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August 13, 2021

Brie Welzer
Director, Science & Standards Development
Green Seal

Dear Ms. Welzer,

I write on behalf of the American Cleaning Institute[1] (ACI) Microbial Cleaning Products Task Force to Green Seal, to provide comment on Green Seal's Proposed Revisions to Criteria for Microbial-Based Cleaning Products. ACI is an industry leader in serving the cleaning products industry; advancing the health and quality of life of people and protecting our planet. We focus on the advancement, promotion, and utilization of science to drive informed dialogue and decision making. We are pleased to have the opportunity to provide comment to the proposed revisions to Green Seal Standards GS-8, GS-37, GS-48, GS-51, GS-52, and GS-53, as relevant.

Below are Green Seal's proposed revisions regarding microbial based cleaning products in spray packaging:

July 2021 Update: Products sold in or designed for use in spray packaging must meet at least one of three requirements:
(1) Include precautionary statements on the product label
(2) Formulate only with microbes listed on the European Food Safety Authority's Qualified Presumption of Safety list
(3) Undergo inhalation exposure testing and meet a maximum threshold of airborne microbes.

Additional Requirements for Products in Spray Packaging. For products formulated with microorganisms and designed for use in, or sold in, spray packaging, at least one of the following requirements must be met:

- The microbial ingredients in the product shall be restricted to those included in the European Food Safety Authority's (EFSA) Qualitied Presumption of Safety (QPS) List.
- The product label shall state the following precautionary statements*
    - Product should not be sprayed into the air.

[1] The American Cleaning Institute® (ACI – www.cleaninginstitute.org) is the Home of the U.S. Cleaning Products Industry® and its members include the manufacturers and formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and chemical distributors.

    - Avoid inhalation of the product.
    - Repeated and prolonged exposure may cause sensitization of the respiratory system.
- The product shall demonstrate, via inhalation exposure testing, an airborne concentration of microbes at or below 1 x 10^4 CFU/m3. Testing parameters shall be in alignment the A.I.S.E. spray protocol (2020) [2].

* Or other substantially similar terms and phrases, as approved by Green Seal

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ACI offers the following response on Green Seal's proposed revision to criteria for microbial based cleaning products (July 21, 2021 update):

Option one (1) of the proposed requirements indicates inclusion of precautionary statements on the product label as a single option. A recommended statement would be to more specifically emphasize that the "*Product is intended for use on surfaces and should not be sprayed into the air*." ACI recommends that the precautionary labeling requirements remain as they stand in currently adopted version of the Standards, as eight (8) required options. Precautionary labeling is likely not sufficient to protect consumers from exposure, while the other options outlined will be more likely to provide consumer protections.

It was indicated by Green Seal in response to ACI's previous comments, that in their literature search no sources were identified that indicated instances of negative health effects associated with application of microbial based cleaning products. Based on this literature evaluation Green Seal determined that consideration of respiratory health hazards in immunocompromised individuals is not warranted [in summary]. ACI highly recommends cautioning against that approach and recommends a thorough review of the following references which do indicate the potential for negative health effects.

- https://doi.org/10.2903/sp.efsa.2010.EN-75

- https://doi.org/10.1080/17476348.2018.1473036

- https://doi.org/10.1186/1471-2180-10-233

[2] Safety assessment of the use of Bacillus-based cleaning products: https://www.sciencedirect.com/science/article/abs/pii/S0278691517306968

ACI emphasizes that the consideration of sensitive populations (e.g. immunocompromised individuals) is essential as it concerns product application and safety.

ACI still strongly supports the comments made on April 26, 2021 regarding recommendations to determine hazardous properties and risk factors of spray cleaning with viable microorganisms. In addition, consideration of quality control processes to identify contaminants should be included in the Standards. Many of these recommendations were also supported by the Panel on Microbial Ecology of the Norwegian Scientific Committee for Food and Environment report (VKM) provided as reference by Green Seal during the previous revision comment period. (https://www.vkm.no/english/riskassessments/allpublications/healthandenvironmentalassessmentofmicrobialbasedcleaningproducts.4.1aaadf0516963f003a25dde5.html)

Item two (2) of the proposed revision suggests *formulating products only with microbes listed on the European Food Safety Authority's Qualified Presumption of Safety list*. ACI recommends that any organisms not within this list be demonstrated to also minimally meet the same strain safety evaluation and requirements as those organisms listed in the QPS. Further, note that the EFSA evaluation is likely to pertain to primarily ingestion and would not necessarily evaluate inhalation hazards. A thorough review and evaluation of strain characteristics as per VKM guidance could be an alternative approach to demonstrate safety, in addition to an appropriate and robust exposure-based approach to assess safety for the specific use application.

Item three (3) of the proposed revision indicates *products should undergo inhalation exposure testing and meet a maximum threshold of airborne microbes*. ACI recommends that Green Seal continues to identify additional sources to support the limit of 1 x 10^4 CFU/m^3. In a literature review, a reference was identified in a 1989 Dutch provisional recommendation. The Dutch Health Council ultimately stated that an exposure level cannot be established for microorganisms. In addition, the original Dutch provisional recommendation limit of 1 x 10^4 CFU/m^3 was for a combination of environmental organisms (bacteria, fungi) and limited single microorganism type at 500 CFU/m^3. There are other references that indicate potentially appropriate ranges and ACI recommends that Green Seal considers additionally reviewing these sources before settling on a proposed limit; links to such sources are listed below. These references are for workplace exposures and additional consideration may be needed in applying to consumer exposure.

Fungal spores: a critical review of the toxicological and epidemiological evidence as a basis for occupational exposure limit setting - PubMed (nih.gov)

Guide on respiratory protection against bioaerosols (irsst.qc.ca)

Bioaerosols and OSH - OSHWiki

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ACI encourages Green Seal to continue their efforts to identify testing laboratories by specifically holding a call for comment to industry for labs capable of conducting these proposed risk assessments (in addition to capabilities of airborne microbial sampling). This product category requires much consideration in assurance of product integrity, application, and safety. We look forward to the opportunity for continued communication regarding this product category.

ACI thanks you for consideration of our input during this public comment period. We are happy to provide more clarity or input on any additional questions you may have as you revise your standards. Please contact me at aqueen@cleaninginstitute.org or 202.441.0617 if I can be of further assistance.

Best regards,

Ashley Queen, Ph.D.
Director, Microbiology and Public Health