PRESS RELEASE

AMOEBA announces the submission in Europe of a new application for approval of its biocidal active substance

Lyon (France), August 12th, 2019 - AMOEBA (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 trial phase, announces that a new application for approval of its biocidal active substance *Willaertia magna C2c Maky* has been submitted to the European Chemical Agency (ECHA). The first phase of the evaluation will be carried out by the Malta Competition and Consumer Affairs Authority (MCCAA).

As a reminder (see Press Release dated 25 February 2019), the Maltese authority has agreed to act as evaluating competent authority for this new application for approval. The active substance that has now entered the evaluation process is Willaertia magna C2c Maky amoeba in its living form, intended for use in cooling towers for the prevention of legionella growth (Product Type 11 - Preservatives for liquid-cooling and processing systems) and the control of the (Product Type 12 - Slimicides).

A pre-submission meeting was held in April 2019 between the MCCAA, its non-governmental experts based in the Netherlands and Amoéba. The purpose of this pre-submission meeting prior to the submission of the application was to discuss the technology and intended use of the biocide, validate the data required for this new submission and agree on the submission date and the various stages of the evaluation.

The MCCAA confirmed to be in favour of consulting the European Chemicals Agency (ECHA) to ensure a harmonised view at European level on the type and level of data required, and in particular concerning the non sufficiently demonstrated efficacy and the hypothetical risk associated with a 'Trojan horse' effect that justified the non-approval at the time of the initial application (see Press Release dated 5 June 2018). This consultation should take place in the coming months.

Considering the 18-month evaluation period set by Regulation (EU) 528/2012, Amoéba considers that the Maltese authority's evaluation report could be available in the second quarter of 2021.

Provided that the competent authority of Malta submits in its assessment report a recommendation for the approval of the new active substance, Amoéba may submit an application for provisional authorisations for biocidal products containing the active substance Willaertia magna C2c Maky, either to the competent authority of Malta and other targeted Member States (national procedure and mutual recognition) or to ECHA (Union authorisation procedure). Provided that these authorities, on the basis of the Maltese authority's assessment report, expect the biocidal product to be sufficiently effective and not to have an immediate or delayed unacceptable effect on human health, animal health or the environment, Amoéba could then consider a provisional marketing authorisation in the designated territories in the first half of 2022.

Reminder of the procedure for registering a biocidal product in Europe:

The marketing of a biocidal product on the territory of the European Economic Area is subject to prior marketing authorisation.

The pre-market assessment of biocidal products and their active substances is regulated and harmonised at European level by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products. The evaluation in Europe is divided into two stages: evaluation of the active substance at European level and evaluation of the end-use products (products) carried out either at European or Member State level, depending on the procedure chosen by the applicant.

- Approval of the active substance

A biocidal product generally contains more than one component. The ingredient active against harmful organisms is called an "active substance". The European Commission assesses the safety of each active substance before it is placed on the market. It must be proven that the substance is safe for human health, animal health and the environment.
The assessment is based on an application dossier, which includes physico-chemical data on the substance, its toxicity, ecotoxicity, behaviour and fate in the environment. The dossier shall also contain efficacy data using a representative product containing the active substance. Once the file has been compiled, the applicant submits his application to an EU country called the evaluating competent authority, which will have previously agreed to assess the application.

The procedure for the approval of an active substance is as follows:

1) *Evaluation phase by the evaluating authority:* The authority verifies the completeness of the file, carries out the evaluation and prepares a first draft competent authority report. This step lasts about 14 months, except for a possible clock suspension of 6 months if additional information is requested. The evaluating authority shall forward its draft assessment report to the European Chemicals Agency (ECHA), the applicant and the other Member States.

2) *Peer review phase* : ECHA organises an expert consultation (peer review) for a period of at least 9 months, including Member States and ECHA. This collective review includes a review of the dossier and discussions in ECHA Working Groups, bringing together experts from different Member States and ECHA. At the end of the collective review, ECHA's Biocidal Products Committee (BPC) publishes its opinion on the approval of the biocidal active substance. On the basis of this opinion of the BPC, the European Commission submits a draft regulation to the Standing Committee on Biocidal Products, which votes on the approval (subject, if necessary, to conditions and restrictions) or non-approval of the active substance by a qualified majority (55% of the Member States, representing at least 65% of the population). The approval of an active substance implies that it is eligible for use in a biocidal product on EU territory. The decision is ultimately adopted by the European Commission, which publishes the implementing decision in the Official Journal of the EU. If the active substance is authorised, it is included in the Annex to Regulation (EU) 540/2011, the European list of approved active substances. An active substance is initially approved for a maximum period of 10 years.

Under EU rules, there is a timeline of 2 to 2.5 years between the date of admissibility of the application and the publication of a regulation approving a new active substance. This time frame varies greatly depending on the complexity of the case.

- Approval of the biocidal product (commercial preparation)

The biocidal product is the form in which the preparation is provided to the user and which contains at least one approved biocidal active substance (see previous chapter) and co-formulants. Before a biocidal product can be placed on the market or used, it must be authorised in the concerned EU country(ies). The same Regulation (EU) No 528/2012 lays down the rules and procedures for the authorisation of biocidal products.

The basic procedure for the authorisation of a biocidal product containing an approved new active substance is as follows, at the choice of the applicant:

- either by national mutual recognition procedure: the application for authorisation of the biocidal product shall be submitted to a reference Member State, which shall carry out the evaluation. Once the product has been approved in that Member State, the other designated Member States (concerned) shall recognise the assessment of the reference Member State and approve the placing on the market of the product in their territory.
- or by Union authorisation procedure: the application for authorisation of the biocidal product is submitted to the European Chemicals Agency (ECHA). The evaluation is delegated to one of the Member States. The approval is made by ECHA and the authorisation is valid for all EEA Member States.

Without waiting for official approval of the new biocidal active substance, the applicant may nevertheless apply for a provisional authorisation to place the biocidal product containing the new active substance on the market:

- if, as part of the approval procedure for a new active substance, the evaluating authority submits in its assessment report (prior to the peer-review at European level, see previous chapter) a recommendation for the approval of the new active substance,
- and whether the competent authorities (in the case of a national procedure) or ECHA (in the case of a Union authorisation procedure) expect the biocidal product to be sufficiently effective and not to have immediate or delayed unacceptable effects on human health, animal health or the environment.

The evaluation period for the provisional authorisation application file is estimated at 12 months. This provisional authorisation is valid for 3 years, renewable for 1 year, and can be converted into a so-called definitive authorisation once the new active substance has been approved by the European Commission.

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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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This press release contains certain forward-looking statements concerning AMOEBA which are based on its own assumptions and hypothesis and on information that are available to us. However, AMOEBA gives no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the reference document of AMOEBA filed with the French Financial Markets Authority (*Autorité des Marchés Financiers*) on April 25, 2019 under number D19-0383 (a copy of which is available on www.amoeba-biocide.com). The forward-looking statements contained in this press release are also subject to risks not yet known to AMOEBA or not currently considered material by AMOEBA. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of AMOEBA to be materially different from such forward-looking statements.