Notes on the discussion session of the Antimicrobial Hard Surfaces: - The Need for Standards Seminar held on 28 Feb 2012 at BSI

1. ***General Background***

1.1. This seminar was sponsored by the Materials Knowledge Transfer Network (KTN). A KTN is a single over-arching national network in a specific field of technology or business application which brings together people from businesses, universities, research, finance and technology organisations to stimulate innovation through knowledge transfer. Knowledge Transfer Networks (KTNs) have been set up to drive the flow of knowledge within, in and out of specific communities. KTNs have been established and are funded by government, industry and academia. They bring together diverse organisations and provide activities and initiatives that promote the exchange of knowledge and the stimulation of innovation in these communities. The Government sponsors 15 KTNs through the Technology Strategy Board.

1.2. The recent hospital results on the effective usage of antimicrobial hard surfaces (AMHS) would indicate that this practice is resulting in significantly improved patient outcomes.

1.3. The food industry has had interest in this technology for many years and made its first submission to BSI in 1998 – without success.

1.4. Therefore there is a definitive commercial demand for fit for purpose AMHS. The main issue is how are these to be *clearly* specified on any purchase order?

1.5. This question can only be answered by 'drilling down' to results from robust testing protocols. Without validated standards, this will not be possible and many false or non-verifiable claims can and will be made and result in a risk to public health

1.6. Four goals for the meeting were identified by BSi: -

1.6.1. A clear view of the issues involved

1.6.2. How can standards provide a solution?

1.6.3. Not just technical problem/issue solutions need to be addressed, but also an understanding of maintaining the surfaces and who would benefit

1.6.4. A clear cut call to action from the interested community was clearly evident from this well attended (68 delegate event).

2. Cleaning, Longevity and Aesthetic Issues

2.1. It was agreed that this technology needs to be introduced as an additional measure and not one that may replace existing cleaning practices.

2.2. The interaction of existing cleaning materials with AMHS will need to be looked at. Many existing cleaning materials were said to contain complexing

or chelating agents such as EDTA or nitriloacetic acid (NTA). These chelating substances are likely to complex copper and silver ions resulting from some AMHS and reduce their antibacterial properties.

2.3. One delegate stated that chelating agents such as NTA will aid the removal of magnesium ions which stabilise the extracellular lipopolysaccharide of pseudomonads and other Gram-negative bacteria, making then more susceptible to cellular death.
Prof Bill Keevil pointed out that some AMHS technology was intrinsically effective against these microbes without additional chemicals.

2.4. A plea was made to consider developing cleaning materials tailored for use on specific AHMS to enhance their antimicrobial properties.

2.5. The issues of how to deal with very high frequency contact materials such as door handles and low frequency contact materials such as wall coatings was raised.

2.6. Scratches arising from sharp and hard objects such as rings and other jewellery have been shown to allow microbes to persist in the microscopic grooves created on visually clean stainless steel and some other solid surfaces. These could not be removed or killed using conventional disinfectants or disinfectant wipes.

2.7. The issue of how to determine and monitor the longevity of AMHS may need to be addressed but a tier two standard should concentrate on lab based efficacy.

2.8. In principle it was felt that any standard should concentrate on the core issue and reference supporting standards. E.g. are suitable British Standard surface abrasion testing protocols available?

2.9. It is important to fully understand the intended uses of all surfaces.

2.10. It was pointed out that in most hospitals there is very little routine cleaning above head height carried out (partly due to health and safety regulations). This could lead to reservoirs of dust (e.g. shed skin scales harbouring a wide range of potential pathogens. This dust would periodically be disturbed and contaminate the (cleaner) lower surfaces.

2.11. The issue of some consumer dislike of the colour of copper surfaces was raised. It was pointed out that there were many copper alloys with more than 60% copper (See 3.1) and some that looked very similar to stainless steel.

2.12. Many oxidising biocides such as hypochlorite are not suitable for use on many metallic surfaces owing to long-term severe corrosion issues, but this is also the case with stainless steel.

2.13. The University of Salford is currently completing a study on the washing of copperized glass and ceramic surfaces. Results are expected in April/May 2012

2.14. It was pointed out that in the food industry pH values of 1 to 11 could be encountered and relevant AMHS would need to be able to accommodate this

3. Production of Standards Issue

3.1. After testing developed by the US EPA regulatory authorities they have accepted that any alloy surface containing more than 60% copper could be specified as an antimicrobial surface EPA public health registration now covers over 350 alloys.

