

Amoéba: Austria recommends the approval of the biocontrol active substance for the European territory

Lyon (France), April 25th, 2022 -5.45 pm - AMOEBA (FR0011051598 - AMEBA), 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 the testing phase, announces that AGES (Agentur für Gesundheit und Ernährungssicherheit¹) the competent authority of the Rapporteur Member State (Austria) in charge of the application for approval of the biocontrol active substance "Lysate of *Willaertia magna* C2c Maky", recommends its approval for use in plant protection on the European territory.

In its draft assessment report, AGES concludes that the active substance is expected to fulfill the approval criteria, confirming the efficacy of the active substance and its absence of harmful effects on human health and the environment when used in accordance with good plant protection practices and under realistic conditions of use.

Based on this conclusion, Austria recommends to the other EU Member States and to the European Food Safety Agency (EFSA) the approval of this active substance and its inclusion on the list of approved phytopharmaceutical active substances.

In its draft assessment report, Austria also recommends:

- that the active substance " Lysate of *Willaertia magna* C2c Maky " should be classified as a low-risk substance. This classification allows, in particular, an accelerated evaluation of the products containing the active substance (according to the regulations, 120 days instead of 365 days) and a longer period of authorization of the active substance before renewal (15 years instead of 10 years).
- that the establishment of a maximum residue level² for "Lysate of *Willaertia magna* C2c Maky" should not be required, based on the non-toxicological profile of the substance.

At this stage, the recommendation for approval is not subject to any restriction.

The major steps to come before the commercialization of products containing the biocontrol active substance "Lysate of *Willaertia magna* C2c Maky" on the European territory are as follows:

1.	Peer review (EU Member States and EFSA) of Austria's draft report and submission of the conclusions to the European Commission	Q2-2022 – Q1-2023
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¹ Agency for Health and Food Safety - Austria

² MRL, regulatory threshold of pesticide residue concentration, beyond which the marketing of a food product is no longer authorized

2.	Publication of the review report by the European Commission and implementing regulation on the decision of the European Commission	Q3-2023
3.	Decisions for the authorizations of products containing the active substance "Lysate of <i>Willaertia magna</i> C2c Maky" by targeted Member States	2024

"The recommendation of approval by Austria is a major step for Amoéba, leading to the future commercialization of our biocontrol products. The positive recommendation confirms both the performance of our substance, the expertise of our teams and the quality of the partners we are working with on this application. The fluent evaluation also shows the importance of the communication between the authority and the applicant, before the submission and during the evaluation, which the Austrian authority has greatly facilitated", says Jean-Baptiste EBERST, Regulatory Director at Amoéba.

"The positive decision of Austria for the use of the active substance Willaertia magna C2c Maky in biocontrol application is a major success for Amoéba, and rewards the unfailing dedication of our teams. This positive conclusion sets the stage for great opportunities and strongly encourages us to explore the full potential of this substance in different fields of application. With this first success, we are looking forward to the decision of Malta regarding the use of the substance in biocidal application with optimism." declares Fabrice PLASSON, CEO of Amoéba.

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.

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

(2): Sources combined by Amoéba from water treaters, Freedonia, 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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