toxin levels in the individuals' body, using Cholestyramine or Welchol, and using VCS to monitor the progress. Cholestyramine is a binding substance, and when used properly, reduces cholesterol levels and specific fatty

substances in blood. While the U.S FDA has approved Cholestyramine for this use, there is no medical or historical evidence suggesting that Cholestyramine is effective as a binding agent in relation to removing mycotoxins from the human body (National Treatment Centres for Environmental Disease, 2018). In Australia, Cholestyramine is branded as Questran, and has been endorsed by the Therapeutic Goods Administration, and listed on the Pharmaceutical Benefits Scheme (Health Direct, n.d), and there are currently Shoemaker Protocol Certified Physicians in Australia, with the permission to administer this medication (Kim, 2018).

Step Five

Step five consists of eradicating bio-film forming MARCoNS. Multiple Antibiotic Resistant Coagulase Negative Staphylococci (MARCoNS) is an antibiotic-resistant staph infection that resides deep in the nose (Kresser, 2015). While this can be acquired through exposure to water damaged buildings, it is not soley linked with water damage, as it can also be contracted from loved ones that carry the organism, or even the family dog (Kresser, 2015).

Step Six

Step six, the final step, involves eliminating gluten and correcting elevated blood marker levels, which are believed to impact on an individuals' mould-related illness.

Through our research, we have found it difficult to find studies or evidence which supports some of the above methodologies and apply direct links to treatment of mould-related illness. We could not find any recognised clinical trials that suggest genomics has any link between water damaged buildings and inhalation.

Online Business

Since his retirement from clinical practice in 2013, Shoemaker has been operating a website in partnership with a family which he assisted in the past. Surviving Mold LLC is incorporated in the state of New Mexico and offers:

- Paid membership services to access Richie Shoemaker, submit questions and access special offers,
- Paid resources, such as e-books, presentations and digital media,
- Paid Visual Contrast Sensitivity (VCS) APTitude testing,
- Other various resources supporting his work, which provides information and tools for the public to refer to, and
- Access to become a certified physician in the Shoemaker Protocol.

Once paid and certification has been achieved, these physicians can begin administering services.

History of Chronic Inflammatory Response Syndrome

Upon further research, Shoemaker was investigated and in 2004 received an official warning letter for administering and instructing individuals to self-administer the FDA-approved veterinary product Staphage Lysate (SPL) (Cohen, 2004). To inject a human subject with SPL, was in violation of the Public Health Services Act (Cohen, 2004). According to SPL's manufacturer, Delmont Laboratories, the product was produced to allow dogs to boost their own defences to provide persistent protection against regular canine pyoderma (Delmont Laboratories, n.d). This dangerous precedent of administrating products registered for veterinary use to human subjects shows a lack of due process.

Casewatch (2013) lists further reprimands, with the Maryland Board cautioning him about "maintaining proper alternative medicine protocols" in 2006, and again in 2009, for doctoring Lyme disease over the internet. In 2010, the Board received a complaint, outlining that Shoemaker was imploring individuals to carry out an online diagnostic test, which provided a very broad symptom response (Casewatch, 2013). Furthermore, the complainant claimed they were then diagnosed with a biotoxin illness and urged to visit Shoemaker's office, while additional information promoting Shoemaker's own research to further convince the complainant to attend the private practice and purchase redundant tests (Casewatch, 2013). An additional complaint was issued in 2010, with a former patient criticising Shoemaker's practice (Casewatch, 2013). It was identified that Shoemaker was administrating cholestyramine, a bile acid, which binds acid in the gastrointestinal tract to prevent reabsorption, as a step in his "treatment" of Chronic Inflammatory Response Syndrome (Casewatch, 2013).

An overall review that was conducted, and found re-occurring flaws, such as the off-label use of potentially toxic drugs throughout a number of his cases (Casewatch, 2013). A further example of this was uncovered, when a patient was prescribed Procrit, a glycoprotein that

stimulates red blood production, when it could have been potentially dangerous to the patient and their circumstances (Casewatch, 2013).

In addition to these complaints, more casualties of Shoemaker and his methods have been recognised since coming forward, with one, stating they were given a medical diagnosis over the phone, advised to have their gallbladder removed and take prescription medication, cholestyramine (Rip Off Report, 2014). The client then went on to write that upon contacting the Maryland Attorney General, they discovered Shoemaker "lost his medical license for fraud and other criminal medical acts", and stating "he's not even allowed to practice medicine at all and … he is giving me a medical diagnosis … over the phone … without any medical records or even seeing me" (Rip Off Report, 2014).

Mould Remediation Process

Mould remediation services are not solely based on only the removal of mould. A holistic approach must be carried out to properly remediate a mould-affected property, including implementing systems to ensure the mould will not return once the remediation has taken place.