3.2. It was generally agreed that British Standards would be needed to cover all types of AHMS not just copper and silver containing surfaces. Standards would be needed to cover antimicrobial properties including the use of soiled 'worst-case' surfaces

3.3. Also subsequent standards may be needed for Residual Self-Sanitizing Activity and Continuous Reduction of Bacterial Contamination as per the US EPA public health registration scheme to address 3.2

3.4. Other British Standards would be needed for soft, absorbent and fabric surfaces and is not the subject of this workshop

3.5. A plea was made to try and initially develop simple protocols that would be robust and would give consistent results across a wide range of testing laboratories. It was pointed out that microbial tests were empirical and the final result was dependent upon the protocol used. (Unlike a typical total chemical analysis such as total lead or cadmium where the result should be independent of the analysis technique used e.g. ICP-OES; ICP-MS or FAAS etc.)

3.6. Concerns were raised that if any proposed standard demanded that a wide range of species and temperatures had to be used then it was felt that the high cost of testing might inhibit take up. Initially a 'worst case' approach should be adopted. This could include applying an organic load on the surface to be tested which will offer some protection to the bacteria.

3.7. It was pointed out that once an initial robust standard was successfully validated and experience gained, then more vigorous and elaborate standards could be developed. One should walk before attempting to run.

3.8. The issue of finding the necessary funding for the validation trials necessary for any standards produced was raised

3.9. The end users of any standard will need assurances that their expectations can be met.

3.10. The maximum measurable log drop needs to be agreed for the method. It was pointed out that high inocula could result in aggregation and biased results

3.11. A member of CH/216 British Standards (BS) Committee: CH/216 Chemical disinfectants and antiseptics indicated that CH/216 was prepared to consider adopting this work.

It was pointed out that the first of a number of approaches to CH/216 on this issue of developing AMHS standards was back in 1998. No progress has been made to date despite a number of determined efforts from the solid surfaces community since 1998.

3.12. Consequently, it is felt that a new BS committee or at the very least a separate sub-group of CH/216 is urgently required with a significant proportion of the membership having experience of AMHS testing

3.13. The ISO/CEN route was rejected as it is likely to take a very long time to reach any consensus

4. Existing Standards

4.1. The existing ISO and ASTM standards are not considered to be fit for purpose *These include: -*
ASTM E 2149-01 Standard test method for determining the antimicrobial activity of immobilized antimicrobial agents under dynamic contact conditions.

JIS Z 2801:2000 Antimicrobial products—Test for antimicrobial activity and efficacy. (Japanese Standards Association, 2000) ISO 22196 was then developed. It is modelled on JIS Z 2801, and the two methods are essentially the same.

ISO 22196:2007 Plastics—Measurement of antibacterial activity on plastic surfaces.
For this test the control and test surfaces are inoculated with microorganisms, in triplicate, and then the microbial inoculum is covered with a thin, sterile film. Covering the inoculum spreads it, prevents it from evaporating, and ensures close contact with the antimicrobial surface under wet 'best case' conditions at an unrepresentative incubation temperature of 35^{o}C.

ISO 20473:2007 Textiles – Determination of antibacterial activity antibacterial finished products

4.2. It was reported that using the ISO 22196 test, silver ion releasing material exhibited >5 log reduction in MRSA viability after 24 h at >90% relative humidity (RH) at 20^{o}C and 35^{o}C but, in the absence of the protective film, only a <0.3 log at ~22% RH and 20^{o}C and no reduction at ~22% RH and 35^{o}C. Copper alloys demonstrated >5 log reductions under all test conditions. Adequate response at lower temperature and humidity levels typical of indoor environments is considered a key requirement.

5. The Way Forward?

5.1. All event slides to be put on the Materials KTN website subject to Presenters' consent

5.2. It was agreed to immediately set up an *'AMHS group website'* on the Materials KTN website which would be open to all interested individuals to comment. This blog site would run to the end of March 2012, then a Webinar would be arranged to discuss and agree a way forward with deadlines and a target challenge

5.3. Then run another full meeting in 12 -14 months at BSI to report progress

5.4. It was also agreed to consider running another workshop of interested parties to discuss the scope of any PAS or BS proposed standard.

5.5. The PAS versus BS options were briefly discussed. A PAS is likely to cost £50K and should allow a first PAS to be produced within 12-18 months. This would require adequate consensus; the necessary ~ £50K funding for this and also funding (~£20K) for validation trials involving a sufficient number of labs (~ 5) could be found from interested parties.

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