Letter to the Editor

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.

Conflict of interest statement
None declared.

Funding sources
None.

References

[1] Maillard JY. Are amine-only-containing products sporicidal? J Hosp Infect 2018;99:115—6.
[2] Steward GC. The exosporium layer of bacterial spores: a connection to the environment and the infected host. Microbiol Mol Biol Rev 2015;79:437—57.
[3] Bottone EJ. *Bacillus cereus*, a volatile human pathogen. Clin Microbiol Rev 2010;23:382—98.
[4] Centers for Disease Control and Infection Prevention. Notes from the field: contamination of alcohol prep pads with *Bacillus cereus* group and *Bacillus* species — Colorado 2010. Morb Mortal Wkly Rep 2011;60:347.
[5] Ihde DC, Armstrong D. Clinical spectrum of infection due to *Bacillus* species. Am J Med 1973;55:839—45.
[6] Burke KE, Lamon JT. *Clostridium difficile* infection: a world-wide disease. Gut Liver 2014;8:1.
[7] prEN 17126. Chemical disinfectants and antiseptics — quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area — test method and requirements (phase 2, step 1). CEN/TC 216. France: AFNOR; 2017.
[8] Büttgen S, Gebel J, von Rheinbaben F, Hornei B, Engelhart S, Exner M. Efficacy of surface and instrument disinfectants with sporicidal claims against spores of *Clostridium difficile* ribotype 027. Hyg Med 2008;33:194—200.

S. Gemein[a]
B. Meyer[b]
J. Gebel[a]
C. Roques[c]
K. Steinhauer[d,*],
On behalf of CEN TC 216, WG1
[a]*Institute for Hygiene and Public Health, University Clinics, Bonn, Germany*
[b]*Ecolab Deutschland GmbH, Monheim am Rhein, Germany*
[c]*Université Paul Sabatier and CHU Purpan, Toulouse, France*
[d]*Schülke & Mayr GmbH, Research & Regulatory Affairs, Norderstedt, Germany*

* Corresponding author. Address: Schuelke & Mayr GmbH, Research & Development, Robert-Koch-Str. 2, Norderstedt, D-22851, Germany. Tel.: +49 40 52100557.
E-mail address: katrin.steinhauer@schuelke.com (K. Steinhauer)