



Biotalys receives regulatory approval by U.S. EPA for its biofungicide EVOCA

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Belgium based Biotalys announced that it has received regulatory approval from the U.S. Environmental Protection Agency (EPA) for its first biofungicide, EVOCA[®]. This product was developed using Biotalys's AGROBODY[®] technology platform and is the first protein-based biofungicide of its kind to be approved by the EPA.

EVOCA is a precision biocontrol solution with a new mode of action** that targets the fungal pathogens botrytis (grey mold) and powdery mildew in high-value fruits and vegetables while minimising the risk to beneficial organisms or the environment.

With this approval in hand, Biotalys can proceed with the dossiers for state registrations in California and Florida, two of the most important growing regions for fruit and vegetables in the United States***. In Europe, EVOCA has entered the peer review phase, and the Netherlands [†] as the rapporteur member state [†] has proposed approval in Europe, subject to the provision for certain additional data as requested during the peer review phase.

Additionally, the company can move forward with building up the U.S. regulatory submission for EVOCA NG [†] its next-generation product [†] currently in the final phases of development. The regulatory review process for EVOCA NG is expected to be significantly shorter, as the product contains the same active ingredient as EVOCA and features enhanced formulation and production methods. Biotalys envisages obtaining registration of EVOCA NG in the U.S. in 2028-29 and in the EU and Brazil in 2029-30, and subsequently launching it commercially in these markets worth around USD 1.2 billion combined.

[†]This approval marks a major regulatory milestone for EVOCA and moves us closer to delivering a new, sustainable tool for farmers to protect their crops,[†] said Kevin Helash, CEO of Biotalys. [†]The product has an entirely new mode of action to target fungal diseases, highlighting the uniqueness of Biotalys's technology platform as a pathway to discovering many new modes of action in the coming years. The EPA's decision reinforces the potential of our technology to help shape the future of agriculture and is a testament to the dedication of our entire team.[†]

EVOCA is developed to provide growers with a novel solution that bridges the efficacy and scale of commonly used chemistries with the environmental advantages of biological solutions.

End of October 2025, the EPA also posted a final rule exempting EVOCA's active ingredient residues on treated crops from tolerance requirements. No maximum residue limits will apply given EVOCA's exemplary safety profile.