Microbial consortia

IBMA members survey

BPWG, Brussels, 10-11 June 2024





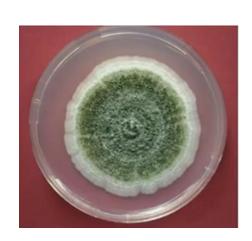
Introduction



- ☐ From 17/05/2024 to 30/05/2024, IBMA conducted a survey to applicants on the intentions to register Microbial Consortia in the EU. The survey was performed following a request of DG SANTE to better understand to what extent IBMA members support the idea of approving microorganisms as consortia, rather than combining different microorganisms at the PPP level after the individual microorganisms are approved.
- ☐ The aim of the survey was to assess the planned/ongoing applications of a microbial consortium for approval
- ☐ A total of 30 participants filled out the survey of 6 questions

Microbial Biocontrol Agents - IBMA's definition

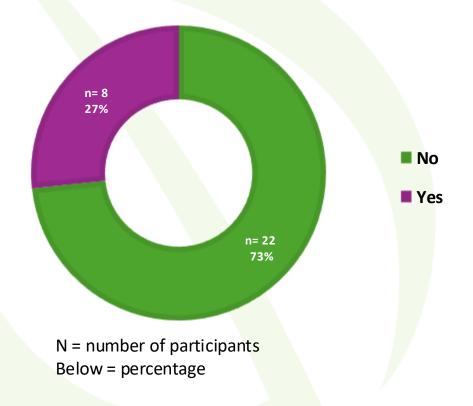
Microbials are based on microorganisms, including but not limited to bacteria, fungi, protozoans, viruses, viroids, mycoplasmas, and may include entire microorganisms, living and dead cells, any associated microbial metabolites, fermentation materials and cell fragments.



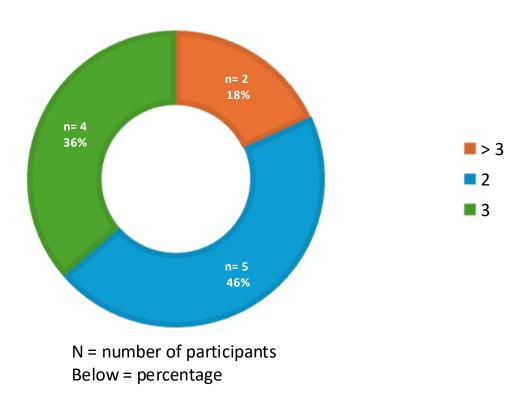
Microbial consortium for approval



Is your company working on preparing a microbial consortium for approval?



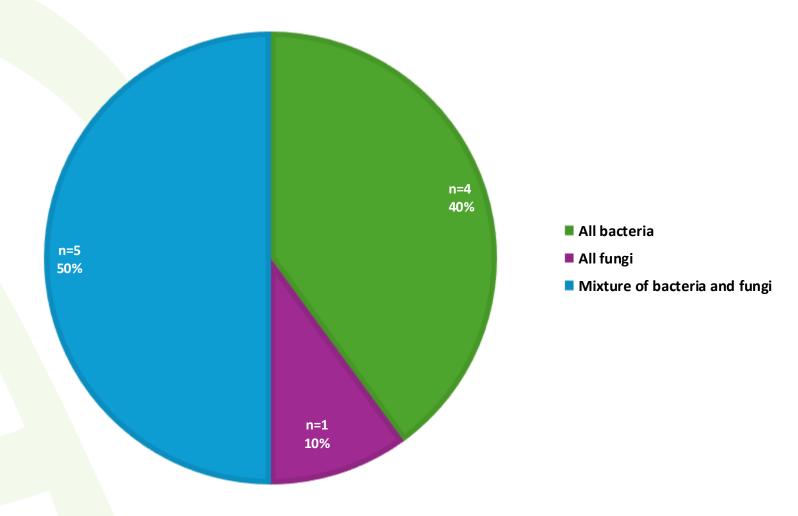
What is the size of the consortium (e.g., 3 microorganisms in the same consortium)?



Types of organisms



What type(s) of microorganisms are in the same consortium?



Provisional dossier's submission date



 8 participants are currently working on preparing a microbial consortium for EU and have provided information on the provisional submission date.

1 participant is not working on a microbial consortium yet, but has a consortium in preparation, that will be likely registered in other



Conclusions



Regarding the submission process, the participants highlighted:
☐ The complexity of existing regulation and high costs;
☐ One respondent mentioned that it is not accelerating or heavily investing in the registration of a consortium due to the complexity of the process, leading to delays for dossier submission
☐ The term "consortium" should be better defined: blend of diverse species (bacteria and/or fungi) or blend of diverse strains from a single species. Mixture of several microorganisms cultured separately, or microorganisms produced in co-culture?
☐ High uncertainty level on the outcome of the EU assessments could mean one member of the consortium could prevent the placing on the market of the final product (e.g. during a renewal process)

Thank you

Microbial Consortia



