

AMOÉBA HAS FILED THE APPLICATION FOR APPROVAL OF ITS BIOCONTROL SOLUTION IN EUROPE

Chassieu (France), May 29, 2020 - AMOÉBA (FR0011051598 - AMEBA), producer of a biological biocide, capable of eliminating bacterial risk in water and human wounds, and a biocontrol product for plant protection, still in the testing phase, informs that the application for approval of the biocontrol active substance '*Willaertia magna* C2c Maky lysate' was submitted on may 28 2020 to the Austrian competent authority AGES (Agentur für Gesundheit und Ernährungssicherheit, Agency for Health and Food Safety) . The biocontrol solution, developed by Amoéba, is intended for a fungicidal use in agriculture.

A file that meets regulatory requirements

This application for approval is the result of three years of work by Amoéba's teams, which, between 2018 and 2020 and with the support of independent laboratories, carried out all the required regulatory studies.

These studies included the assessment of :

- 1) the efficacy of the active substance "*Willaertia magna* C2c Maky lysate" in crop protection,
- 2) its level of toxicity to humans,
- 3) its fate and behaviour in the environment,
- 4) its possible harmfulness to non-target organisms such as bees, earthworms, fish or terrestrial and aquatic arthropods.

The results of all these studies, carried out in accordance with Good Experimental and Laboratory Practices, have shown on the one hand a significant efficacy of the active substance and on the other hand an absence of hazard for humans and the environment. These characteristics, which will have to be validated by the European Commission, could allow Amoeba's biocontrol solution, once approved, to be classified as a "low risk" active substance.

One of the most active agencies in Europe for plant protection products

The Austrian competent authority, AGES (Agentur für Gesundheit und Ernährungssicherheit, Agency for Health and Food Safety), that will assess the dossier, is among the most active authorities in terms of risk assessment of plant protection active substances. Austria is one of the four EU Member States which have reviewed the largest number of plant protection active substances over the last 20 years¹.

¹ Ranking of Member States in terms of number of active substances reviewed and approved: Italy (56); Netherlands (51); France (46); Austria (40); Sweden (35); Greece (30); Germany (26); Spain (23); 16 others (130). Source : <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>, (14 may 2020).



A possible approval mid-2023

The dossier submission is in line with Amoéba time schedule. The approval procedure that is starting will take between 2.5 and 3.5 years, with an expected decision in 2023.

The main steps are as follows:

- **Evaluation phase by the rapporteur Member State** (*approximately 14 months*): at the end of which the draft report is submitted to the European Food Safety Authority (EFSA).
- **Risk assessment phase** (*7 to 11 months*): EFSA carries out the risk assessment and risk communication on food safety aspects and then organises a consultation with experts and publishes a scientific report containing its conclusions.
- **Risk management phase** (*9 to 12 months*): the European Commission presents a draft regulation to the Standing Committee on the Food Chain and Animal Health, which ultimately votes on the approval or non-approval of the active substance. In general, an active substance is approved for a period of 10 years, or even 15 years if it is classified as "low risk".

These timeframes could be reduced depending on the deployment of the "Farm to Fork Strategy" strategy of the European Commission (published on May 20th, 2020²) who "*will also facilitate the placing on the market of pesticides containing biological active substances and [...] will act to reduce the length of the pesticide authorisation process by Member States*".

A test and pre-marketing phase already under way with eight partners

The regulatory timetable could lead to a marketing authorisation for products containing the active substance in 2024. However, in view of the positive results of the tests carried out over the past two years, Amoéba has signed research partnerships, which may lead to pre-marketing agreements, with eight recognized players in the crop treatment field (BASF, Syngenta, Bayer, Philagro Nichino, De Sangosse, Stähler Switzerland, Evergreen Garden Care and Certis Europe). Through this unprecedented number of agreements, Amoéba's active substance is supplied to the partners to be tested against different pathogens affecting many types of crops.

The data from these tests will complement the regulatory data to support the products registration and achieve optimal use of the amoeba lysate in all intended applications.

"From the first laboratory results obtained in 2017 on the efficacy of our amoeba lysate against downy mildew, we realized the true potential of our discovery in biocontrol applications. We then set ourselves an ambitious schedule with the specific goal of submitting our application for approval of the biocontrol active substance within 3 years. The submission was made in line with our expectations and in accordance with the deadlines agreed with the competent authority AGES. In parallel with the regulatory process, Amoéba will continue its new phase of technical evaluation of the amoeba lysate in 2020, on 3 continents and in 11 countries, representing a total of more than 145 tests, including 75 for the company. This strategy is in line with the European Green Pact's desire to reduce the use of plant protection products in order to provide the agricultural world with new, healthy solutions with proven efficacy," explains Fabrice PLASSON, Chairman and CEO of Amoéba.

² <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020DC0381&from=EN>



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About AMOEBA:

Amoéba's ambition is to become a major player 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 ⁽⁴⁾. In the future, the Company is looking at developing new applications such as chronic wound care, estimated at € 751 million ⁽³⁾ 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 a trial phase for biocidal and plant protection 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-biocide.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): BCC Research, "Markets for Advanced Wound Management Technologies," Wellesley, MA, 2017

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

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