Mould requires temperatures and a food source to grow, but most importantly it requires a water source to thrive. The water source is the easiest factor to control, and mould remediation specialists should be able to assist with identifying these sources, while also making recommendations to assist in removing the water source. Once the water source(s) have been identified, and all necessary recommendations have been implemented, mould will no longer have the ideal environment that it requires to grow.

Ideal techniques and processes used during mould remediation should include:

- The disposal of water damaged or heavily mould-affected materials that cannot be restored,
- HEPA vacuuming affected surfaces to remove fine particles and loose materials,
- Dehumidification, to remove excess moisture in the indoor environment,
- Wiping of affected materials with mould cleaning solution,
- Lowering particle counts to acceptable levels through air filtration units, and
- Fogging treatments, to make any mould spores non-viable.

The result should be all affected materials being treated, with microbial growth being removed, and having indoor air quality at acceptable levels.

There are various institutions, agencies and organisations that have opinions on how to perform mould remediation, however one of the largest and most referenced is the Institute for Inspection Cleaning and Restoration Certification (IICRC). The IICRC, originally named the International Institute of Carpet and Upholstery Cleaning Inc., has created numerous

publications, which outline procedures for carpet cleaning and installation, cleaning of floor coverings and upholstery, as well as water damage restoration and mould remediation.

The IICRC provides training via its approved instructors and schools, in which participants can partake in a 4-day course, and upon successful completion, can become an Applied Microbial Remediation Technician (ARMT). These certifications are heavily marketed throughout the restoration industry, giving consumers confidence in their restoration of choice. However, due to the lack of governing bodies overseeing mould remediation in Australia, it is possible for any member of the public to attend the IICRC course and be labelled as a mould "expert".

Additionally, the IICRC offers a Mould Remediation Reference Guide, known as the "ANSI/IICRC S520:2015" through an online store. The S520 is a standard of care and is not a best practice or a method/technique, that has consistently shown results superior to those achieved by other means, however it is relied upon and used by, many mould remediators within Australia.

One major flaw of the S520 is the use of containment, once a property has mould growth and elevated air borne mould spore counts the entire property is affected. The S-520 stipulates to contain the room or areas in which visible mould growth is present. By isolating and treating only one section of the property the remainder of the property is left as is, not receiving any remediation. The S520 stipulates the once remediation inside the containment zone is completed the indoor environment professional is brought back in to "verify the containment passes the verification process before being dismantled". (S520-2015 p52) Of course once the containment is dismantled the airborne mould spores from the non-contained area immediately contaminate the area that was remediated.

Conclusion

The ingestion of common dietary items such as corn, grain, coffee, wine, which all contain a degree of mycotoxins, in some cases large, regulated quantities, is deemed to be safe by the FSANZ and FDA. This is one of the most common forms of exposure to mycotoxins. Some of the greatest exposures to microbes can be found in farming environments and in comparison, the exposure to inhaled mycotoxins in a non-occupational setting is insignificant.

Whilst moulds' relationship with asthma, and as an allergen, is scientifically linked there is no peer reviewed literature to link CIRS or inhaled mycotoxin related illnesses from mould spores.

Post Hurricane Katrina, the largest study of the relationship between mould exposure and allergic response, was completed in New Orleans found no relationship between mould, exposure and sensitivity to mould allergens with those people living in damp or mould affected homes.

ERMI has no relevance to Australian homes as it was developed in The United States of America and fails to take in account Australian property types, construction methods, climate, regional location and mould ecology.

The way in which ERMI was developed means all results are indexed to a database of American homes and given a rating based on their percentile rank. In this method Australian homes would be ranked from a data set of 1096 American homes.

The ERMI test is more a measure of the cleanliness of a home and cannot be used to correlate indoor air quality or indicate the cause, location or extent of any current problems.

The developing body, the EPA, has declared that ERMI has not been validated for routine public use in homes, schools or other buildings and that there is the potential for firms to

overstate the implications of the ERMI tool to persuade others to undertake more costly remediation.

CIRS has a wide range of symptoms, and individuals are self-diagnosing after reading the literature based on Richie Shoemaker's website and referrals from his business network, even through there are no supported, peer-reviewed or clinical studies on CIRS.

The Shoemaker protocol guides website visitors through a questionnaire and recommends the completing of a VCS test even though this test is not to be used as a diagnostic tool for any one condition. Shoemakers use of the HERTSMI-2 test is based off the ERMI tool and inherently suffers the same faults and flaws. Not only does he attempt to diagnose a buildings' condition but also the health of his patients through use of this tool.

The practices and procedures that Shoemaker uses are not only scientifically flawed, but also, in this author's opinion, reckless, due to Shoemaker encouraging patients to take off-label medications, which are not registered for the Shoemaker's protocols intended purpose.

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