

## PRESS RELEASE

# Amoeba: Malta recommends the non-approval of the "biocide" active substance for the European territory

**Lyon (France), May 3<sup>rd</sup>, 2022 - 17h45 - AMOÉBA (FR0011051598 - ALMIB)**, producer of a biological biocide capable of eliminating bacterial risk in water and human wounds, and of a biocontrol product for plant protection, still in development phase, announces that the MCCA (Malta Competition and Consumer Affairs Authority), the competent authority of the reporting Member State (Malta) evaluating the application for approval of the biocidal active substance "*Willaertia magna* C2c Maky", recommends its non-approval for a biocidal use in cooling towers in Europe.

On the basis of the application for approval of the biocidal active substance "*Willaertia magna* C2c Maky", the Maltese authority concluded in its draft report that the active substance is not likely to fulfill the approval criteria, considering that the innate efficacy was not sufficiently demonstrated and that a Trojan horse effect cannot be excluded under realistic conditions of application and use.

Malta therefore recommends to the other EU Member States and to the European Chemicals Agency (ECHA) that the substance should not be approved and therefore not included in the list of authorized biocidal active substances.

The Maltese draft assessment report will now be discussed at the European level between Member States under the aegis of ECHA, before a decision by the European Commission in mid-2023.

*"The Trojan Horse effect is purely hypothetical and has never been characterized as a danger. Regarding the efficacy, European regulations require at the stage of the active substance approval to demonstrate the capacity of the substance to produce a sufficient effect on a relevant target organism: the studies conducted by Amoeba have largely shown this ability of Willaertia magna C2c Maky against legionella. Again, the evaluators question the methodology of our studies while the biocidal standards are exclusively developed for chemicals and do not exist for microorganisms, creating a barrier to access the biocidal market for this type of natural substance. The recommendation of non-approval by Malta is hence an outcome tinged with misunderstanding."*, declares Jean-Baptiste EBERST, Regulatory Director at Amoéba.

*"At the dawn of the greatest environmental and health challenges, the unfavorable decision of the Maltese authority causes disappointment and dismay to Amoeba and its teams. This conclusion goes against the objectives of the European Commission, which has just published its roadmap on the restriction of harmful chemicals. Nevertheless, **we have just secured Amoéba on a more than €12 billion market** thanks to the positive recommendation on biocontrol, which is a major step forward for a Greentech. Our plant in Chassieu, already 100% dedicated to biocontrol, will provide us with biocontrol active substance for the years to come. We are also convinced by the strong potential of the amoeba and are pursuing our development and research in other application areas."* states Fabrice Plasson, CEO of Amoéba.

## Pending application for authorization of its biocide in the United States and Canada

Amoéba reminds that the application for approval of the biocidal active substance, the living amoeba *Willarta magna* C2c Maky, and biocidal products containing it, filed in April 2021 with the U.S. Environmental Protection Agency (U.S. EPA), is still under review. The conclusions are expected by mid-2022.

In Canada, the application for registration of the active substance and biocidal products containing it, submitted in 2019, is under evaluation. The decision of the Canadian agency could be communicated in 2022.

## Continued development of the biocontrol application

At the same time, Amoéba continues to develop its biocontrol application, especially through collaborations with its partners and other major players in the plant protection sector through new field trial campaigns.

In Europe, the Austrian authority has recommended in April 2022 the approval of the biocontrol active substance.

In the United States, the application for approval of the active substance and products containing it, also submitted in 2020, is being evaluated.

Finally, in Brazil, an experimental permit was obtained in February 2021, allowing the Company to initiate field trials on soybean, coffee and banana. Such trials in Brazil are required for an application for approval.

### **About Amoéba :**

Amoéba's ambition is to become the world leader in the treatment of bacterial risk in the fields of water, healthcare and plant protection. Our biological solution is an alternative to chemical products widely used today. Amoéba is currently focusing on the market of industrial cooling towers estimated at €1.7Bn (1) on a global chemical biocide market for water treatment, evaluated at €21Bn (2) and on the biocontrol market for plant protection estimated globally at €1.6Bn (3). In the future, the Company is looking at developing new applications such as chronic wound care, estimated at € 751 million (4) in the USA. Sales of associated products with healthcare, biocides and crop protection are subject to the Company being granted local regulatory market authorizations. The company is currently in the testing phase for biocidal and phytosanitary applications and does not market any products.

Created in 2010, based in Chassieu (Lyon, France) with a subsidiary in Canada and in the United States, Amoéba is quoted on the compartment C of Euronext Paris. The Company is a member of the BPIfrance Excellence network and is eligible for the PEA-PME SME equity savings plan setup. More information on [www.amoeba-nature.com](http://www.amoeba-nature.com).

(1): Amoéba data combined from sources: DRIRE 2013, Eurostat, ARHIA 2013

(2): Sources combined by Amoéba from water treaters, Freedomia, Eurostat et MarketsandMarkets

(3): Biopesticides Worldwide Market 2013, CPL, Wallingford, UK

(4): BCC Research, "Markets for Advanced Wound Management Technologies," Wellesley, MA, 2017

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