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Response to J-Y. Maillard: Are amine-only-containing products sporicidal?

Sir,

J-Y. Maillard made a very important point in reflecting that, during efficacy testing of disinfectants, demonstration of neutralization of the biocidal effect at the end of contact time is crucial. We also agree that ‘it is thus puzzling and possibly concerning that products containing amines alone are being used as sporicides in healthcare settings’ [1].

As referenced by Maillard, resistance of bacterial spores is intrinsic and is based on structural properties, such as the core protecting the bacterial spore from chemical or physical damage [1]. In this context, Steward points to the specific differences of the exosporium layer in different spore-forming bacteria [2]. In general, bacteria of the phylum Firmicutes use spore formation as a survival mechanism to persist in the environment even under unfavourable conditions. Phylogenetically, the phylum Firmicutes includes aerobic bacterial species, such as Bacillus spp., as well as anaerobic species such as Clostridium spp. Whereas an exosporium layer has been clearly identified for Bacillus cereus and Bacillus anthracis, it is lacking in Bacillus subtilis. Regarding the anaerobic spore-forming bacterium Clostridium difficile, no clear evidence for an exosporium layer was found by Stewart and the existence of a crust layer was hypothesized [2].

Thus, when discussing sporicidal efficacy in the healthcare setting it becomes clear that differentiation regarding aetiology, clinical prevalence, and morphological characteristics needs to be considered. Only a few reports for B. cereus, and no reported outbreak in the clinical setting have been found in the literature for the aerobic spore-forming bacterium B. subtilis, indicating the inferior role of aerobic spore-forming bacteria in the healthcare setting [3–5]. However, numerous reports of C. difficile outbreaks exist, and C. difficile is regarded as a well-established pathogen worldwide [6]. Thus, there is a need to provide the healthcare setting with sporicides that have been tested under reliable and robust test conditions, specifically targeting C. difficile as the most important pathogen in the clinical environment.

Reflecting the need of hygienic prevention measures to fight spore-forming C. difficile, we wish to point out that just recently a European standard for sporicidal testing of disinfectants in the healthcare area has been proposed by the European standards committee CEN/TC 216 working group 1 as a prEN and will be published in autumn 2018 as EN 17126 [7]. This standard is perfectly in line with the author’s view ‘that a sporicide should kill $10^3$ to $10^6$ spores’; the pass criterion for this standard is a 4 log$_{10}$ reduction in spores of C. difficile. In addition, a strain of particular clinical relevance (ribotype 027) has been chosen as a test organism of this standard. This strain has been demonstrated to be less susceptible to disinfectants, when compared to other type strains of this species [8].

Reflecting the state of the art, prevention measures in the clinical setting should therefore include disinfectants with a proven efficacy against C. difficile spores according to the proposed standard.

We would like to encourage the author and all interested and other knowledgeable experts to join the standards committee and contribute to the further development of an appropriate state of the art.

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